In the
United States Court of Appeals
For the Seventh Circuit

No. 11-1471

PLUMBERS AND PIPEFITTERS LOCAL UNION 719
PENSION FUND and CARPENTERS PENSION FUND
OF WEST VIRGINIA, on behalf of a class,

Plaintiffs-Appellants,

v.

ZIMMER HOLDINGS, INC.; DAVID C. DVORAK; and
JAMES T. CRINES,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division.
No. 1:08-cv-01041-SEB-DML—**Sarah Evans Barker**, *Judge*.

ARGUED OCTOBER 18, 2011—DECIDED MAY 21, 2012

Before EASTERBROOK, *Chief Judge*, and RIPPLE and KANNE, *Circuit Judges*.

EASTERBROOK, *Chief Judge*. Two pension funds that own shares of Zimmer Holdings, Inc., charge it with defrauding its investors by downplaying the significance

of difficulties it was having manufacturing some of its products and the high failure rate one surgeon reported for another of its products.

Zimmer designs and makes orthopaedic reconstructive devices (and related products) that it sells throughout the world. One of its products is the Durom® Acetabular Component (the Durom Cup), which is used to replace the socket in a hip joint. One side of the Durom Cup is a porous ceramic designed to bond with the hip bone; the other is forged titanium designed to allow a leg bone (or a titanium replacement for one) to move freely. The Wikipedia article "Hip replacement" provides an overview of the components and procedures.

One well-known surgeon, Lawrence Dorr, reported unacceptably high failure rates after using the Durom Cup in his patients. See William T. Long, Manish Dastane, Michael J. Harris, Zhinian Wan & Lawrence D. Dorr, *Failure of the Durom Metasul® Acetabular Component*, 468 Clinical Orthopaedics & Related Research 400 (2010). Zimmer announced Dr. Dorr's preliminary findings in 2008 and promised to investigate. Later Zimmer attributed his failure rate—which it said was substantially higher than that experienced by other surgeons—to improper surgical technique. It stopped selling the Durom Cup in the United States while preparing new instructions for implantation; Zimmer continued to sell the Durom Cup with the original instructions in other nations. About a month later, Zimmer returned the Durom Cup to sale in this country; it remains available. This suit contends that Zimmer's statements were false:

that the problem stemmed from poor design or quality control in the manufacture of its product rather than Dr. Dorr's technique, and that Zimmer pretended otherwise in order to avoid a decline in the price of its stock.

Plaintiffs also contend that Zimmer delayed revealing quality-control problems at its plant in Dover, Ohio. According to plaintiffs, Zimmer learned of problems in late 2007 but did not reveal them in its January 2008 quarterly report and earnings call. On April 3, 2008, Zimmer announced that production of some orthopaedic products at Dover would be suspended until improvements could be made and that a few products would be recalled. Zimmer estimated that recalls plus sales foregone before production resumed would cost the company about $70 to $80 million. (Zimmer did not close the Dover plant; the decision affected only some of its production lines.) Plaintiffs contend that events at Dover reveal that the quarterly reports and earnings guidance Zimmer released in January and April were materially false. The Dover plant returned to full production, and plaintiffs do not contend that the estimated cost of the suspension and recall was substantially off the mark. In January Zimmer had projected 10% to 11% revenue growth for the year and net earnings of $4.20 to $4.25 per share; in July it cut this projection to 8.5% to 9% growth and net earnings of $4.05 to $4.10 per share. Plaintiffs maintain that Zimmer committed fraud by not using these lower estimates in January.

The district court dismissed the complaint, finding that it flunks the pleading standards of the Private Securi-

ties Litigation Reform Act of 1995 (PSLRA), 15 U.S.C. §78u-4. See 673 F. Supp. 2d 718 (S.D. Ind. 2009), relying on *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). The judge wrote that the complaint satisfies neither the materiality requirement nor the need to show scienter (that is, the defendants' knowledge that they were lying) under the *Tellabs* standard: "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." 551 U.S. at 314. Plaintiffs proposed to amend the complaint to satisfy the judge's concerns. In a comprehensive opinion, 2011 U.S. Dist. LEXIS 9253 (S.D. Ind. Jan. 28, 2011), the district court held that the proposed amendment would be futile. The judge did, however, withdraw the ruling that Zimmer's statements were not material, anticipating that the Supreme Court's decision in *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), then under advisement, might undercut this aspect of the earlier ruling. That left the scienter holding as the basis of the district court's judgment.

