Paula Kuyat, et al v. BioMimetic Therapeutics, Inc., et al Doc. 6012004967 Att. 1

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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

PAULA KUYAT, et al.
Plaintiff,

CHARLES M. SARAFIN, individually and on behalf of all others similarly situated,
Plaintiff-Appellant,

v.

BIOMIMETIC THERAPEUTICS, INC., SAMUEL E. LYNCH, and LAWRENCE E. BULLOCK,
Defendants-Appellees.

No. 13-5602

Appeal from the United States District Court
for the Middle District of Tennessee at Nashville.
No. 3:11-cv-00653—Kevin H. Sharp, District Judge.

Argued: December 4, 2013

Decided and Filed: March 28, 2014

Before: BOGGS, ROGERS, Circuit Judges; STEEH, District Judge.*

COUNSEL

ARGUED: Patrick V. Dahlstrom, POMERANTZ, GROSSMAN HUFFORD DAHLSTROM & ROSS LLP, Chicago, Illinois, for Appellant. Randall W. Bodner, ROPES & GRAY LLP, Boston, Massachusetts, for Appellees. **ON BRIEF:** Patrick V. Dahlstrom, POMERANTZ, GROSSMAN HUFFORD DAHLSTROM & ROSS LLP, Chicago, Illinois, Murielle J. Steven Walsh, POMERANTZ GROSSMAN HUFFORD DAHLSTROM & GROSS LLP, New York, New York, for Appellant. Randall W. Bodner, Christopher G. Green, Andrew J. O'Connor, ROPES & GRAY LLP, Boston, Massachusetts, Nicholas M. Berg, ROPES & GRAY LLP, Chicago, Illinois, Douglas H. Hallward-Driemeier, ROPES & GRAY LLP, Washington, D.C., Glenn B. Rose, HARWELL HOWARD HYNE GABBERT & MANNER, Nashville, Tennessee, for Appellees.

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* The Honorable George Caram Steeh, III, United States District Judge for the Eastern District of Michigan, sitting by designation.

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OPINION

ROGERS, Circuit Judge. In this securities fraud action, the plaintiffs contend that BioMimetic Therapeutics, Inc. misled investors about Augment Bone Graft's prospects for Federal Drug Administration (FDA) approval. According to the plaintiffs, the FDA privately communicated to BioMimetic that the FDA expected the device's clinical trials to prove that Augment was effective based on an analysis of all of the study's participants. The clinical trials did not achieve those results. But if BioMimetic removed from its analysis study participants that did not actually receive treatment, then the data did indicate that the device was effective. Based on these two analyses, BioMimetic expressed optimism about Augment's chances for FDA approval to investors. The plaintiffs claim that those statements were misleading because BioMimetic did not tell investors everything it knew about the FDA's expectations—particularly the FDA's desire for the trials to show that the device was effective based on an analysis of the entire study population. However, the plaintiffs' complaint does not plead a strong enough inference of scienter, and therefore the district court did not err in granting BioMimetic's motion to dismiss the plaintiffs' complaint.

BioMimetic develops and manufactures products that help heal damaged bones and muscles. Augment is one of the company's flagship products; it is designed to encourage bone growth in patients that undergo foot and ankle surgeries. Historically, doctors treated these damaged bones and muscles by transplanting healthy tissue from one part of the patient's body to the damaged area via a process known as an autograft. Augment is different from an autograft because the device promotes bone growth via drugs and can be done in a single operation, while autografts require conducting a second surgery to harvest the material from another part of the patient's body. If Augment works as intended, the device will obviate the need for a surgeon to conduct the second surgery.

Before BioMimetic can sell Augment in the United States, the FDA must approve the device. Obtaining FDA approval requires a company (known as a sponsor in this context) to navigate the complex premarket approval process. To receive premarket approval, a sponsor must conduct clinical trials that demonstrate the device's efficacy and safety. Before obtaining permission to conduct the clinical trials, the sponsor must receive FDA clearance to test the device on humans. And before the FDA will grant its permission to conduct those tests, the sponsor must submit a proposed study plan that governs how the study will be performed and its data analyzed. This plan is known as a protocol. Sometimes the FDA will object to the initial protocol proposed by the sponsor and will issue a conditional approval letter that allows the trials to begin but that requires refinement of the protocol. In those cases, the sponsor will need to supplement its proposed protocol to address the FDA's concerns.

