In the

United States Court of Appeals

For the Seventh Circuit

Nos. 14-2282 & 14-2909

SIDNEY HILLMAN HEALTH CENTER OF ROCHESTER, et al.,
Plaintiffs-Appellants,

v.

ABBOTT LABORATORIES, INC., and ABBVIE, INC.,
Defendants-Appellees.

Appeals from the United States District Court for the
Northern District of Illinois, Eastern Division.
No. 1:13-cv-05865 — **Sara L. Ellis**, *Judge*.

ARGUED FEBRUARY 20, 2015 — DECIDED APRIL 13, 2015

Before RIPPLE, KANNE, and TINDER, *Circuit Judges*.

TINDER, *Circuit Judge*. Appellants are a group of multi-employer benefit funds challenging the dismissal of their putative class action alleging that Abbott Laboratories, Inc., and its subdivision AbbVie, Inc. (collectively, "Abbott"), violated the Racketeer Influenced and Corrupt Organizations Act ("RICO") through efforts to promote the anticonvulsant medication Depakote for ineffective and unsafe uses. The district court dismissed the case with prejudice as barred by the statute of limitations, concluding that a reasonable benefit fund would have discovered its injuries in 1998, when the funds first reimbursed the cost of an "off-label" prescription for Depakote. We reverse.

I. BACKGROUND

According to the allegations in the complaint, which we accept as true for purposes of this appeal, *see Fox v. Am. Alt. Ins. Corp.*, 757 F.3d 680, 681 (7th Cir. 2014), Abbott engaged in a scheme from 1998 to 2012 to illegally market Depakote for applications that had not been approved by the Food and Drug Administration ("FDA"). Unapproved applications are known as "off-label" uses. *See United States v. King-Vassal*, 728 F.3d 707, 709 (7th Cir. 2013). Physicians may, and often do, prescribe drugs for off-label uses, *id.*, but pharmaceutical companies are generally prohibited from marketing drugs for those same applications, *see, e.g., United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 113 (1st Cir. 2014); *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332–33 (D.C. Cir. 2010). The funds allege that Abbott, in promoting Depakote, not only misrepresented its safety and efficacy for off-label uses but also paid kickbacks to physicians, and established and funded intermediary entities like the Council for Excellence in Neuroscience Education, to promote the drug for off-label uses. Abbott then took steps to conceal its role in these activities. These efforts dramatically increased Depakote sales, which reached a high of $1.5 billion by 2007.

The funds were not the first to bring Abbott's marketing scheme to light. Four *qui tam* actions were filed against Abbott between October 2007 and January 2010, alleging that its off-label marketing of Depakote violated the False Claims Act and caused excessive charges to government benefit programs. These actions were unsealed in February 2011, when the federal government and multiple state governments intervened. Meanwhile, in November 2009, Abbott disclosed in a public filing with the Securities and Exchange Commission ("SEC") that the Department of Justice ("DOJ") was investigating its marketing of Depakote. In May 2012, Abbott pleaded guilty to illegally promoting Depakote from 2001 through 2006 for uses that had not been shown to be effective in clinical trials. In connection with this plea, Abbott agreed to pay $1.6 billion to settle the criminal and *qui tam* actions against it.

Fifteen months later, in August 2013, the funds filed this lawsuit asserting that Abbott's off-label marketing of Depakote constituted a civil RICO violation. The funds sought to represent a class of "[a]ll third party purchasers in the United States and its territories who, during the period from 1998 through 2012, reimbursed and/or paid some or all of the purchase price for Depakote for indications not approved by the FDA." They also sought to bring state-law claims of deceptive business practices and unjust enrichment on behalf of New York, Illinois, and Massachusetts subclasses.

