PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 17-2136

TRANA DISCOVERY, INC.,

Plaintiff – Appellant,

v.

SOUTHERN RESEARCH INSTITUTE,

Defendant – Appellee.

Appeal from the United States District Court for the Eastern District of North Carolina at Raleigh. Terrence W. Boyle, Chief District Judge. (5:13-cv-00848-BO)

Argued: December 11, 2018 Decided: February 7, 2019

Before KING, DIAZ, and RICHARDSON, Circuit Judges.

Affirmed by published opinion. Judge Richardson wrote the opinion, in which Judge King and Judge Diaz concurred.

ARGUED: Gary K. Shipman, SHIPMAN & WRIGHT, LLP, Wilmington, North Carolina, for Appellant. James Conrad Lester, MAYNARD, COOPER & GALE, P.C., Birmingham, Alabama, for Appellee. **ON BRIEF:** William C. Reiss, SHIPMAN & WRIGHT, LLP, Wilmington, North Carolina, for Appellant. Thomas W. Thagard III, John C. Neiman, Jr., MAYNARD, COOPER & GALE, P.C., Birmingham, Alabama, for Appellee.

RICHARDSON, Circuit Judge:

Plaintiff-Appellant Trana Discovery, Inc. has developed a technology that it believes can help find new drugs to treat HIV. It collaborated with Defendant-Appellee Southern Research Institute, a contract research organization, to put its technology to work by testing chemical compounds for signs that they inhibited the reproduction of HIV. When the testing yielded inconsistent results, Trana sued Southern for fraud and negligent misrepresentation.

In Trana's view, Southern made two actionable misrepresentations in its research reports. First, Southern allegedly failed to identify certain promising compounds as potential HIV treatments. Trana calls these test results "false negatives." Second, Southern falsely identified other compounds as potential treatments when in fact they were not. Trana refers to these latter results as "false positives." After discovery, the district court granted summary judgment for Southern on both theories. We affirm.

I.

A. Background

Trana was founded in 2000 by scientists with expertise in "transfer RNA" (or "tRNA"), a molecule in the human body. Some viruses, including HIV, use tRNA to reproduce. Trana's scientists developed a proprietary test (in the lingo of biochemists, an "assay") that could quickly identify chemical compounds with the potential to inhibit HIV's reproduction by targeting the virus's use of tRNA. The parties refer to the compounds identified by Trana's test as "hits."

Trana's proprietary test is a "biochemical" test, meaning that it does not use living cells. A positive result in this test only shows that a "hit" compound *might* treat HIV in a living person. So it is just a first step in the development of a marketable HIV drug, a long process that ultimately includes clinical trials and FDA approval. The virtue of Trana's test is that it can winnow down a universe of thousands (or even hundreds of thousands) of compounds to a much smaller number of "hits" worth pursuing.

The next logical step is to see whether those "hits" also have antiviral activity in a "biological" test—one that does use living cells. Yet even if a "hit" showed activity in a biological test, that would still be only a preliminary step in the drug-development process. Trana's goal was not to complete that arduous process on its own, but to entice a large pharmaceutical company into a partnership deal that would reward Trana handsomely for its intellectual property (the testing technology itself and any promising compounds it identified). To do that, Trana had to show that its testing technology could successfully identify compounds with promise as HIV drugs.

Trana entered into a three-way arrangement with Southern and the National Institute of Allergy and Infectious Diseases ("NIAID"), a component of the National Institutes of Health (a federal government agency). The arrangement involved three separate agreements. The first was between Southern and NIAID. Under the agreement, NIAID paid Southern to identify "hit" compounds using Trana's biochemical test; Southern would then be paid to use standard biological (*i.e.*, cell-based) tests to follow up on the "hits." The second agreement, between Southern and Trana, permitted Southern to use Trana's proprietary biochemical test. Under the third agreement, between Trana and

NIAID, Trana would retain certain exclusive rights to the "hit" compounds (including the right to patent them) for a specified time. All sides stood to benefit from the arrangement, in different ways. The public, represented by NIAID, would benefit from research into potential HIV drugs; Southern would be compensated for its work; and Trana would reap the potential commercial rewards flowing from testing paid for by taxpayers.

