

United States Court of Appeals For the First Circuit

No. 16-1304

ANDREW HAGERTY, ex rel. UNITED STATES;

Relator, Appellant,

STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT;
STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF
HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA;

STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF
MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF
MONTANA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW
MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF
OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF
TEXAS; COMMONWEALTH OF VIRGINIA; STATE OF WASHINGTON; STATE OF
WISCONSIN; DISTRICT OF COLUMBIA

Plaintiffs,

v.

CYBERONICS, INC.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. F. Dennis Saylor, IV, U.S. District Judge]

Before

Barron, Selya, and Stahl,
Circuit Judges.

Joseph S. Hall, with whom Silvia A. Strikis, Katherine C. Cooper, Rachel Proctor May, Kellogg, Huber, Hanson, Todd, Evans & Figel, P.L.L.C., Suzanne E. Durrell, Durrell Law Office, Robert M.

Thomas, Jr., and Thomas & Associates were on brief, for appellant. William M. Katz, Jr., with whom Melissa Michelle Davis, J. Patrict Bredehoft, Richard B. Phillips, Thompson & Knight LLP, Timothy H. Madden, and Donnelly, Conroy & Gelhaar LLP were on brief, for appellee.

December 16, 2016

STAHL, Circuit Judge. Relator-Appellant Andrew Hagerty ("Hagerty") brought a qui tam action against Appellee Cyberonics, Inc. ("Cyberonics") alleging, among other things, that Cyberonics violated the False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., and related state statutes. Specifically, Hagerty alleged that Cyberonics promoted medically unnecessary replacements of batteries in nerve stimulator devices used to treat epilepsy patients, which in turn resulted in patients and medical providers filing false claims for reimbursement from government health care programs.

The district court dismissed all but two of Hagerty's claims under Federal Rule of Civil Procedure 12(b)(6), including the FCA allegations, holding that Hagerty's First Amended Complaint was not pled with the particularity required by Federal Rule of Civil Procedure 9(b).¹ Following this dismissal, the district court also denied Hagerty's request for leave to file a Second Amended Complaint on the basis of undue delay. Hagerty now challenges the district court's ruling on both fronts, maintaining that his First Amended Complaint satisfies Rule 9(b) and asserting

¹ Hagerty's surviving claims against Cyberonics were his allegations regarding retaliatory discharge under 31 U.S.C. § 3730(h) (Count 31) and wrongful termination and retaliation in violation of public policy under Mass. Gen. Laws ch. 12, § 5J (Count 33). These claims were voluntarily dismissed without prejudice and are not on appeal. Hagerty also does not separately address the dismissal of his other state law claims in his briefing to this court. We similarly decline to do so in our opinion.

that the district court abused its discretion when denying his motion for leave to file a Second Amended Complaint. After careful consideration, we affirm.

I. Facts & Background

We recite the relevant facts as they appear in Hagerty's First Amended Complaint. See Hochendorfer v. Genzyme Corp., 823 F.3d 724, 730 (1st Cir. 2016). The Vagus Nerve Stimulator (VNS) is a medical device that is implanted in patients with refractory epilepsy, a severe form of the disease in which a patient's seizures seriously interfere with their quality of life and do not respond to other medications or treatment. The VNS works by delivering short electrical pulses to the vagus nerve through a wire. Each VNS system contains a battery, and the entire VNS system must be surgically replaced when the battery nears the end of its life.

Patients with refractory epilepsy often qualify for coverage under government healthcare programs like Medicare and Medicaid. Some treatments for refractory epilepsy, including placement of the VNS, are reimbursed by those programs. These programs impose certain requirements on healthcare providers, such as signing a Provider Agreement with the Centers for Medicare and Medicaid Services ("CMS"). In these agreements, providers certify, among other things, that their claims for reimbursement

relate to a reasonable and medically necessary treatment. 42 U.S.C. § 1395y(a)(1)(A).