The Durom Cup was failing in the United States at an unacceptably high rate. Plaintiffs say that this must have been caused by design or manufacturing problems, because Dr. Dorr believed that surgeons had used proper methods. Zimmer announced, however, that it thought the problem one of technique and that it was taking the device off the market, in the United States only, for a brief period (which turned out to be one month) in order to revise the instructions for use and provide additional education to surgeons. Given the

conflict between Dr. Dorr and Zimmer, plaintiffs contend, a jury could infer that Zimmer was lying and knew it. We agree with the district court that this approach is unavailing.

Zimmer did not try to hide the failures Dr. Dorr had encountered. Dorr made a public announcement, and so did Zimmer, which added (what was anyway evident) that lower sales and more products-liability litigation might ensue. Three months before Dorr made his public statement in April 2008, Zimmer had announced that the Durom Cup was challenging to implant and that changes in labeling or training might be required. No one could predict how serious the problem would turn out to be, so Zimmer's decision not to try to quantify the effect in January can't be treated as a fraud. Zimmer knew that results in Europe had been better. While Dorr was reporting failure rates of 20% or so, a group in Europe was reporting failure rates of less than 1%. The Durom Cup had been used in Europe since 2003 but had not been introduced in the United States until mid-2006; perhaps European surgeons had confronted and overcome challenges that colleagues in the United States were facing. The different success rates can't have been caused by design or manufacture: all Durom Cups have one design and are made in the same plant.

Corporate executives who know that one group of surgeons experiences success, and another group failure, with the very same medical device could believe that the different outcomes had been caused by dif-

ferences in the way the surgeons had implanted the device. That's what Zimmer's executives said they had concluded. The complaint does not establish an inference of scienter that is "at least as compelling as any opposing inference of nonfraudulent intent." Indeed, even today plaintiffs have not supplied a cogent reason to think that Zimmer's statements were false, let alone *knowingly* false. The Food and Drug Administration has never concluded that the Durom Cup was defectively designed or made, indeed never even issued a warning or caution concerning the Durom Cup.

As for the Dover facility and its products: plaintiffs say that Zimmer's management knew of the quality-control problems and should have announced them earlier. Yet quality control is an issue at all medical companies. Knowing of "problems," which are common, differs from knowing that a facility must be closed and some of its products recalled. In the proposed amended complaint, plaintiffs offered examples of events that, in their view, show that Zimmer must have known that the income and earnings projections made in January 2008 were bound to be embarrassed by looming problems at Dover:

- David C. Dvorak, Zimmer's CEO, decided not to invest in quality systems that might have avoided problems at the Dover facility.
- Before the FDA inspection, Dvorak and other executives attended meetings at which quality issues were discussed.
- Dvorak hired a specialist to help the company avoid FDA warning letters.

- Zimmer coached a team of employees on what to say to an FDA inspector.

The district judge replied: "In terms of their relevance to scienter, these allegations miss the mark. It is irrelevant that Defendant Dvorak or anyone else at Zimmer knew that an FDA inspection occurred, took actions to mitigate any consequences of that inspection, or that the company was concerned with the quality of its [orthopaedic surgical products]. These facts are not inconsistent with the statements at issue." 2010 U.S. Dist. LEXIS 9253 at *55-56. That is to say, once again the complaint lacks cogent support for a contention that Zimmer's statements were false, let alone fraudulent.

We asked plaintiffs' counsel at oral argument for the best evidence that *anything* Zimmer said throughout the first six months of 2008 was false. Counsel pointed to this exchange during a conference call between financial analysts and Dvorak on January 29, 2008.