After the sponsor completes the clinical trials, it can submit an application for premarket approval to the FDA. If the agency detects potential problems with the application, it can issue a "deficiency letter" that asks the sponsor to address any problems the letter identified. The FDA can also choose to refer the premarket approval application to a panel of outside experts. After a public meeting, these experts vote on whether they think the device is safe, effective, and whether its benefits outweigh its risks. If the device makes it through all of these steps, then the FDA itself will decide whether or not it will approve the device. The FDA is not bound by the expert panel's recommendation and can choose to approve the device or declare it "not approvable."

BioMimetic filed for permission to conduct clinical trials in June 2005. The protocol submitted with that application proposed that the "primary effectiveness analysis" (i.e., the analysis that would determine whether Augment was effective relative to a control group of patients receiving a traditional autograft implant) would be conducted based on an intent-to-treat (ITT) population. An ITT population includes every patient that is randomly assigned to a treatment group (in this case, either Augment or an autograft). By contrast, a modified intent-to-treat (mITT) population is a subset of the ITT population that excludes individuals that meet certain criteria (e.g.,

patients that are initially assigned a treatment group but that do not actually receive treatment).

The FDA approved Augment for clinical trials, but wanted BioMimetic to revise its protocol. BioMimetic submitted a supplement that included an amended definition of "intent to treat" on April 16, 2007. The supplement stated: "The Intent-to-Treat (ITT) population is defined as all randomized subjects who received treatment post randomization. Patients who are randomized and unable to be treated will be considered as surgical screening failures and will not [be] included in the Intent-to-Treat (ITT) patient population." This was not a standard definition of ITT. Because the proposed definition excluded patients that were randomly sorted into treatment groups, the definition did not actually describe an ITT population. Rather, the population that BioMimetic proposed to analyze for its primary effectiveness analysis would more accurately be described as an mITT population. Thus what BioMimetic was proposing to do, albeit in a somewhat roundabout way, was analyze an mITT population rather than an ITT population.

BioMimetic's proposed change was not lost on the FDA. In a May 18, 2007 letter, the FDA wrote that BioMimetic had "corrected the deficiencies cited in our . . . conditional approval letter," and approved the April 16 supplement (which contained the proposed change from ITT to mITT). But the letter also explicitly addressed the new definition of ITT. The FDA wrote:

> You should also give serious consideration to the following items which are considered essential for the analysis of your data for the purposes of determining safety and effectiveness for a future PMA application: . . .
>
> 2. The Intent-to-Treat population should be defined as all randomized subjects in the treatment groups to which they were assigned, regardless of whether they actually received the assigned treatment or not. All subjects should be analyzed as randomized even if no treatment or other treatment was actually received. You may analyze additionally a group of patients excluded from the ITT due to "surgical screening failure" . . . ; however, this should be considered and referred to as a "modified ITT" population versus the "ITT" population (i.e., "true ITT" population) defined above. You should plan to analyze the true

> ITT population. You may also analyze a modified ITT (i.e., patients with "surgical screening failures" who are excluded from the ITT) and the per-protocol population.

BioMimetic proceeded to conduct clinical trials over the next couple of years. The trials ended and BioMimetic issued a press release summarizing the study's results on October 13, 2009. That date is the beginning of the class period. According to the release, Augment was effective when an mITT population was analyzed (i.e., the trial produced statistically significant results), but not when the analysis was conducted on the ITT population.

The company addressed the conflicting results of the study in a phone call with investors that same day. In response to an analyst who asked whether the FDA would consider only the ITT results, Russ Pagano, BioMimetic's Vice-President for Clinical and Regulatory Affairs said:

> So, does FDA look at the ITT? No. FDA really looks at the totality of the dataset, and I think if you do that here, regardless of how you weight anything, you would see a classic—kind of classic pattern of a noninferiority outcome in that you're going to have a number of outcomes. If you're truly noninferior to a product in that just typically you're going to have a couple that probably do not make it statistically and hopefully you'll have the bulk that do. So, I think from a statistical point of view, we kind of hit the classic pattern of what you would expect.
>
> FDA—that said, FDA does look at everything. They also said our protocol calls out for we pre-specified [sic], as we talked about the takeouts, if you will, from the MITT. FDA approved that. However, what they do, just to be totally transparent, they frequently in approval letters will put what they call PMA advisories, where they then make some suggestions of things you should do per your PMA. It's in one of these PMA advisories that they state that they would like to see a true traditional ITT, which basically includes everybody.