On February 4, 2013, Hagerty filed a qui tam complaint under seal against Cyberonics, alleging that it engaged in a fraudulent scheme to encourage doctors and patients to prematurely and unnecessarily replace batteries in VNS systems. Hagerty, having gained knowledge of the scheme firsthand as a former sales representative of Cyberonics, further alleged that this scheme caused significant monetary damages to government healthcare programs by inducing patients and medical providers to file false claims for reimbursement in violation of 31 U.S.C. § 3729(a). On October 29, 2013, the government filed a notice declining to intervene in the case, and on December 5, 2013 the complaint was unsealed and served on Cyberonics. Cyberonics then moved to dismiss the complaint on April 28, 2014 on several grounds, including under Rule 12(b)(6) for failure to state a claim and Rule 9(b) for failure to allege instances of fraud with particularity.

Hagerty amended his pleadings and filed his First Amended Complaint on May 19, 2014. The First Amended Complaint alleged that in 2005, the FDA approved the VNS as a treatment for depression, and, anticipating that much of its future growth would come from this market, Cyberonics hired 300 new salespersons. Cyberonics then allegedly began lobbying CMS to approve Medicare

reimbursement for VNS therapy in depressive patients, which CMS ultimately declined to grant. Facing a dire financial situation², Cyberonics reportedly decided to refocus its sales efforts on epilepsy patients, with a particular interest in re-sales to already existing VNS patients.

The First Amended Complaint emphasized that this new sales plan was driven by a "carrot and stick" approach, where sales representatives were rewarded for meeting "aggressive sales quotas," were placed in a Performance Improvement Program if they did not achieve 75% of their revenue goals in a given quarter, and were terminated the following quarter if their performance did not improve. Hagerty alleged that, under such conditions, Cyberonics' sales representatives resorted to fraudulent sales tactics, such as refusing to provide doctors and patients with accurate VNS battery life calculations and encouraging doctors and patients to replace these batteries prematurely.³

The First Amended Complaint further alleged that approximately 50% of Cyberonics' revenue came from Medicare and Medicaid, with additional revenues coming from TRICARE, the

² At the time CMS denied its request, Cyberonics was allegedly \$132.5 million in debt.

³ Cyberonics employees purportedly represented that these batteries should be replaced after four or five years despite their average lifespan being between eight and nine years. As a result of this new sales tactic, Hagerty alleges that Cyberonics erased its debt by 2010 and avoided bankruptcy.

Department of Defense, the Department of Veterans Affairs, and the Federal Employee Health Benefits Program. Hagerty went on to list sixteen hospitals which he claimed had performed and billed for VNS therapy implants in epileptic patients, and specifically named the Southbury Training School, Monson Development Center, and Wrentham Development Center as "long-term care facilities . . . in which vulnerable patients were subjected to unnecessary surgeries to implant replacement devices." The First Amended Complaint further identified a Dr. Pena, who had three patients undergo battery replacement procedures between September 30, 2010 and November 18, 2010. It also identified a Dr. Thompson, who allegedly told Hagerty that a Cyberonics sales representative falsely told physicians to replace VNS batteries prematurely. Moreover, the First Amended Complaint alleged that Hagerty reviewed an internal patient list and saw that several of Dr. Thompson's patients had received VNS device replacements in 2010.

By way of conclusion, the First Amended Complaint projected that at least 10,000 medically unnecessary VNS device replacements had occurred at these hospitals and centers since 2007. Coupled with an estimated cost of \$20,000 per procedure and an assumption that government healthcare programs covered approximately 50-60% of these procedures, Hagerty reasoned that government healthcare programs lost at least \$100 million as a result of Cyberonics' scheme.

Cyberonics again moved to dismiss the case. On March 31, 2015, the district court granted the motion, finding that Hagerty had not pled his allegations with the requisite particularity required by Rule 9(b). On August 14, 2015, Hagerty moved for leave to file a Second Amended Complaint. Three months later, the district court denied Hagerty's motion on the basis of undue delay.⁴ This appeal followed.

II. Analysis

Hagerty insists that his First Amended Complaint satisfied Rule 9(b)'s particularity requirement and, regardless of the district court's view on that matter, that he should have been given leave to file a Second Amended Complaint. We review the granting of a motion to dismiss de novo, United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009), and the denial of a motion to amend for abuse of discretion, United States ex rel. Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 10 (1st Cir. 2016) (citing United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 116 (1st Cir. 2010)).

⁴ Cyberonics alternatively argues that the district court also denied Hagerty's motion because any amendment would have been futile. Since, as we will explain, the district court's denial was justified under an undue delay analysis, we decline to consider the futility of Hagerty's proposed amendments.