As the arrangement proceeded, decisions had to be made about what type of cells to use in the follow-up biological tests Southern performed. Research scientists have different cell types available to them. One type, known as peripheral blood mononuclear cells (or "PBMCs," a kind of white blood cell), must be gathered from human donors; these cells are therefore expensive to obtain. Another type is called a "CEM" cell, a kind of cancer cell. Scientists commonly use cancer cells in biological research, and because cancer cells tend to reproduce prodigiously, they can be grown cheaply in a lab.

Testing the same compounds in different cell types can yield different results. For example, in 2007, Southern performed a PBMC test on 29 compounds for Trana. Two of the compounds showed some antiviral activity. Trana then sent the two compounds to a pharmaceutical company, which tested them using cancer cells in 2008. The company found no antiviral activity in either compound and explained to Trana that the inconsistent results might be caused by the use of different types of cells. J.A. 809.

B. "False Negatives"

Trana's first theory of liability—for "false negatives," as alluded to above—arose from a decision to use CEM cells instead of PBMCs in testing performed in 2009.

Shortly before that, Southern had tested 13 "hit" compounds in PBMCs with no positive results. Hoping the disappointing results were due to the small sample size, the parties decided to perform biological tests on a much larger set of around 150 "hits." Testing that many compounds in PBMCs would have been expensive, costing the government around $150,000. By contrast, Southern estimated that testing the compounds in CEM cells would cost as little as $20,000.

NIAID approved Southern's use of CEM cells in the larger biological test. After consulting with Southern, NIAID's project officer noted that a CEM-cell test would be cheaper—a trait surely appealing to a budget-conscious government official (although presumably not to Trana, as it stood to gain the commercial benefit from the testing without paying for it).

This use of CEM cells, in Trana's view, was negligent: Southern should have used PBMCs or, at a minimum, advised NIAID and Trana of the benefits of using PBMCs, which might have led NIAID to select a PBMC test. Instead, Southern apparently told Trana that there was no good reason not to use CEM cells. One of Trana's expert witnesses, distinguished HIV scientist Mark Wainberg, opined that using CEM cells rather than PBMCs, which he described as the "gold standard," fell short of the standard of care for HIV research laboratories. And according to Trana, this negligence led to false information in the research report containing Southern's findings.

Southern issued the research report in June 2009 after using CEM cells to test the larger batch of compounds (which ultimately numbered 136). This report identified several compounds that demonstrated antiviral activity and thus showed promise for

investigation as HIV drugs. In most of the tested compounds, however, the CEM-cell test revealed no antiviral activity. The June 2009 report listed the compounds in a table titled "Antiviral Efficacy of Hit Compounds against HIV-1_{IIIB} in CEM-SS Cells." J.A. 4577–80.

This same batch of compounds was retested three years later in PBMCs, revealing some antiviral activity for two of the compounds the 2009 report identified as inactive. These two compounds are Trana's purported "false negatives." This inconsistency did not result from an error in the 2009 testing: retesting confirmed that these two compounds were indeed inactive in CEM cells. Instead, it resulted from the fact that testing in different cell types sometimes yields different results.

Trana's "false negatives" claim is that, had Southern performed a PBMC test in 2009, these two compounds would have exhibited antiviral activity in PBMCs. Armed with these additional positive results in 2009, Trana believes it would have been more likely to obtain a lucrative partnership with a pharmaceutical company. Another one of Trana's expert witnesses offered an opinion estimating the damages Trana suffered by missing that opportunity.

C. "False Positives"

Trana's second theory of liability concerns two "false positives" in a report Southern issued in June 2010. This report presented the results of a CEM-cell test performed on another batch of "hits" identified by Trana's proprietary test. That report identified seven particular "hit" compounds as exhibiting antiviral activity in CEM cells. Two of these compounds in fact had no activity in CEM cells, as retesting in 2012

showed. Southern concedes that these two positive results in the June 2010 report were incorrect. The error resulted from research misconduct by a Southern employee, who was ultimately debarred from federal-government contracting for three years, *see* Findings of Research Misconduct, 79 Fed. Reg. 35,546 (June 23, 2014). Trana claims that the misstatements in the June 2010 report were both negligent (due to Southern's inadequate supervision of its rogue employee) and fraudulent (on the part of the employee herself, whose intent, Trana argues, can be imputed to Southern).