> Q: All right, and you mentioned you talked about investing in compliance and systems. Do you currently have any issues with the FDA, any warning letters, that usually takes a few months for those to be posted, that they may have been issued or 483'ed?
>
> A: We don't have any warning letters at this point.

This statement is true. FDA inspectors had not issued a warning letter at any of Zimmer's plants. Plaintiffs call the answer fraudulent because of what they describe as a materially misleading omission: the question asked

about warning letters or "483"s, and the answer concerned only warning letters.

In industry jargon, a "483" is an observation by an inspector, providing information about "significant objectionable conditions" (not serious enough to merit a warning or any formal action by the agency) that the inspector believes will be useful to the company. The shorthand "483" derives from the fact that these observations are recorded on the FDA's Form 483. As the questioner remarked, it might take time for any warning or Form 483 to be prepared and transmitted after an inspection. But inspectors often make observations verbally with written follow-up, and the questioner was interested in this possibility. The complaint alleges that an inspector at Dover made eight verbal 483 observations to the plant's managers during a nine-day visit that ended on January 29, 2008, the day of the conference call (which began at 8 A.M.). It is not clear how quickly these 483 observations reached Zimmer's CEO. Only one of the eight concerned quality control; others dealt with recordkeeping and a recall that occurred in 2006. At all events, it is hard to call a truthful answer to a compound question "fraud."

Oral exchanges are less precise than written ones. Dvorak did not know what question was coming, had to answer off the cuff, and did not have an opportunity to review the question and edit his answer before the next question was posed. This question mentioned warnings first, and Dvorak said that Zimmer had not received any. The questioner could have followed up

about 483 observations, but didn't. In the language of *Tellabs*, nothing here supports an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." The worst one could say about Zimmer's answer is that it was evasive, which is short of fraudulent. Cf. *Bronston v. United States*, 409 U.S. 352 (1972) (evasive answer cannot be basis of a perjury conviction).

Plaintiffs contend that we should infer scienter because Dvorak and other top managers had an incentive to make Zimmer look good in order to keep their jobs, improve their bonuses, and increase the value of their stock options. This is too generic to satisfy *Tellabs*. A similar assertion could be made about every firm in the world, but the fact that managers benefit from higher stock prices does not imply that any particular manager committed fraud. Quite the contrary. Managers usually do best when a firm has long-term success. Those who boost prices fraudulently for six months or so—as plaintiffs say Dvorak and Zimmer's other top managers did—and then see market capitalization decline, may find themselves on the street, and their stock options won't vest. If, as plaintiffs maintain, Dvorak and other managers told a series of lies during the first half of 2008 about one plant and one product that together produced less than 10% of the firm's income (Zimmer says that it was only 2% of global revenue and 3.6% of the year's profit), and affected earnings by only 15¢ a share, they were putting their fortunes and careers at stake in exchange for very little return. This aspect of

plaintiffs' arguments thus undermines, rather than strengthens, the inference of scienter.

At any given time, one or another product of a drug or medical-device producer with a portfolio of thousands (Zimmer has more than 130,000 unique product codes) is harder to make or less successful than hoped. Quality-control issues at pharmaceutical and medical-device producers are endemic, as customers and regulators always want higher quality even though investors want only "enough" quality. Investing beyond the point of diminishing returns injures rather than helps investors; competent managers will do just what Zimmer's were alleged to have done and take a beady-eyed view of proposals to invest tens of millions in new capital equipment at every plant encountering problems that might be solved more cheaply. The allegations of this complaint concern the problems Zimmer faced in 2008; in a different year the headaches would have come from a different plant or a different product, but the fact that these particular problems occurred—and that information came out over time, as more news accumulated—does not imply that any manager was lying to investors.

Plaintiffs point to many other supposedly false statements and a host of detail that supposedly shows that one or another statement was knowingly false. The district court's two lengthy opinions address all of these other statements. We have covered only the highlights—but, because these highlights are plaintiffs' strongest arguments, there is no need to fill the Federal

Reporter with the rest. We agree with the way the district court addressed them, and its judgment is

AFFIRMED.