Abbott moved to dismiss in part on the basis of timeliness, arguing that, because the lawsuit alleges injury dating back to 1998, it falls outside the four-year statute of limitations for civil RICO claims. In response, the funds argued that equitable tolling or estoppel should apply, contending that they could not have discovered the existence of their claims before the 2012 guilty plea because

Abbott had taken steps to conceal its marketing scheme. They also noted that it is unusual to dismiss a case as untimely at the pleadings stage because the statute of limitations is an affirmative defense that typically depends on factual determinations. The funds argued that nothing in the complaint could serve as an admission that the limitations period had expired and "[t]here are thus unresolved factual determinations that make it inappropriate for the Court to grant Defendants' motion to dismiss on statute of limitations grounds."

The district court granted Abbott's motion and dismissed the funds' claims with prejudice pursuant to Federal Rule of Civil Procedure 12(b)(6). In doing so, the court concluded that the statute of limitations for the RICO claim began to run in 1998, when the funds initially reimbursed a prescription for off-label use of Depakote. The court acknowledged that "[o]ff-label prescription of drugs is not illegal and is a routine practice among physicians." But the court decided that, given that third-party purchasers are sophisticated entities in the business of monitoring prescription reimbursements, a reasonable benefit fund would have discovered its injuries from Abbott's actions when it began paying for off-label prescriptions for Depakote. The court applied similar reasoning to bar the state-law claims.

The district court further rejected the funds' equitable arguments. The court refused to toll the limitations period until the time of the guilty plea in 2012 because, it reasoned, tolling is appropriate only for "relatively brief" delays and should not shift the start of the limitations period from the time of the initial injury to when a plaintiff becomes aware of possible racketeering. The court additionally concluded that equitable estoppel did not apply because, in its view, Abbott's efforts to conceal its off-label promotion of Depakote were not designed to hinder potential lawsuits.

II. DISCUSSION

The civil RICO statute is silent about the statute of limitations, so the Supreme Court established a four-year limitations period by analogy to the Clayton Act. *See Agency Holding Corp. v. Malley-Duff & Assocs., Inc.,* 483 U.S. 143, 156 (1987). The Court initially left open the question of the start of this period, leading to a three-way circuit split. *See Rotella v. Wood*, 528 U.S. 549, 553 (2000). Prior to *Rotella*, the majority of circuits, including this one, recognized some form of an "injury discovery" rule "starting the clock when a plaintiff knew or should have known of his injury." *Id.*; *see McCool v. Strata Oil Co.*, 972 F.2d 1452, 1464–65 (7th Cir. 1992); *see also Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 450 (7th Cir. 1990) (recognizing "the 'discovery rule' of federal common law, which is read into statutes of limitations in federal-question cases … in the absence of a contrary directive from Congress"). Other circuits held either that the claim "accrues only when the claimant discovers, or should discover, both an injury and a pattern of RICO activity," or that the "period began to run as soon as the plaintiff knew or should have known of the injury and the pattern of racketeering activity, but began to run anew upon each predicate act forming part of the same pattern." *Rotella*, 528 U.S. at 553–54.

The Supreme Court rejected both of these latter approaches in favor of the majority view. *See Rotella*, 528 U.S. at 555 (rejecting "injury and pattern discovery" rule); *Klehr v.*

A.O. Smith Corp., 521 U.S. 179, 187 (1997) (rejecting "last predicate act" rule). Although "RICO has a unique pattern requirement," and "a pattern of predicate acts may well be complex, concealed, or fraudulent," the Court reasoned that establishing "a less demanding basic discovery rule than federal law generally applies would clash with the limitations imposed on Clayton Act suits"—on which the RICO limitations period is based. *Rotella*, 528 U.S. at 556–57. The Court noted that both RICO and the Clayton Act "share a common congressional objective of encouraging civil litigation to supplement Government efforts to deter and penalize the respectively prohibited practices." *Id.* at 557. "It would, accordingly, be strange to provide an unusually long basic limitations period that could only have the effect of postponing whatever public benefit civil RICO might realize." *Id.* at 558. Therefore, the Court emphasized, "discovery of the injury, not discovery of the other elements of a claim, is what starts the clock." *Id.* at 555.