A. The FCA and Rule 9(b)

The FCA penalizes those who present, or cause to be presented, "false or fraudulent claim[s] for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1). Thus, fraud under the FCA has two components: the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent. United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 124 (1st Cir. 2013) ("Because FCA liability attaches only to *false claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough. Rather, a complaint based on [the FCA] must sufficiently establish that false claims were submitted for government payment as a result of the defendant's alleged misconduct.") (internal citations omitted).

Federal Rule of Civil Procedure 9(b), meanwhile, requires that a complaint state these components with "particularity," meaning relators like Hagerty must allege the "who, what, when, where, and how of the alleged fraud." Id. at 123 (internal citation and quotation marks omitted). Still, we have repeatedly emphasized that there is no "checklist of mandatory requirements" that each allegation in a complaint must meet to satisfy Rule 9(b), United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 233 (1st Cir. 2004), abrogated on other grounds by Gagne, 565 F.3d at 46 n.7, and that a "somewhat

'more flexible' standard" applies in qui tam actions where the defendant is alleged to have induced third parties to file false claims, Kelly, 827 F.3d at 13 (1st Cir. 2016) (quoting United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29-30 (1st Cir. 2009)).

A relator can meet this more accommodating standard by "providing 'factual or statistical evidence to strengthen the inference of fraud *beyond possibility*' without necessarily providing details as to each false claim." Ge, 737 F.3d at 123-24 (quoting Duxbury, 579 F.3d at 29) (emphasis added). Such evidence generally includes, inter alia, the "'specific medical providers who allegedly submitted false claims,' the 'rough time periods, locations, and amounts of the claims,' and 'the specific government programs to which the claims were made.'" Kelly, 827 F.3d at 13 (quoting Ge, 737 F.3d at 121, 124).

As the district court noted, "the allegations concerning [Cyberonics' scheme] are unquestionably adequate to survive a motion to dismiss." United States ex rel. Hagerty v. Cyberonics, Inc., 95 F. Supp. 3d 240, 264 (D. Mass. 2015). Nonetheless, the First Amended Complaint's factual and statistical evidence struggles to connect these allegations with the submission of any false claims to government programs.

Hagerty compares his complaint to those we deemed adequate in Duxbury and United States ex rel. Escobar v. Universal

Health Servs., Inc., 780 F.3d 504 (1st Cir. 2015), overruled on other grounds by 136 S. Ct. 1989 (2016). In Duxbury, the relator alleged that the defendant-company paid kickbacks to eight named medical providers, thereby inducing these providers to submit false claims for reimbursement to Medicare. Duxbury, 579 F.3d at 30. Despite being a "close call," we held that the complaint satisfied Rule 9(b) because "Duxbury ha[d] identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." Id., see also Ge, 737 F.3d at 124 (noting allegations in Duxbury were "barely adequate" under Rule 9(b)).

Similarly, in Escobar, we concluded that the relator satisfied Rule 9(b) by alleging "twenty-seven separate dates on which claims were submitted in connection with [care provided by unlicensed and unsupervised personnel], each time including the relevant billing codes, amount invoiced, and the name of the [defendant's] staff member who provided the treatment for which reimbursement was sought." 780 F.3d at 515. Though the allegations concerned claims made in connection with a single patient's care, we allowed the complaint's other, more general, allegations to proceed because they stemmed from a "systematic failure" to enforce licensure and supervision requirements that necessarily "infected" other claims with fraud. Id.

The allegations in Hagerty's First Amended Complaint are neither as specific as those in Duxbury nor as systematic as those in Escobar. Despite referencing a long list of healthcare providers who performed and billed for VNS replacement surgeries, the complaint does not allege whether these providers submitted reimbursement claims to the government for unreasonable and medically unnecessary procedures. Likewise, the complaint does not allege how many false claims these providers purportedly submitted or how Cyberonics' actions caused their submission. And though Hagerty identifies several doctors and hospitals with patients who had VNS replacement surgeries, he does not allege that any government healthcare program covered these patients or that any medical provider submitted claims for reimbursement on their behalf.

