United States Court of Appeals
For the Eighth Circuit

No. 15-3468

West Virginia Pipe Trades Health & Welfare Fund; Employees' Retirement System of the State of Hawaii; Union Asset Management Holding AG

Plaintiffs - Appellants

v.

Medtronic, Inc.; William A. Hawkins; Gary L. Ellis; Richard E, Kuntz; Julie Bearcroft; Richard W. Treharne; Martin Yahiro

Defendants - Appellees

Thomas A. Zdeblick; J. Kenneth Burkus; Scott D. Boden

Defendants

Appeal from United States District Court
for the District of Minnesota - Minneapolis

Submitted: October 19, 2016
Filed: December 28, 2016

Before GRUENDER, BEAM, and SHEPHERD, Circuit Judges.

GRUENDER, Circuit Judge.

West Virginia Pipe Trades Health and Welfare Fund, Employees' Retirement System of the State of Hawaii, and Union Asset Management Holding AG (collectively, "Appellants") appeal the grant of summary judgment to Medtronic, Inc. in their securities fraud class action. The district court granted summary judgment to Medtronic after determining that Appellants' claims are time-barred. For the reasons discussed below, we vacate the summary judgment order and remand for further proceedings.

I.

Appellants are retirement and investment funds who brought a consolidated class action for securities fraud against Medtronic and several of its officers and senior managers for actions related to Medtronic's INFUSE product. INFUSE is the trade name of rhBMP-2, a bone morphogenetic protein that causes the body to develop new bone tissue. Medtronic developed INFUSE as an alternative to bone grafting procedures, and the FDA approved it for use in lower back spinal fusion surgeries in 2002. In a traditional autograft spinal fusion procedure, the vertebrae are fused using a bone graft taken from the patient's hip bone. In the INFUSE procedure, the vertebrae are fused using a thimble-shaped titanium cage containing an INFUSE-soaked collagen sponge. INFUSE is a key component of Medtronic's multi-billion dollar spinal segment.

Medtronic sponsored the FDA clinical trials, and all thirteen of the resulting articles included authoring physicians who had financial interests in INFUSE. Pharmaceutical companies frequently sponsor the medical research of their products. However, the FDA specifically considered conflicts of interest during the INFUSE approval process. The FDA approved INFUSE only for use in lumbar spinal fusion surgeries, some dental surgeries, and for treating certain shin fractures. However, up to eighty-five percent of INFUSE use was off-label. In 2008, the FDA issued a public health notification associating off-label uses of INFUSE with life-threatening throat

and neck swelling. In 2008, an unrelated party brought a class action against Medtronic alleging that it violated securities laws by promoting off-label use of INFUSE. *See Minneapolis Firefighters' Relief Ass'n v. Medtronic, Inc.*, 278 F.R.D. 454, 456 (D. Minn. Dec. 12, 2011). In 2011, the FDA refused to approve AMPLIFY, a high-strength version of INFUSE, because of concerns it may cause cancer.

In 2010, articles in the *Milwaukee Journal Sentinel* expressed concern that the doctors authoring the Medtronic-sponsored INFUSE clinical studies had significant financial ties to Medtronic and reported test results twice as favorable as those of independent studies. Letters to the editor of the *Journal of Bone and Joint Surgery* raised questions about the link between INFUSE and retrograde ejaculation (a condition that causes male sterility). One of the physicians who authored the INFUSE clinical studies, Dr. Kenneth Burkus, penned a response denying any link. On May 25, 2011, the *Milwaukee Journal Sentinel* published an article stating that Medtronic and doctors with financial ties to Medtronic were aware of the risk of retrograde ejaculation but did not disclose it.

On the same day, Dr. Eugene Carragee, an independent doctor from the Stanford University School of Medicine, published a clinical study in *The Spine Journal* linking INFUSE with a risk of sterility in men. A commentary on Dr. Carragee's study by Dr. James Kang of the University of Pittsburgh School of Medicine noted that the original Medtronic-sponsored publications did not report any adverse events despite the incidence of retrograde ejaculation, and Dr. Kang concluded that the conflict of interest was the only explanation for the difference between the studies. The *New York Times* summarized Dr. Carragee's study and incorporated a response from one of the authors of a Medtronic-sponsored study, Dr. Thomas Zdeblick, who implied that the Carragee study was misleading.