Pagano and Samuel Lynch, BioMimetic's President and CEO, also argued that there was regulatory precedent for conducting an analysis on an mITT population. They explained that Medtronic had obtained approval for a device based on an analysis similar to the one BioMimetic had used. Finally, BioMimetic argued to investors that the mITT

results were more relevant from a clinical perspective, and that the company had defined who would be excluded from the mITT population before the trials began in order to avoid injecting bias into the study (the principal danger of using an mITT rather than an ITT population).

The market reacted negatively after the company released the study data: shares fell 16% in after-hours trading after the results of the study were revealed. The price of BioMimetic stock subsequently experienced a "roller coaster ride" as investors grappled with the implications of the results.

The clinical trials had other problems as well. According to the plaintiffs, BioMimetic enrolled an insufficient number of participants in the study, compromised the trial's effectiveness data by failing to provide baseline imaging against which to compare post-surgical results, allowed an abnormally high number of protocol deviations, damaged the integrity of the study by losing documentation, failed to perform pharmacokinetics studies, neglected to monitor patients who experienced increased antibody production as a result of being exposed to a human growth factor used by Augment until their antibodies returned to baseline levels, declined to conduct reproductive studies on the potential effects of exposure to Augment's human growth factor on pregnant women, and bolstered the study's safety data by failing to report all adverse events in the study.

After reviewing BioMimetic's application for premarket approval, the FDA sent the company a deficiency letter on September 3, 2010. This letter asked for clarification and additional data relating to numerous parts of the application. Notably for the purposes of this case, the deficiency letter questioned BioMimetic's use of an mITT population for the primary effectiveness analysis. But in a response letter, BioMimetic explained to the FDA that the Agency had approved the analysis of an mITT population in the May 18, 2007 letter and reiterated the company's arguments that the mITT results were more relevant and that exclusion of certain patients had not biased the study.

After BioMimetic responded to the deficiency letter, the FDA sent BioMimetic's premarket approval application to an advisory panel of experts. On May 9, 2011, three

days before the meeting with the panel, the FDA released a briefing document to the public. Among other things, the document expressed concern over BioMimetic's use of an mITT population in its analysis. The document explained:

> FDA believes that the ITT analysis population as defined in the PMA should be considered the primary analysis. In addition, FDA advised the sponsor at the IDE stage that both analysis populations should be supportive of non-inferiority. Note that the ITT analysis population preserves the benefits of randomization, while the mITT analysis population does not (due to excluding subjects for mis-randomization or not receiving treatment according to protocol.)

The briefing document apparently made investors question Augment's prospects—the company's stock price fell 35% the day the document was released. Despite the criticism of the clinical trials in the briefing document, the advisory panel voted to recommend that the FDA approve the device, albeit narrowly. Only ten of the eighteen panel members voted that Augment's benefits outweighed its risks. The market reacted negatively to the narrow vote, and BioMimetic's stock price experienced a 10% decline from that day to the next. The class period ended three days later on May 15, 2011.

On January 3, 2012, the FDA issued a non-approvable letter. The letter explained that the Agency would not approve Augment unless BioMimetic provided additional information about the trials. The FDA's concerns stemmed at least in part from the fact that it concluded that it needed "to evaluate the 'robustness' of the data, given the differences in the outcome of the intent-to-treat and the modified-intent-to-treat patient population analyses."

The plaintiffs filed suit on July 6, 2011, approximately two months after the release of the briefing document. Their complaint alleges that BioMimetic was aware of numerous deficiencies in Augment's clinical trials, but spoke optimistically to investors about the device's prospects for FDA approval. According to the complaint, these rosy assessments amounted to securities fraud. The district court disagreed and granted BioMimetic's motion to dismiss. The court concluded that the plaintiffs had not pled facts indicating a strong inference of scienter as required by the Private Securities Litigation Reform Act of 1995 (PSLRA) and *Tellabs, Inc. v. Makor Issues & Rights,*

Ltd., 551 U.S. 308 (2007). The district court reasoned that the May 18, 2007 FDA letter gave BioMimetic a basis for telling investors that it had permission to analyze an mITT population because the letter stated that it approved the supplement where the change occurred. The district court also concluded that the company's disclosures (of the study data, during the investor phone call, and in the company's various SEC filings) were extensive enough that no material information was withheld from investors. Thereafter, the plaintiffs moved under Rule 59 to alter the court's order granting the motion to dismiss and for permission to amend their pleadings to address the May 18, 2007 letter. The plaintiffs attached to the motion a proposed amended complaint that included evidence from Dr. Gaurino, an expert on the FDA approval process, and additional allegations relating to the May 18, 2007 letter. The district court denied the motion, concluding that the plaintiffs had unduly delayed by waiting until after the motion to dismiss was granted before asking for permission to amend their complaint. This appeal followed.