Similarly, the First Amended Complaint alleged that Cyberonics employees tried to contact patients about scheduling VNS replacement surgeries without first consulting their doctor. The complaint, however, contains no assertion that these efforts actually resulted in patients scheduling, doctors performing, or government healthcare programs reimbursing the contemplated surgeries. See Kelly, 827 F.3d at 15 (holding that relators failed to tie their allegations of misconduct to "specific fraudulent claims for payment"); Ge, 737 F.3d at 124 (rejecting a "per se rule that if sufficient allegations of misconduct are made, it

necessarily follows that false claims and/or material false information were filed"). Simply put, we cannot infer, based on the allegations before us, that Cyberonics' actions "infected" other VNS reimbursement claims with fraud.

The complaint's most specific allegation comes where Hagerty states that three healthcare providers, Southbury Training School, Monson Development Center, and Wrentham Development Center, had patients who were "seriously disabled" and eligible for various government healthcare programs, and that the VNS replacement surgeries conducted on those patients necessarily resulted in the submission of at least some false reimbursement claims. But again, without any allegation that the patients were actually covered by government programs or that certain replacement procedures conducted on these patients were medically unnecessary, Hagerty has "[a]t most . . . [only] raise[d] facts . . . suggest[ing] fraud was possible."⁵ United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007), overruled on other grounds by Allison Engine v. United States ex rel. Sanders, 553 U.S. 662 (2008).

⁵ Only one patient from these facilities is actually identified in the complaint: "F.P.," a Medicare-eligible epileptic whose VNS device was replaced on May 12, 2010. Paralleling the broader problems with Hagerty's allegations, there is no indication that F.P. was an actual Medicare recipient, that his replacement surgery was unnecessary, or that any false claim was submitted on his behalf.

Fighting an uphill battle, Hagerty supplements his factual allegations with certain statistical allegations which, he claims, compel the inference he wants us to recognize. First, the complaint alleges that a majority of the patients receiving replacement devices are covered by government healthcare programs and that approximately half of Cyberonics' revenues came from these programs. Second, the complaint estimates that there have been "over 10,000 medically unnecessary and unreasonable VNS device replacements" since 2007 and that patients covered by government healthcare programs "account for at least 50-60% of these unnecessary replacements."

These statements are too broad to be given much weight. Hagerty does not allege that any particular patient was actually covered by a government program, provides no basis for his estimate of 10,000 unnecessary procedures, and does not link Cyberonics' revenues to these procedures. Viewed individually or as a whole, Hagerty's "evidence and arguments proceed more by insinuation than any factual or statistical evidence that would strengthen the inference of fraud beyond possibility." See Kelly, 827 F.3d at 15 (internal marks omitted). Accordingly, we affirm the district court's dismissal of Hagerty's First Amended Complaint.

B. Motion to Amend

Hagerty also claims that the district court abused its discretion when it denied his motion to amend the First Amended

Complaint on the basis of undue delay. Federal Rule of Civil Procedure 15(a) provides that a party may, in certain circumstances, amend a pleading without leave of a court.⁶ In all other cases, however, a party may only amend its pleadings with the opposing party's written consent or the court's leave. Fed. R. Civ. P. 15(a)(2).

Though courts "should freely give leave when justice so requires," id., amendments may be denied for several reasons, including "undue delay, bad faith, dilatory motive of the requesting party, repeated failure to cure deficiencies, and futility of amendment," Rost, 507 F.3d at 733-34 (citing Foman v. Davis, 371 U.S. 178, 182 (1962)). As relevant here, undue delay, on its own, may be enough to justify denying a motion for leave to amend.⁷ Calderón-Serra v. Wilmington Trust Co., 715 F.3d 14, 20

⁶ A party may amend a pleading once as a matter of course within "21 days after serving it," or "if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier." Fed. R. Civ. P. 15(a)(1).

⁷ Hagerty cites to a long list of our decisions, including Hayes v. New England Millwork Distrib., Inc., 602 F.2d 15, 19 (1st Cir. 1979), and Klunder v. Brown Univ., 778 F.3d 24, 34 (1st Cir. 2015), which, he claims, requires us to also find that the delay was prejudicial to the opposing party. Hayes, however, noted that "[w]hile courts may not deny an amendment solely because of delay and without consideration of the prejudice to the opposing party, it is clear that 'undue delay' can be a basis for denial[.]" 602 F.2d at 19 (internal citations omitted). Similarly, although Klunder states that "[i]n reviewing a district court's decision on whether or not to grant an amendment, [appellate courts] routinely focus [their] analysis on the prejudice to the non-moving party,"