Long before the misconduct was revealed, however, it was already apparent that these "false positive" compounds were not promising. In November 2010, Southern reported the results of a PBMC test covering the seven compounds that had tested positive in CEM cells in the June 2010 report. The two "false positives" showed no antiviral activity in PBMCs, and Southern concluded generally that "the antiviral activity of these seven compounds is not high enough to pursue additional development." J.A. 307. In December 2010, Southern advised Trana that "these compounds will only serve as possible probes to identify other compounds that may have better specificity and greater therapeutic indices," and that "these specific compounds do not have potential for further development." J.A. 5061–62.

D. The Lawsuit

In 2013, Trana filed this diversity action against Southern, bringing claims for negligent misrepresentation, constructive fraud, negligence, and fraud under North Carolina law. The district court dismissed Trana's constructive fraud and negligence

claims, a decision Trana does not appeal. The remaining fraud and negligent misrepresentation claims proceeded to discovery, which lasted just over two years.

After discovery closed, the district court granted summary judgment for Southern. When evaluating Trana's "false negatives" theory, the district court struck Professor Wainberg's opinion insofar as it related to the standard of care that applied to Southern in conducting the biological tests. Without Professor Wainberg's opinion, the district court concluded, there was insufficient evidence to establish the relevant standard of care, disposing of the "false negatives" claim. Turning to the "false positives" theory, the district court found that it too failed, because Trana failed to introduce adequate evidence of damages. The court also observed that there appeared to be insufficient evidence that Trana justifiably relied on the "false positive" results.

Trana timely appeals. We review the district court's grant of summary judgment de novo. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig. (No II)*, 892 F.3d 624, 645 (4th Cir. 2018). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact." Fed. R. Civ. P. 56(a). "To survive summary judgment, 'there must be evidence on which the jury could reasonably find for the nonmovant.'" *Lee v. Town of Seaboard*, 863 F.3d 323, 327 (4th Cir. 2017) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)).

II.

Based on the record before it, the district court properly granted summary judgment for Southern on Trana's two theories of liability.

A. "False Negatives"

We begin with the purported "false negatives" in the June 2009 report. Trana claims that report contained errors that were merely negligent, and not fraudulent. In Trana's view, Southern mistakenly, but honestly, believed that it was appropriate to use CEM cells in the testing. In its haste to show negligence, however, Trana has overlooked the other basic requirement of a negligent misrepresentation claim: a misrepresentation. That is, the defendant must have provided false information. *Schlieper v. Johnson*, 672 S.E.2d 548, 552–53 (N.C. Ct. App. 2009); *Jordan v. Earthgrains Companies, Inc.*, 576 S.E.2d 336, 339–40 (N.C. Ct. App. 2003); *Pinney v. State Farm Mut. Ins. Co.*, 552 S.E.2d 186, 191–92 (N.C. Ct. App. 2001); Restatement (Second) of Torts § 552(1) (Am. Law Inst. 1977). According to Trana, "the CEM data [in the June 2009 report] falsely identified the relevant compounds as inactive, and it is that falsity that is the basis of Trana's claim." Reply Brief of Appellant at 10; *see also* J.A. 122 (alleging that "Southern's June 2009 Report was false in that it reported as inactive two compounds that were in fact bioactive and potential lead compounds").

In reality, the information in the June 2009 report was not false. The report accurately stated the results of the biological test Southern performed: the so-called "false negative" compounds did not inhibit HIV reproduction *in CEM cells*. Even without the report's express caveat, Trana was well aware from earlier discussions that CEM cells, not PBMCs, would be used. And Trana concedes that these two compounds were in fact inactive in CEM cells. The report did not say that these compounds would also be inactive in other cell types, such as PBMCs. Nor did the report say that the

compounds lacked potential as HIV drugs. Trana has not explained how the true statements in the June 2009 report could have constituted a misrepresentation at all, much less a negligent one.