The plaintiffs' complaint did not adequately plead facts giving rise to a strong inference of scienter as required by the PSLRA. 15 U.S.C. § 78u-4(b)(2)(A). The plaintiffs' theory is that BioMimetic knew that the Augment clinical trials went poorly, but nevertheless spoke favorably about the device's prospects for FDA approval. In particular, the plaintiffs argue that the FDA had privately communicated that it expected BioMimetic to obtain statistically significant results based on an analysis of the ITT population, but that the company characterized those results as less important than the analysis of the mITT population.[1]

The plaintiffs' complaint identifies numerous misleading statements allegedly made by the company. Many of those statements cast a favorable light on Augment's clinical trials and the device's chances for success. For example, BioMimetic characterized the study as producing "positive top line results," said that the company

[1]The plaintiffs argued that other deficiencies in the study, for example the fact that Biomimetic did not conduct pharmacokinetics studies, also support an inference of fraud. These arguments are not convincing. Unlike the allegations regarding the use of mITT and ITT, there are no allegations supporting the notion that the defendants knew that these other supposed deficiencies would hurt Augment's prospects for FDA approval.

was "encouraged by the results seen to date in Augment's clinical development," and stated that it felt "confident in the PMA [the company] submitted for Augment earlier this year." The plaintiffs assert that these statements were misleading because BioMimetic knew that the FDA expected it to obtain statistically significant results based on an ITT population and so the results were not nearly as positive as BioMimetic's statements otherwise suggested. Other statements related directly to which population the FDA approved for the primary effectiveness analysis for the device. In a 2009 earnings call, the company stated: "we met our pre-specified primary endpoint and believe that we have demonstrated a clear picture of non-inferiority," and the company referred to the mITT population as "the pre-specified primary study population" in a 2010 press release. These statements were alleged to be false because the company knew that mITT was not the approved population.

The plaintiffs' complaint does not give rise to a strong inference of scienter. According to *Tellabs*, a court addressing whether a plaintiff has pled a strong enough inference of scienter must "take into account plausible opposing inferences" that the facts in the complaint generate. 551 U.S. at 323. A plaintiff only clears the high hurdle imposed by the PSLRA if "a reasonable person [would] deem the inference of scienter at least as strong as any opposing inference." *Id.* at 326. *Frank v. Dana Corp.*, 646 F.3d 954, 961 (6th Cir. 2011) reemphasizes that we must conduct a holistic review of the pleadings. Under such a review, a reasonable person would conclude that the inference of scienter in this case is not as strong as the opposing inference. BioMimetic could legitimately believe that the statistically significant results it achieved based on an analysis of the mITT population would be sufficient to obtain approval by the FDA. BioMimetic proposed analyzing an mITT population for its primary effectiveness analysis in its April 16, 2007 supplement. The FDA subsequently approved the supplement that proposed this change, giving the company reason to believe it had permission to conduct the primary analysis on the mITT population. The clinical trials occurred, and an analysis based on an mITT population yielded statistically significant results, thereby indicating that Augment achieved non-inferiority. The allegations in the complaint therefore indicate that the trials showed that the device was effective based

on an analysis that BioMimetic believed the FDA had approved. All of the supposedly misleading statements are consistent with that interpretation. While BioMimetic may have ultimately been mistaken about which population the FDA wanted the company to use for the primary effectiveness analysis, there are no facts suggesting the company knew this at the time its representatives spoke.

The May 18, 2007 letter does not support an inference of scienter. The letter does make clear that the FDA expected BioMimetic to conduct an analysis of both a "true ITT" and an mITT population. But the letter does not indicate that the FDA wanted the primary effectiveness analysis to be conducted on the ITT population. Rather, the letter concerns itself with ensuring that BioMimetic defined ITT and mITT properly in the premarket approval application by telling the company that the "Intent-to-Treat population should be defined as all randomized subjects in the treatment groups to which they were assigned, regardless of whether they actually received the assigned treatment or not." The letter says nothing either way about whether ITT must or must not serve as the primary benchmark for success.