On June 22, 2011, the Senate Finance Committee issued a press release announcing an investigation into Medtronic and INFUSE. The press release

expressed concern over Medtronic's undisclosed financial ties with doctors. The next day, the *Wall Street Journal* summarized the Committee press release and reported the amount of royalties Dr. Burkus and Dr. Zdeblick had received. On June 28, 2011, *The Spine Journal* devoted its entire issue to articles concerning INFUSE and included an article authored by Dr. Carragee that extensively analyzed the Medtronic-sponsored clinical studies. Dr. Carragee explained that the studies employed significantly flawed methodologies and failed to report adverse events. However, Dr. Carragee specifically refrained from drawing any conclusion about the doctors' motives.

In October 2012, the Senate Finance Committee released its investigation report on INFUSE. The Committee found that Medtronic "was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic." The Committee also found that Medtronic employees added language designed to exaggerate the disadvantages of standard spinal fusion techniques and recommended against publishing a complete list of adverse events associated with INFUSE. Finally, the committee found that Medtronic had attempted to adopt weaker safety rules for its clinical trials.

Appellants filed suit on June 27, 2013 against Medtronic, its officers and senior managers, and the doctors who authored the Medtronic-sponsored clinical studies. Appellants alleged a number of securities laws violations, including making false statements and employing a scheme to defraud the market. The district court initially dismissed Appellants' scheme liability claims against the physician-authors and dismissed some of the false statement claims against Medtronic. However, the district court did not dismiss one false statement claim, the scheme liability claim, or the control liability claim against Medtronic. The litigation proceeded, and Medtronic eventually moved for summary judgment on all claims. The district court granted the motion, holding that the two-year statute of limitations barred all claims.

Appellants only appeal the grant of summary judgment on their scheme liability claim. In addition to the statute of limitations, Medtronic argues alternatively that *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011), and *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148 (2008), bar Appellants' scheme liability claim as a matter of law because it attempts to hold Medtronic secondarily liable for the fraudulent statements of others.

II.

A. Statute of Limitations

The court reviews a grant of summary judgment *de novo*, viewing the facts in the light most favorable to the nonmovant. *Harris v. Mortg. Prof'ls, Inc.*, 781 F.3d 946, 948 (8th Cir. 2015). Summary judgment is appropriate when "the movant is entitled to judgment as a matter of law." *Id.* (quoting Fed. R. Civ. P. 56(a)). "We review the district court's determination of statute-of-limitations de novo." *In re ADC Telecomms., Inc. Sec. Litig.*, 409 F.3d 974, 976 (8th Cir. 2005).

Section 10b of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), makes illegal the use of a manipulative or deceptive device in connection with the sale or purchase of a security by any instrumentality of interstate commerce. 17 C.F.R. § 240.10b-5 implements § 10b, *see Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 980 (8th Cir. 2012), and establishes two kinds of liability: false statement liability (17 C.F.R. § 240.10b-5(b)) and scheme liability (17 C.F.R. § 240.10b-5(a), (c)). Scheme liability concerns the use of "any device, scheme, or artifice to defraud" and "any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5(a), (c). 28 U.S.C. § 1658(b) establishes the relevant statute of limitations:

> [A] private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws, as defined in section 3(a)(47) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(47)), may be brought not later than the earlier of—
>
> (1) 2 years after the discovery of the facts constituting the violation; or
>
> (2) 5 years after such violation.