Even after *Rotella*, as we will discuss later, there remains some ambiguity about the contours of the accrual rules for civil RICO claims. But the funds here argue that, even under a stringent understanding of those rules, the district court erred in determining at the pleading stage when a reasonable third-party purchaser should have discovered that it had been injured by Abbott's actions. They emphasize that the basis of their claims is that they were harmed by increased costs due to Abbott's illegally marketing of Depakote, not merely by reimbursing off-label prescriptions, which are common and permissible. *See, e.g.*, *King-Vassal*, 728 F.3d at 709 ("[O]ff-label prescriptions by physicians are quite common."); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001) (observing that off-label use of medical devices "is generally accepted"). In fact, off-label prescriptions are particularly high for anticonvulsants, at one point constituting as much as 74 percent of all such prescriptions. *See* Randall S. Stafford, *Regulating Off-Label Drug Use–Rethinking the Role of the FDA*, 358 New Eng. J. Med. 1427, 1427 (2008), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp0802107. Thus, the funds argue, it is not clear at this stage of the proceedings that a reasonable third-party purchaser would have had any reason to discover Abbott's illegal marketing scheme based simply on reimbursing off-label prescriptions.

Abbott first responds that the funds waived these arguments by not sufficiently raising them in the district court. In the district court, it argues, the funds focused on equitable doctrines, not the problems with factual determinations regarding discovery of their injuries. But "[w]aiver is not meant as an overly technical appellate hurdle," and the nuances of a litigant's arguments may differ from their stance in the district court without resulting in waiver. *Fox v. Hayes*, 600 F.3d 819, 832 (7th Cir. 2010). And in the funds' response to Abbott's motion to dismiss, they argued, even if in a relatively cursory fashion, that "unresolved factual determinations [made] it inappropriate for the Court to grant Defendants' motion to dismiss on statute of limitations grounds." We believe that this discussion was sufficient to preclude waiver. Moreover, even if the funds had not raised their appellate arguments in the district court, the court clearly addressed the question of when the limitations period began, and "it is well settled that the waiver rule does not prevent a party from attacking on appeal the legal theory upon which the district court based its decision," *Hedge v. Cnty. of Tippecanoe*, 890 F.2d 4, 8

(7th Cir. 1989); *accord Allison v. Ticor Title Ins. Co.*, 979 F.2d 1187, 1194 (7th Cir. 1992).

Abbott next argues that a reasonably diligent benefit fund should have known that it was paying for off-label use and, with some investigation, even about Abbott's illegal marketing scheme. To demonstrate this, Abbott points to news articles raising concerns about off-label marketing and Depakote as early as 2006. Abbott also argues that we may take judicial notice of the fact that insurers are sophisticated entities with ready access to medical databases and information about healthcare matters. *See Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 826 (7th Cir. 1999). Similarly, Abbott maintains that the funds' fiduciary duty under ERISA to act in the interest of their participants and beneficiaries, *see* 29 U.S.C. § 1104(a)(1), requires them to investigate potential off-label reimbursements, *cf. O'Reilly v. Hartford Life & Accident Ins. Co.*, 272 F.3d 955, 961 (7th Cir. 2001) (noting, with respect to a disability insurance claim, that fiduciary duties in ERISA require "reasonable inquiry" into claimant's condition and skills, though not a "full-blown" investigation); *Harris v. Amgen, Inc.*, 770 F.3d 865, 881–82 (9th Cir. 2014) (reversing dismissal of claim for breach of ERISA fiduciary duties through purchase of pension-plan stock at prices inflated by illegal off-label marketing).

These arguments may eventually carry considerable weight, and we express no opinion on the funds' ultimate ability to show that their lawsuit was timely filed (or for that matter, succeed on the merits of their RICO claim). But given the allegations of the complaint, we are convinced that the district court erred by dismissing this case based on the statute of limitations without giving the parties an opportunity for discovery into when a reasonable benefit fund should have known about its injuries from off-label marketing.