(1st Cir. 2013); see also United States ex rel. Wilson v. Bristol-Myers Squibb, Inc., 750 F.3d 111, 119-20 (1st Cir. 2014). In these cases, a movant has "[at the very least] the burden of showing some valid reason for his neglect and delay." Perez v. Hosp. Damas, Inc., 769 F.3d 800, 802 (1st Cir. 2014) (quoting In re Lombardo, 755 F.3d 1, 3 (1st Cir. 2014)) (alteration in original). In assessing whether a movant has carried this burden, courts must take into account "[w]hat the plaintiff knew or should have known and what he did or should have done." Leonard v. Parry, 219 F.3d 25, 30 (1st Cir. 2000).

A significant amount of time clearly passed here. See, e.g., In re Lombardo, 755 F.3d at 3-4 (discussing cases that imposed on the movant the burden to explain grounds for delay when the delay was fourteen, fifteen, and seventeen months, respectively). The district court aptly summarized Hagerty's listless approach toward amending his complaint as follows:

Hagerty filed his initial complaint on August 8, 2012. He filed the present action on February 4, 2013. After Cyberonics filed a motion to dismiss, Hagerty amended the complaint on May 19, 2014. Cyberonics moved to dismiss the first amended complaint . . . on June 18, 2014. The Court ruled on that motion on March 31, 2015. Hagerty did not move for leave to file a second amended complaint until August 14, 2015. That motion was filed (1) more than three years after Hagerty filed the initial lawsuit; (2) more than two and a half years after he filed the initial complaint . . . ; (3) more than

778 F.3d at 34, its immediate citation to the Hayes language identified above signifies that we were referring to delay, not undue delay. Id.

fourteen months after he filed the first amended complaint; (4) more than thirteen months after Cyberonics moved to dismiss the first amended complaint; and (5) more than four months after the Court's memorandum and order on the motion to dismiss.

United States ex rel. Hagerty v. Cyberonics, Inc., 146 F. Supp. 3d 337, 343-44 (D. Mass. 2015).

Hagerty's proffered explanations for his delay are twofold. First, Hagerty argues that the only relevant period of delay was the four months after the granting of the motion to dismiss and places responsibility for any delay accruing before the dismissal squarely on the district court. We can easily reject this argument, however, because nothing prevented Hagerty from moving for leave to plead any new information once he became aware of it. Where we have excused delay based on the actions of a district court, it has been because the district court did not promptly deal with a motion to amend, not because the district court took its time evaluating a motion to dismiss. See Farkas v. Tex. Instruments, Inc., 429 F.2d 849, 851 (1st Cir. 1970). In the motion to amend cases, the delay is attributable to the district court because the motion evidences the movant's proactive approach to addressing known weaknesses in the First Amended Complaint.

Second, Hagerty maintains that he could not have known or anticipated the deficiencies that would form the basis of the district court's dismissal of his First Amended Complaint. He specifically contends that unlike in other cases where the amended

complaints were dismissed due to the plaintiff's lack of diligence, see Acosta-Mestre v. Hilton Intern. of P.R., Inc., 156 F.3d 49, 53 (1st Cir. 1998), he has shown "care and attentiveness" towards assuaging the district court's concerns about his complaint. But Cyberonics' motion to dismiss, filed in June 2014, put Hagerty on notice of the deficiencies in the complaint, and he made no attempt to fix these deficiencies until August 2015. See Feliciano-Hernández v. Pereira-Castillo, 663 F.3d 527, 538 (1st Cir. 2011) (upholding district court's undue delay determination where motion to amend was filed "nearly a year after the motion to dismiss was filed"); ACA Fin. Guaranty Corp. v. Advest, Inc., 512 F.3d 46, 57 (1st Cir. 2008) ("Plaintiffs may not, having the needed information, deliberately wait in the wings . . . with another amendment to a complaint should the court hold the first amended complaint was insufficient. Such an approach would impose unnecessary costs and inefficiencies on both the courts and party opponents.").

Thus, we conclude both that Hagerty did not meet his burden of providing a valid reason for his delay and that the district court did not abuse its discretion in denying his motion for leave to amend.

III. Conclusion

The judgment of the district court is AFFIRMED.