The 2010 Deficiency Letter is similarly ambiguous. In the letter, the FDA stated that the original protocol called for the primary analysis to be performed using the ITT population, that BioMimetic had not justified its switch from ITT to mITT, and that using an mITT population risks introducing bias into the analysis. In its response letter, BioMimetic explained that it understood the May 18 letter to have meant that the primary study population "could be considered a modified intent to treat [population] and [be] presented in the PMA" so long as it was labeled as such (i.e., labeled as mITT and not ITT). Then BioMimetic proceeded to justify the propriety of analyzing an mITT population by making essentially the same arguments it had made to investors when the results of the trials were revealed: the company had excluded patients from the mITT population in a manner that avoided introducing bias into the study, and an analysis of an mITT population was a better indicator of whether the device was effective. It is hard to imagine that BioMimetic would risk the agency's ire by defending its use of mITT as the primary population based on the FDA's prior approval if the FDA had clearly not

given such approval. Like the May 18, 2007 letter, nothing in the deficiency letter indicates that the FDA told BioMimetic to use an ITT population for the primary effectiveness analysis.

The briefing document, by contrast, clearly does state that the primary analysis should be based on the ITT population. But this document was released at the end of the class period and well after the allegedly misleading statements were made. The document does indicate that BioMimetic must have known that the FDA expected ITT to be the primary analysis by the end of the class period, but the document has little bearing on what the company did or did not know at the time the allegedly misleading statements were made, and it does not support a strong inference of scienter. Similarly, a district court in California concluded that a complaint did not plead facts creating a strong inference of scienter because the complaint did "not allege any facts showing that, at the time Defendants made their forward-looking statements, FDA compliance problems existed, Defendants actually knew of the[] problems, or that the[] problems would preclude FDA approval . . . ." *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1126 (C.D. Cal. 2005).

Of course the lack of statistically significant results undoubtedly hurt Augment's prospects—but BioMimetic fully disclosed the results of the study and told investors that the FDA wanted to see an analysis of both the ITT and mITT populations. And the market apparently understood the significance of the results of the study because BioMimetic's stock price dropped 16% after the company released the data. It is doubtful that the company intended to defraud investors in light of its willingness to disclose information that harmed its share prices. Other courts have concluded that disclosing adverse information to the public negates an inference of scienter. *See, e.g.*, *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1425 (9th Cir. 1994).

Furthermore, nothing in the record indicates that the FDA declared that the presence or absence of statistically significant results in an analysis of the ITT population was the FDA's absolute requirement. According to BioMimetic's press release discussing the non-approvable letter, the FDA sought additional information

from BioMimetic so that the FDA could "evaluate the 'robustness' of the data, given the differences in the outcome of the intent-to-treat and the modified intent-to-treat patient population analyses." That statement does not suggest that the lack of statistically significant results in the ITT population necessarily doomed Augment in the FDA's eyes. While perhaps the lack of statistically significant results in the ITT population played a part in the FDA's decision, nothing in the relevant materials suggests that the company knew those results would be the device's downfall or that such a lack was so obvious an impediment to the device's success that BioMimetic's failure to perceive the risk of non-approval was reckless—i.e., that the company engaged in "highly unreasonable conduct" that was "an extreme departure from the standards of ordinary care," *PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 681 (6th Cir. 2004)

In fact, several factors indicate that BioMimetic rightfully expressed optimism about the device's prospects. The FDA had previously approved other devices based on mITT analyses. Augment proved itself by obtaining regulatory approval in both Canada and Australia. BioMimetic had previously succeeded in obtaining approval for GEM 21S, a product that contained the same drug as Augment. And the advisory panel of experts vindicated BioMimetic's optimism by voting to recommend that the FDA approve the device.

In summary, the more compelling inference that can be drawn from the pleadings is that BioMimetic was justified in expressing optimism about Augment's prospects for success despite the lack of statistically significant results produced by an analysis of the ITT population. BioMimetic may have ultimately been wrong about which population would be analyzed for the primary effectiveness analysis, but a reasonable person would more easily than not infer that BioMimetic believed that it had permission to use an mITT population for the analysis at the time that it spoke to investors. *See Tellabs*, 551 U.S. at 323. Therefore, the district court properly dismissed the plaintiffs' complaint.