When pressed at oral argument to identify the misrepresentation underlying its claim, Trana suggested looking to Southern's alleged promise (in its agreement with NIAID) to use state-of-the-art testing technology. This claim, assuming it is properly before us, fails as a matter of law. A contractual promise cannot constitute a merely negligent misrepresentation. A promise is a statement of intention, not fact, meaning it is false only if the promisor never honestly intended to carry it out. *See Gadsden v. Johnson*, 136 S.E.2d 74, 77–78 (N.C. 1964); Restatement (Second) of Torts § 530(1) & cmt. c. It can be intentionally false, but not negligently so. Nor can a later breach of the promise transform it into a falsehood. A party's representation that it is currently in compliance with a contractual promise could perhaps be false if the party were actually in breach. But the June 2009 report did not contain that representation: it merely said that the testing was "conducted under" the NIAID contract, J.A. 4573, which was true.

Stripped to its core, the "false negatives" theory represents an attempt to shoehorn a claim for professional negligence or breach of contract into one for negligent misrepresentation. Trana claims that Southern breached a duty (arising perhaps from industry standards, perhaps from contract) to use PBMCs, or at least to inform Trana and NIAID of the benefits of using PBMCs. But Trana has not shown that any breach introduced false information into the June 2009 report. Thus, this theory fails.

Trana's "false negatives" theory appears to suffer from other flaws as well. We have particular doubts about the viability of Trana's expert testimony on damages. Trana's damages expert advanced the theory that the later positive PBMC results for these two compounds, if obtained in 2009, would have made it more likely that a pharmaceutical company would partner with Trana—a possibility the expert tried to quantify. But he admitted at deposition that he had not accounted for evidence in the record suggesting that a pharmaceutical company would not be impressed by these compounds. An expert must offer an opinion that fits the case at hand, not some other, hypothetical case, and a damages model that simply ignores key evidence veers into speculation. *See, e.g.*, *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000). In light of our holding above, however, we see no need to consider this issue in detail or to pass on the district court's decision to exclude Professor Wainberg's opinion on the standard of care.

B. "False Positives"

Trana's "false positives" theory fares no better. It founders on the requirement of "reasonable" or "justifiable" reliance (North Carolina courts use the term "reasonable" for fraud claims and "justifiable" for negligent misrepresentation claims, though the difference does not matter for our purposes). *Dallaire v. Bank of America, N.A.*, 760 S.E.2d 263, 267 (N.C. 2014); *Marcus Bros. Textiles v. Price Waterhouse, LLP*, 513 S.E.2d 320, 327 (N.C. 1999). Trana claims that it relied on the June 2010 report's erroneous identification of two compounds as bioactive in filing patent applications.

When the truth came out, Trana abandoned those applications, meaning the money spent on them was wasted.

We think it clear that any reliance on the "false positives" for patent purposes became unreasonable in November 2010. At that time, Trana learned the two compounds showed no antiviral activity in PBMCs and were not viable candidates for additional development. Even more so by December 17, 2010, when Southern's project manager advised Trana directly that these two compounds lacked potential. Trana has not presented any theory that explains the reasonableness of pursuing patents on compounds that it knew had no commercial value.

To even have a shot at establishing reasonable reliance, Trana must therefore show that it incurred patent expenses related to the two "false positive" compounds between the report dated June 25, 2010, and (at the latest) December 17, 2010. Trana's best evidence appears to be an interrogatory response listing the patents it pursued. But none of the filing dates in that document falls within the relevant window of time. J.A. 5853–54. And at oral argument, Trana's counsel could not represent that any relevant patents were filed before January 2011. Trana's failure to address this critical timing issue dooms its claim.

Trana also suggested at oral argument that it reasonably relied on press releases referencing the two "false positive" compounds. The record references two press releases from November and December 2010 that touted the results of recent research. J.A. 111–12, 5635–36. But these press releases were issued by Trana, not Southern. They also summarized the results of the testing generally and do not make separate

claims about these two compounds. And regardless, it would make no sense for Trana to rely on press releases intended for public consumption when it had privately received Southern's candid advice rejecting the viability of the compounds. On this record, no reasonable jury could find for Trana on the reliance issue, and so we need not address the parties' remaining arguments or the district court's ruling on damages.

* * *

This case supports the old adage favoring "quality over quantity." The parties engaged in over two years of discovery and produced a remarkably voluminous record for summary judgment and appeal. Yet the sheer mass of evidence could not make up for Trana's inability to establish key elements of its claims. Accordingly, the judgment of the district court is

AFFIRMED.