"Dismissing a complaint as untimely at the pleading stage is an unusual step, since a complaint need not anticipate and overcome affirmative defenses, such as the statute of limitations." *Cancer Found., Inc. v. Cerberus Capital Mgmt., LP*, 559 F.3d 671, 674 (7th Cir. 2009). "Further, these defenses typically turn on facts not before the court at that stage in the proceedings." *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012). It is true that, "if a plaintiff alleges facts sufficient to establish a statute of limitations defense, the district court may dismiss the complaint on that ground." *O'Gorman v. City of Chicago*, 777 F.3d 885, 889 (7th Cir. 2015); *see Cancer Found.*, 559 F.3d at 674–75 ("[D]ismissal is appropriate when the plaintiff pleads himself out of court by alleging facts sufficient to establish the complaint's tardiness."). But we have cautioned that this "irregular" approach is appropriate "only where the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense." *Chi. Bldg. Design, P.C. v. Mongolian House, Inc.*, 770 F.3d 610, 613–14 (7th Cir. 2014) (quotations omitted); *see United States v. N. Trust Co.*, 372 F.3d 886, 888 (7th Cir. 2004). As long as there is a conceivable set of facts, consistent with the complaint, that would defeat a statute-of-limitations defense, questions of timeliness are left for summary judgment (or ultimately trial), at which point the district court may determine compliance with the statute of limitations based on a more complete factual record. *See Clark v. City of Braidwood*, 318

F.3d 764, 767 (7th Cir. 2003) (reversing dismissal because, "at this stage, the question is only whether there is *any* set of facts that if proven would establish a defense to the statute of limitations, and that possibility exists" (citation omitted)); *Early v. Bankers Life & Cas. Co.*, 959 F.2d 75, 80 (7th Cir. 1992) ("[W]hen a complaint is dismissed at the pleadings stage the question is not what are the facts, but is there a set of facts that if proved would show that the case had merit?").

The district court's departure from orthodoxy was not justified here. Even if the funds had the duty and ability to monitor off-label prescriptions, that conclusion is not clear from the complaint and requires factual determinations not appropriately made at the pleadings stage. It also remains unclear when the funds actually became aware that they were paying for off-label use. *Compare Rotella*, 528 U.S. at 558–59 (emphasizing that plaintiff did not deny that he knew of his injury more than ten years before filing suit). Moreover, "[i]t is not the date on which the wrong that injures the plaintiff occurs, but the date—often the same, but sometimes later—on which the plaintiff discovers that he has been injured." *Cada*, 920 F.2d at 450. At this stage, there is insufficient information to decide when a reasonable third-party purchaser should have discovered that it had paid more for off-label uses than it otherwise would have had to because of an illegal marketing scheme. *Cf. Barry Aviation, Inc. v. Land O'Lakes Mun. Airport Comm'n*, 377 F.3d 682, 688–89 (7th Cir. 2004) (reversing dismissal of RICO claim on timeliness grounds when "at some point, no doubt, a reasonable person would have investigated whether [a] disappointing business pattern was the product of fraudulent misrepresentations by the defendants, but the complaint before us does not preclude the possibility that this date was within the applicable statute of limitations"); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, Nos. 13-13113, 14-10784, 2014 WL 7009339, at *3–4 (D. Mass. Dec. 12, 2014) (refusing to conclude at the pleading stage that similar RICO claim accrued when plaintiff first reimbursed off-label use versus when plaintiff became aware of illegal off-label marketing); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at *22 (D. N. J. July 10, 2009) (refusing to dismiss similar RICO claims as untimely when complaint did not establish conclusively that plaintiffs knew or should have known of illegal marketing, and an FDA warning letter and other public information did not put them on notice).