"'[D]iscovery' as used in this statute encompasses not only those facts the plaintiff actually knew, but also those facts a reasonably diligent plaintiff would have known." *Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 648 (2010). However, mere inquiry notice is not sufficient. *See id.* at 651. The following elements comprise a scheme liability claim under 17 C.F.R. § 240.10b-5(a) and (c): "the defendant (1) committed a deceptive act (2) with *scienter*, (3) that the act affected the market for securities or was otherwise in connection with their purchase or sale, and (4) that defendants' actions caused the plaintiffs' injuries." *In re Parmalat Sec. Litig.*, 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006). Although the law is unsettled as to whether all of the scheme liability elements are "facts constituting the violation" within the meaning of § 1658(b)(1),[1] at a minimum the commission of a deceptive act and scienter are "facts constituting the violation." *See Merck*, 559 U.S. at 648-49 (quoting 28 U.S.C. § 1658(b)(1)). Accordingly, if Appellants did not discover or with reasonable diligence would not have discovered the particular facts constituting the deceptive act and the facts showing scienter prior to June 27, 2011, the statute of limitations does not bar Appellants' claim.

[1]In *Merck & Co., Inc. v. Reynolds*, the Supreme Court specifically left unresolved whether facts concerning a plaintiff's reliance, loss, and loss causation are among the facts constituting the violation that must be discovered in order for the statute of limitations to begin to run. 559 U.S. at 649.

While Appellants may have had reason to be suspicious of Medtronic's conduct concerning INFUSE prior to June 27, 2011, we conclude that a reasonably diligent plaintiff would not have discovered facts sufficient to plead scienter based on public information existing prior to June 27, 2011.[2] To plead scienter adequately, "plaintiffs must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (quoting 15 U.S.C. § 78u-4(b)(2)). "To qualify as 'strong' within the intendment of § 21D(b)(2) [of the PSLRA, 15 U.S.C. § 78u-4(b)(2)], . . . an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* The *Milwaukee Journal Sentinel* articles in late 2010 described in detail the significant financial ties between Medtronic and the physician-authors. These articles also explained that Medtronic-sponsored studies produced test results twice as favorable as independent studies and noted that independent doctors attributed INFUSE's success largely to the positive findings of Medtronic-affiliated surgeons. However, the December 26, 2010 article explained that "[t]here is no evidence any of the surgeons who have published articles on BMP-2 received royalties they did not deserve."

Additionally, Dr. Kang's commentary on May 25, 2011 characterized the problem as industry-wide, emphasizing that favorable reported results are a natural consequence of corporate-sponsored research generally. However, he emphasized that corporate-sponsored research is "absolutely needed to help advance innovation and patient care," but independent studies must check corporate-sponsored research's tendency toward bias. Other articles in *The Spine Journal* and the *Milwaukee Journal Sentinel* also discussed the concerns with INFUSE as exemplifying broader problems in the pharmaceutical industry and the FDA approval process. As a result, on May

[2]Accordingly, we need not resolve whether any elements other than the commission of a deceptive act and scienter are facts constituting the violation.

25, 2011, one could reasonably infer that the problems with Medtronic's studies were not due to fraud but due to the nature of corporate-sponsored research. Thus, the available information did not create the strong inference that Medtronic intended to employ a scheme to defraud the market by manipulating the clinical studies. That scienter did not become apparent until October 2012 when the Senate Finance Committee released its findings that Medtronic had intentionally edited the studies to omit unfavorable results.

In finding to the contrary, the district court emphasized three conclusions: (1) Dr. Carragee's May 25, 2011 *Spine Journal* article and the subsequent news reports were sufficient to demonstrate scienter because they "showcase[d] early revelations of Medtronic's drive to dominate the marketplace with INFUSE;" (2) the *Minneapolis Firefighters* litigation provided facts sufficient to plead scienter; and (3) the October 2012 Committee report fell outside the class period and was not tied to a drop in Medtronic stock, so it does not bear on the statute of limitations. We disagree. First, a desire to dominate the marketplace does not constitute scienter to perpetrate fraud on the market. Rather, it is a mainstream corporate goal companies regularly achieve by legitimate means. That some companies may use fraudulent means to accomplish that goal does not provide a strong inference that Medtronic intended to defraud the market. Second, none of the allegations in the *Minneapolis Firefighters* litigation would provide sufficient information to plead scienter in this case. *Minneapolis Firefighters* concerned Medtronic's alleged promotion of off-label INFUSE use. It did not provide relevant information that would have allowed Appellants to assert a claim that Medtronic intentionally perpetrated a scheme to defraud the market by paying doctors to conceal INFUSE's on-label use risks. *See Minneapolis Firefighters' Relief Ass'n*, 278 F.R.D. at 456. Finally, whether the Committee report caused any market reaction concerns the element of loss causation, not scienter. Accordingly, the content of the report remains relevant to establishing when Appellants could have first pleaded scienter.