The district court moreover did not abuse its discretion in refusing to grant the plaintiffs leave to amend their complaint. The plaintiffs asked the district court for permission to amend on two occasions: the first time was in the final sentence of their

brief in opposition to BioMimetic's motion to dismiss, and the second came in the form of a post-judgment motion made after the district court granted the motion to dismiss. Although FRCP 15 instructs courts to "freely give leave" to amend, that liberal policy does not apply to the plaintiffs' one-sentence request. A "request for leave to amend almost as an aside, to the district court in a memorandum in opposition to the defendant's motion to dismiss is . . . not a motion to amend." *La. Sch. Emps.' Ret. Sys. v. Ernst & Young, LLP*, 622 F.3d 471, 486 (6th Cir. 2010) (internal quotation marks omitted). Plaintiffs' motion contained precisely that kind of throwaway language. The final sentence of their memorandum in opposition reads: "Alternatively, Plaintiffs request leave to amend the Complaint in the event that the Court finds that it falls short of the applicable pleading standards in any respect." Furthermore, the plaintiffs did not submit a copy of the revised complaint at the time they filed their memorandum in opposition. Normally, a party seeking an amendment should attach a copy of the amended complaint. *See Shillman v. United States*, 221 F.3d 1336, 2000 WL 923761, at *6 (6th Cir. 2000) (unpublished table decision). Both because the plaintiffs did not present an adequate motion and because they did not attach a copy of their amended complaint, the district court did not abuse its discretion in refusing to allow the plaintiffs to amend their complaint based on the final sentence of the plaintiffs' memorandum in opposition.

The district court also did not abuse its discretion in denying the plaintiffs' post-judgment motion. In this case, the timing of plaintiffs' motion is relevant. *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002). Plaintiffs made their motion after the district court granted BioMimetic's motion to dismiss. "[I]n the post-judgment context, we must also take into consideration the competing interest of protecting the finality of judgments and the expeditious termination of litigation." *Id.* (internal quotation marks omitted). Balancing these interests requires a court to "be particularly mindful of not only potential prejudice to the non-movant, but also the movant's explanation for failing to seek leave to amend prior to the entry of judgment." *Id.*

The plaintiffs put forward no good excuse for delaying until after the district court's judgment. The plaintiffs sought to amend their complaint to address BioMimetic's arguments relating to the May 18, 2007 FDA letter by including evidence from Dr. Gaurino, an expert on the FDA approval process. But the plaintiffs had access to the FDA letter ten months before they filed their post-judgment motion. Furthermore, plaintiffs had apparently retained Dr. Gaurino long before the FDA letter was revealed. They thus presumably had access to his views on the letter when it was attached to BioMimetic's motion to dismiss. This court has previously explained that a district court "acts within its discretion in denying a Rule 15 and a Rule 59 motion on account of undue delay—including delay resulting from a failure to incorporate previously available evidence." *Leisure Caviar, LLC v. U.S. Fish & Wildlife Serv.*, 616 F.3d 612, 616 (6th Cir. 2010) (internal quotation marks and alterations omitted).

The plaintiffs' excuse—that they had no way of knowing that the May 18, 2007 letter would factor heavily in the district court's decision—does not pass muster. Rule 15's permissive amendment policy should not permit plaintiffs to "use the court as a sounding board to discover holes in their arguments, then reopen the case by amending their complaint to take account of the court's decision." *Id.* (internal quotation marks omitted). We recently rejected a similar argument in *Ricker v. Zoo Entm't, Inc.*, 534 F. App'x 495 (6th Cir. 2013). There, the plaintiff argued that "he 'was unaware of what defects, if any, the Court would perceive in the Complaint,' and first deserved 'the opportunity to analyze the supposed deficiencies in the Complaint to determine whether he [could] cure them.'" *Id.* at 501. The plaintiffs' explanation in the instant case is identical. The district court did not abuse its discretion in *Ricker*, and neither did the court in this case. The propriety of refusing to grant leave to amend is buttressed by the fact that the usual liberal standards under Rule 15 do not apply to cases governed by the PSLRA. "[T]he purpose of the PSLRA would be frustrated if district courts were required to allow repeated amendments to complaints filed under the PSLRA." *Miller v. Champion Enters. Inc.*, 346 F.3d 660, 692 (6th Cir. 2003).

For the foregoing reasons, we AFFIRM the judgment of the district court.