Granted, the funds do not contest that they are sophisticated, and we have been willing to hold sophisticated entities to a higher standard. *See KDC Foods, Inc. v. Gray, Plant, Mooty, Mooty & Bennett, P.A.*, 763 F.3d 743, 751 (7th Cir. 2014) (refusing "a more forgiving application of the discovery rule" for Wisconsin fraud claim because, "with corporate players, a different quantum of expertise and knowledge is in play"); *Whirlpool Fin. Corp. v. GN Holdings, Inc.*, 67 F.3d 605, 610 (7th Cir. 1995) (observing that, for claim accrual purposes, "[a] reasonable investor is presumed to have information available in the public domain"). But Abbott is sophisticated as well and is alleged to have taken significant effort to conceal its underhanded marketing. Furthermore, at this stage, there is simply not enough information in the record to determine when even a sophisticated benefit fund should have uncovered its injuries from off-label promotion.

Abbott emphasizes that certain news articles and judicial opinions—of which we may take judicial notice, *see Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012)—give a glimpse into how the funds might operate in regard to off-label prescriptions. But these sources present conflicting information. It seems beyond dispute that the funds had a duty to act in the best interests of their beneficiaries and had ready access to medical information. But even so, as the Eleventh Circuit has pointed out, once a drug is placed on an insurer's list of medications approved for coverage based on FDA-approved uses, the insurer may be contractually obligated to pay the drug's price anytime it is prescribed, "regardless of the facts surrounding that prescription." *Ironworkers Local Union 68 v. Astrazeneca Pharms., LP*, 634 F.3d 1352, 1366 (11th Cir. 2011). Thus, the insurers in *Ironworkers* "had to pay if the drug was prescribed for an FDA-approved use or an off-label use—even if the prescription was medically unnecessary or inappropriate." *Id.* Although techniques like preauthorization review can limit improper prescriptions, these techniques are not employed universally, *see id.* at 1366–67, and are not alleged to have been in place here. Perhaps a failure to employ preauthorization review is unreasonable, or a reasonable fund, even without this type of review, should have investigated for improper marketing after reimbursing widespread off-label prescriptions for Depakote. But these questions, in our view, should be left for summary judgment, when they can be reviewed with a more complete record.

Abbott also asserts that the funds are experienced litigants, with one having even brought a similar RICO claim against another drug manufacturer for off-label marketing of

Lipitor. *See* Complaint, *Sidney Hillman Health Ctr. v. Pfizer, Inc.*, No. 06-cv-2410 (S.D.NY. Mar. 28, 2006). But the fact that one fund filed a similar claim against a different pharmaceutical company, regarding a different drug, is of little value in showing when the funds should have been on notice of their injuries here.

The funds contend that their argument for remand is further supported by case law stating that the limitations period for RICO claims begins to run only when plaintiffs have reason to discover *who* injured them. But as Abbott points out, our decisions on this issue are somewhat inconsistent.

On the one hand, we noted in *Barry Aviation* that generally "accrual occurs when the plaintiff discovers that he has been *injured* and who *caused* the injury." 377 F.3d at 688 (quotation omitted). This language was arguably dicta, but we have echoed that formulation since then. *See Jay E. Hayden Found. v. First Neighbor Bank, N.A.*, 610 F.3d 382, 386 (7th Cir. 2010) (remarking that the limitations period "starts running when the prospective plaintiff discovers (or should if diligent have discovered) both the injury that gives rise to his claim *and the injurer or (in this case) injurers*" (emphasis added)); *Cancer Found.*, 559 F.3d at 674 (holding that period "begins to run when the plaintiffs discover, or should, if diligent, have discovered, that they had been injured *by the defendants*" (emphasis added)). Moreover, in *In re Copper Antitrust Litigation*, 436 F.3d 782, 789–90 (7th Cir. 2006), we relied on *Barry Aviation* to reverse the dismissal on statute-of-limitation grounds of claims against a defendant accused of antitrust violations, reasoning that a dispute of fact existed regarding when a diligent inquiry by the plaintiffs would have revealed the defendant's role in causing their injuries.