As a result, because Appellants could not have discovered with reasonable diligence sufficient information to plead scienter with the particularity necessary to survive a motion to dismiss prior to June 27, 2011, Appellants brought their complaint within the two-year statute of limitations. The district court did not reach the five-year statute of repose, and we decline to reach it now in the first instance.

B. Secondary Liability

In the alternative, Medtronic argues that Appellants' scheme liability claim is barred as a matter of law by *Janus Capital Group, Inc.*, 564 U.S. 135 (2011), and *Stoneridge Investment Partners, LLC*, 552 U.S. 148 (2008). Medtronic initially raised this question in a motion to dismiss. The district court denied the motion as to this issue and allowed the scheme liability claim to proceed. The summary judgment proceedings did not address this argument. We review the questions of law *de novo*, taking the Appellants' pleadings as true for this purpose. *See Schmidt v. Des Moines Pub. Sch.*, 655 F.3d 811, 815 (8th Cir. 2011); *Frey v. City of Herculaneum*, 44 F.3d 667, 671 (8th Cir. 1995).

As a threshold matter, Appellants contend that the law of the case doctrine prevents this court from considering this argument. Appellants' law of the case argument is incorrect. While the district court rejected Medtronic's *Janus* and *Stoneridge* arguments at the motion to dismiss stage, this court is not bound by the district court's determination. "The law of the case doctrine prevents the relitigation of a settled issue in a case and requires courts to adhere to decisions made in earlier proceedings . . . ." *United States v. Bartsh*, 69 F.3d 864, 866 (8th Cir. 1995). However, the law of the case doctrine provides that once an appellate court has decided an issue in a case, the district court cannot revisit that determination on remand. *See In re Raynor*, 617 F.3d 1065, 1068 (8th Cir. 2010). It does not stand for the reverse proposition "that superior courts are bound by the decisions of inferior courts." *Id.* It is well established that this court may affirm on any basis the record

supports. *Christiansen v. W. Branch Cmty. Sch. Dist.*, 674 F.3d 927, 934 (8th Cir. 2012).

Medtronic's argument involves two related but distinct questions. The first involves a line of precedent rejecting implied private causes of action for aiding and abetting a violation of § 10b. In *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, the Supreme Court refused to extend the text of § 10b to encompass a private cause of action against actors that aid and abet other actors' violations of § 10b. 511 U.S. 164, 191 (1994). After *Central Bank*, Congress passed the Private Securities Litigation Reform Act, which declined to create a private cause of action for aiding and abetting and instead placed the authority to prosecute claims against aiders and abetters with the Securities and Exchange Commission. *Stoneridge*, 552 U.S. at 158. *Janus* followed, and the Supreme Court reinforced *Central Bank*'s rejection of aiding and abetting liability by holding that a private claim brought under Rule 10b-5 for making false statements may only be brought against the "person or entity with ultimate authority over the statement, including its content and whether and how to communicate it." 564 U.S. at 142. The Court explained: "Such suits—against entities that contribute 'substantial assistance' to the making of a statement but do not actually make it—may be brought by the SEC but not by private parties." *Id.* at 143 (citation omitted).

