

12-2414-cv
ONY, Inc. v. Cornerstone Therapeutics, Inc.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2012

(Argued: April 25, 2013 Decided: June 26, 2013)

Docket No. 12-2414-cv

ONY, INC.,

Plaintiff-Appellant,

— v. —

CORNERSTONE THERAPEUTICS, INC., CHIESI FARMACEUTICI S.P.A., RANGASAMY
RAMANATHAN, M.D., JATINDER J. BHATIA, M.D., KRISHNAMURTHY C. SEKAR, M.D.,

Defendants-Appellees,

NATURE AMERICA, INC. DBA NATURE PUBLISHING GROUP, EDWARD E. LAWSON, M.D.,
AMERICAN ACADEMY OF PEDIATRICS, PREMIER, INC. DBA PREMIER RESEARCH SERVICES,
FRANK R. ERNST, PHARM.D.,

*Defendants.**

Before:

WINTER, CALABRESI, and LYNCH, *Circuit Judges.*

* The Clerk of the Court is directed to amend the official caption in the case to conform to the caption listed above.

Appeal from a May 21, 2012 judgment of the United States District Court for the Western District of New York (William M. Skretny, *C.J.*) dismissing plaintiff's complaint in its entirety. Defendants are various corporate sponsors, authors, and publishers of a scientific journal article comparing the effectiveness of several types of surfactants. Plaintiff complains that the article – and the distribution of selections from it – violates the Lanham Act and New York General Business Law § 349, and also constitutes tortious injurious falsehood and interference with prospective economic advantage. The district court correctly concluded that plaintiff has failed to state a claim based on publication of the article itself because the challenged statements are protected scientific opinion. We further conclude that plaintiff has failed adequately to allege that defendants Chiesi and Cornerstone distributed misleading excerpts of the article.

AFFIRMED.

MITCHELL J. BANAS, JR., *of counsel*, Jaeckle Fleischmann & Mugel, LLP,
Buffalo, New York, *for plaintiff-appellant*.

J. KEVIN FEE (Kristin H. Altoff, Jordana S. Rubel, *on the brief*), Morgan,
Lewis & Bockius, Washington, D.C., *for defendants-appellees*.

GERARD E. LYNCH, *Circuit Judge*:

This case asks us to decide when a statement in a scientific article reporting research results can give rise to claims of false advertising under the Lanham Act, deceptive practices under New York General Business Law § 349, and the common-law torts of injurious falsehood and interference with prospective economic advantage. We conclude that, as a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation. We further conclude that the secondary distribution of excerpts of such an article cannot give rise to liability, so long as the excerpts do not mislead a reader about the conclusions of the article.

BACKGROUND

The following factual background is taken from the complaint, whose allegations we accept as true, and from the materials referenced in the complaint. Plaintiff ONY, Inc. (“ONY”) and defendant Chiesi Farmaceutici, S.p.A. (“Chiesi”) are two of the biggest producers of surfactants, biological substances that line the surface of human lungs. Surfactants are critical to lung function: they facilitate the transfer of oxygen from inhaled air into the blood stream.¹ Although the human body naturally produces surfactants,

¹ Surfactants do this by lowering the surface tension of the liquid surface of alveoli, the air sacs that serve as the venue for oxygen exchange. Surfactants also help to ensure that the alveoli inflate evenly and do not overinflate.

prematurely born infants often produce inadequate surfactant levels. Infants with such a deficiency are at a higher risk for lung collapse and Respiratory Distress Syndrome (“RDS”), a condition that can result in respiratory failure and death. The non-human surfactants produced and sold by, among others, ONY and Chiesi are the primary treatment for RDS. The FDA has approved three surfactants for treatment of RDS in neonatal infants. ONY produces one derived from bovine lung surfactant that bears the trade name “Infasurf.” Chiesi produces a competing surfactant derived from porcine lung mince that goes by “Curosurf.”² Chiesi, an Italian pharmaceutical firm, contracts with its co-defendant Cornerstone Therapeutics, Inc. (“Cornerstone”) to distribute and market Curosurf in the United States.