On the other hand, however, the Supreme Court has never clearly adopted the funds' preferred rule, even if some language quoted in *Rotella* hints that it might. *See* 528 U.S. at 556 ("'The prospect [of filing a timely lawsuit] is not so bleak for a plaintiff in possession of the critical facts that he has been hurt and *who has inflicted the injury*.'" (emphasis added) (quoting *United States v. Kubrick*, 444 U.S. 111, 122 (1979)). Further, we have never overruled decisions from before *Barry Aviation* adopting a simple "injury discovery" rule, *see McCool* 972 F.2d at 1464–65; *Cada*, 920 F.2d at 450, and have emphasized—albeit not in the RICO context—that a plaintiff "doesn't have to know who injured him" to file suit because, "[i]f despite the exercise of reasonable diligence he cannot discover his injurer's (or injurers') identity within the statutory period, he can appeal to the doctrine of equitable tolling to postpone the deadline for suing until he can obtain the necessary information," *Fid. Nat'l Title Ins. Co. v. Howard Sav. Bank*, 436 F.3d 836, 839 (7th Cir. 2006); *see Cancer Found.*, 559 F.3d at 676 (cautioning that, "to know you've been injured and make no effort to find out by whom is the very laxity that statutes of limitations are designed to penalize"). Ultimately, because we conclude that dismissal was unwarranted at this stage even under the standard articulated in *McCool* and *Cada*, we need not decide today whether a delay in discovering a wrongdoer's identity might extend the start of the limitations period for RICO claims.

Finally, in case the funds' equitable arguments resurface on remand, we agree with the district court that, based upon the facts alleged in the complaint, those arguments are unpersuasive. "'Equitable tolling is granted sparingly only when extraordinary circumstances far beyond the litigant's control prevented timely filing.'" *Simms v. Acevedo*, 595 F.3d 774, 781 (7th Cir. 2010) (quoting *Wilson v. Battles,* 302 F.3d 745, 749 (7th Cir. 2002)). The doctrine applies "when the plaintiff, exercising due diligence, was unable to discover evidence vital to a claim until after the statute of limitations expired." *Moultrie v. Penn Aluminum Int'l, LLC*, 766 F.3d 747, 752 (7th Cir. 2014). Furthermore, "a plaintiff who invokes equitable tolling to suspend the statute of limitations must bring suit within a reasonable time after he has obtained, or by due diligence could have obtained, the necessary information." *Cada*, 920 F.2d at 451. Similarly, equitable estoppel, also called fraudulent concealment, applies only when plaintiffs act with reasonable diligence to discover and file their claims. *See Klehr*, 521 U.S. at 194–95 ("[A] plaintiff who is not reasonably diligent may not assert 'fraudulent concealment.'"); *Jay E. Hayden Found.*, 610 F.3d at 388 ("[I]n a RICO case, the plaintiff must both use due diligence to discover that he has been injured and by whom even if the defendant is engaged in fraudulent concealment, and diligently endeavor to sue within the statutory limitations period or as soon thereafter as feasible.").

Here, the funds acknowledge that they did not allege that they acted diligently in seeking information about their claims, or in fact attempt any investigation. Moreover, even assuming that the SEC filing in 2009 disclosing the DOJ's investigation of Abbott's off-label marketing did not alert the funds to their injuries, surely the 2012 guilty plea and corresponding $1.6-billion settlement did so. Yet the funds still waited more than a year to file suit. We thus are not persuaded that the equitable doctrines at issue apply to extend the limitations period.

We REVERSE the dismissal of the funds' RICO claims and REMAND for further proceedings consistent with this opinion. Because the state law claims were dismissed based on similar reasoning, they are reinstated as well.