The broader scope of scheme liability under Rule 10b-5(a) and (c) potentially offers plaintiffs a means to circumvent *Janus*—a situation we encountered in *Public Pension Fund Group v. KV Pharmaceutical Co.*, 679 F.3d 972 (8th Cir. 2012). In that case, investors asserted false statement claims against a pharmaceutical company for misrepresenting its compliance with FDA regulations in its SEC filings. The investors also attempted to assert a scheme liability claim against two of the pharmaceutical company's officers, alleging only that the officers had knowledge of the company's misrepresentations. We rejected the scheme liability claim, emphasizing that "a scheme liability claim must be based on conduct beyond

misrepresentations or omissions actionable under Rule 10b-5(b)." *Id.* at 987. Otherwise, plaintiffs could simply recast false statement claims barred under *Janus* as scheme liability claims. *See id.* Without alleging that the officers engaged in conduct beyond misrepresentations, allegations that the officers simply knew about the company's misrepresentations were insufficient to support a scheme liability claim. *Id*. Accordingly, a plaintiff cannot support a scheme liability claim by simply repackaging a fraudulent misrepresentation as a scheme to defraud. Rather, a plaintiff must allege some deceptive act other than the fraudulent misrepresentation.

In coming to this conclusion, this court relied on two cases from our sister circuits. *KV Pharm. Co.*, 679 F.3d at 987. These cases provide good examples of the kinds of scheme liability claims that do not allege separate deceptive conduct. In *WPP Luxembourg Gamma Three Sarl v. Spot Runner, Inc.*, the Ninth Circuit explained that the plaintiff had not alleged facts separate from those of its Rule 10b-5(b) omission claim because "[t]he fraudulent scheme allegedly involved the Defendant-Appellees planning together to not disclose the Founders' sale of securities in the secondary offering, and then not disclosing those sales; fundamentally, this is an omission claim." 655 F.3d 1039, 1058 (9th Cir. 2011). The Ninth Circuit distinguished a Massachusetts case where the defendant allegedly worked to boost the company's market price through activities other than omissions in investor reports. *Id.* (citing *Swack v. Credit Suisse First Boston*, 383 F. Supp. 2d 223, 237 (D. Mass. 2004)). Likewise, in *Lentell v. Merrill Lynch & Co.*, the Second Circuit rejected a scheme liability claim where the only market-manipulating conduct alleged was making a number of misrepresentations. 396 F.3d 161, 177 (2d Cir. 2005). District courts relying on *KV Pharmaceutical* have likewise adhered to this distinction in evaluating scheme liability claims. *See, e.g.*, *Cotter v. Gwyn*, 2016 WL 4479510 at *7-8 (E.D. La. Aug. 25, 2016) (sustaining a scheme liability claim where plaintiff alleged that defendant company approved and facilitated self-interested transactions in addition to failing to report them); *In re Smith Barney Transfer Agent Litig.*, 884 F. Supp. 2d 152, 161 (S.D.N.Y. 2012) (sustaining a scheme liability claim

where plaintiff alleged that defendants not only misleadingly disclosed fees but also channeled cost savings away from the mutual fund to which they properly belonged); *William L. Thorp Revocable Trust v. Ameritas Inv. Corp.*, 57 F. Supp. 3d 508, 527 (E.D.N.C. 2014) (rejecting a scheme liability claim where the only alleged deceptive acts were the oral misrepresentations of an investment agent to his client).

Here, Appellants allege conduct beyond mere misrepresentations or omissions actionable under Rule 10b-5(b). Appellants' scheme liability claim alleges that Medtronic shaped the content of medical journals by "pa[ying] physicians . . . to induce their complicity in concealing adverse events and side effects associated with the use of INFUSE and overstating the disadvantages of alternative bone graft procedures." Although the scheme liability claim also includes allegations that Medtronic edited language in the clinical studies that the physicians ultimately published, the act of paying physicians to induce their complicity is the allegation at the heart of the scheme liability claim. Paying someone else to make a misrepresentation is not itself a misrepresentation. Thus, Appellants do not merely repackage allegations of misrepresentation as allegations of a scheme.[3] *Janus* and *KV Pharmaceuticals* require some conduct other than a misrepresentation to support a scheme liability claim. They do not hold that the alleged scheme can never involve any misrepresentation in order for the scheme liability claim to survive. *See, e.g.*, *In re Smith Barney*, 884 F. Supp. 2d at 161 (sustaining scheme liability claim where alleged conduct included but was not limited to misleadingly disclosing fees). Accordingly, because Medtronic's alleged deceptive conduct goes beyond mere misrepresentations or omissions, *Janus* does not bar Appellants' scheme liability claim.

[3]Notably, the Appellants did not assert a false statement claim based on the clinical trials.

The second part of Medtronic's argument concerns whether Appellants have sufficiently pleaded that the market relied on Medtronic's conduct as a matter of law. In *Stoneridge*, Charter Communications and its suppliers engaged in sham transactions designed to enable Charter to falsify its financial statements. 552 U.S. at 152-55. Investors sued the suppliers, asserting both a false statement claim and a scheme liability claim. While the investors argued that the suppliers' participation in the sham transactions enabled Charter to falsify its statements, the Supreme Court held that the investors could not demonstrate that they relied on the suppliers' conduct. *Id.* at 159. "Reliance by the plaintiff upon the defendant's deceptive acts is an essential element of the § 10(b) private cause of action. It ensures that, for liability to arise, the 'requisite causal connection between a defendant's misrepresentation and a plaintiff's injury' exists as a predicate for liability." *Id.* (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 243 (1988)). The Court rejected the false statements claim, concluding that the causal connection between the suppliers and the falsified financial statements was too attenuated to support a finding of market reliance where the suppliers' conduct did not satisfy any presumption of reliance and the investing public did not have knowledge of the suppliers' deceptive acts. *Id.*

The Court also rejected the scheme liability claim, emphasizing that "this [scheme liability] approach does not answer the objection that petitioner did not in fact rely upon respondents' own deceptive conduct." *Id.* at 160. Since Charter filed the fraudulent financial statements, the suppliers did not make a misrepresentation that the public relied on. The suppliers' participation in sham transactions did not reach the public and "nothing respondents did made it necessary or inevitable for Charter to record the transactions as it did." *Id.* As a result, the causal link between the false financial statements and the suppliers' conduct was too remote to demonstrate reliance. *Id.* at 161. Instead, the Court determined that allowing the scheme liability claim against the suppliers would "revive in substance the implied cause of action against all aiders and abettors except those who committed no

deceptive act in the process of facilitating the fraud." *Id.* at 162-63. As a result, under *Stoneridge*, a plaintiff asserting a scheme liability claim must demonstrate that the causal connection between the defendants' alleged deceptive act and the information on which the market relied is not too remote to support a finding of reliance.

Unlike the conduct at issue in *Stoneridge*, the causal connection between Medtronic's alleged deceptive conduct and the information on which the market relied is not too remote to support a finding of reliance. Medtronic's alleged deceptive conduct consists of manipulating the clinical trials by paying the physician-authors to conceal adverse effects and to overstate the disadvantages of alternative procedures. Appellants alleged in their complaint that investors directly relied on the resulting favorable clinical trials. Indeed, according to the Appellants' amended complaint, in speaking with potential investors, Medtronic's CEO specifically emphasized that the company's products' strong clinical trial performance undergirded Medtronic's competitiveness and sustainability. As a result, taking the allegations as true, Medtronic's deceptive conduct directly caused the production of the information on which the market relied. Unlike the suppliers' conduct in *Stoneridge*, Medtronic's purported conduct would not merely assist or enable the physician-authors to deceive the market. Rather, Medtronic's alleged conduct would deceive the market with the assistance of the physician-authors. A company cannot instruct individuals to take a certain action, pay to induce them to do it, and then claim any causal connection is too remote when they follow through. In this way, Medtronic's alleged manipulative conduct directly caused the biased clinical trial results that the market relied upon. This alleged causal connection is sufficient to support a finding of reliance. Thus, *Stoneridge*'s concern about resurrecting private aiding and abetting claims does not arise here. Accordingly, we decline to adopt Medtronic's alternate ground for affirmance.

III.

For the reasons discussed above, we vacate summary judgment and remand for proceedings not inconsistent with this opinion.