The parties vigorously contest the relative effectiveness of their products – in the marketplace, in the scientific literature, and in the instant lawsuit. The parties agree that two variables are particularly relevant to this comparison: mortality rate and length of stay. Mortality rate means the percentage of infants treated with a particular surfactant who do not survive. Length of stay refers to the amount of time an infant remains in the hospital for treatment. These two variables are not entirely independent: in some cases the length of stay is shortened by death, which is reflected in the mortality rate. Put differently, some of the same causes of increased mortality rate (low birth weight, shorter

² The third surfactant, “Survanta,” which is produced from bovine lung mince, is manufactured by Abbott Pharmaceuticals, which is not a party to this lawsuit.

gestational period) also cause shorter lengths of stay. Conversely, infants with shorter hospitalization might have had less serious medical conditions from the beginning, independent of treatment variables. At the same time, a particularly effective drug may both reduce mortality rate and shorten length of stay.

In 2006, as part of its effort to promote and sell Curosurf, Chiesi hired defendant Premier, Inc. (“Premier”) to build a database and conduct a study of the relative effectiveness of the different surfactants. Premier engaged one of its employees, Frank Ernst, to carry out the necessary technical work. Chiesi then hired several medical doctors, including defendants Rangasamy Ramanathan, Jatinder J. Bhatia, and Krishnamurthy Sekar (the “physician defendants”), to present findings based on Premier’s database at various medical conferences. Specifically, the physician defendants presented findings at the May 2007 annual meeting of the Pediatric Academic Societies that Curosurf was associated with a 20% lower mortality rate than either Infasurf or Survanta. At the October 2007 annual meeting of the European Pediatric Society, the physician defendants, along with Ernst and others, presented additional findings; specifically, they presented evidence showing that Curosurf was associated with a 15% shorter length of stay than either Infasurf or Survanta. Despite the differences between the data presented at the two conferences, both presentations were based on the same data set, namely the one compiled by Premier and Ernst.

In 2011, the physician defendants, along with Ernst, eventually decided to publish some of the findings from the same data set in a peer-reviewed journal. They submitted their article to the Journal of Perinatology, the leading journal in the field of neonatology, which is the study of newborn infants.³ The article was published in the September 1, 2011 volume of the journal after being peer reviewed by two anonymous referees. See R. Ramanathan et al., Mortality in Preterm Infants with Respiratory Distress Syndrome Treated with Poractant Alfa, Calfactant or Beractant: A Retrospective Study, 33 J. Perinatology 119 (2011).

According to ONY, the article contains five distinct incorrect statements of fact about the relative effectiveness of Curosurf versus Infasurf: (1) that Infasurf “was associated with a 49.6% greater likelihood of death than” Curosurf; (2) that Curosurf “treatment for RDS was associated with a significantly reduced likelihood of death when compared with” Infasurf; (3) that the authors’ “model found [Infasurf] to be associated with a significantly greater likelihood of death than” Curosurf; (4) that the authors’ study showed “a significant greater likelihood of death with” Infasurf than Curosurf; and (5) the summary concluding sentence:

In conclusion, this large retrospective study of preterm infants with RDS found lower mortality among infants who received

³ The Journal of Perinatology is also the official journal of the Section of Perinatal Pediatrics of the American Academy of Pediatrics, the leading pediatrics organization in the United States.

[Curosurf], compared with infants who received either [Infasurf] or [Survanta], even after adjusting for patient characteristics such as gestational age and [birth weight], and after accounting for hospital characteristics and center effects.

Id.; Proposed Am. Compl. ¶ 35. Plaintiff also alleges that the circumstances surrounding the article's publication were unusual: Bhatia is an Associate Editor, and Sekar is a member of the editorial board, of the Journal of Perinatology. Plaintiff alleged in its complaint that one of the two peer reviewers objected to its publication, but the other peer reviewer recommended the article for publication, and the Editor-in-Chief broke the tie. Plaintiff does not allege, however, that the publication of the article based on the affirmative opinions of one reviewer and the Editor-in-Chief was a departure from accepted or customary procedure. Further, the article was published in an "open access" format, which allows it to be viewed electronically by the general public without paying the typically applicable fee or ordering a subscription; the fees associated with such publication were paid by Chiesi and Cornerstone.

The article's conclusions were not unqualified. The authors considered the objection that the retrospective nature of the study might cause a disparity between the groups included in the study. More specifically, the authors noted that the article's finding may "most likely . . . be due to different surfactant doses administered to the infants included in the database," because Curosurf was, on average, prescribed in higher doses than its competitors. Finally, the authors disclosed that the study was sponsored by

Chiesi, that Ernst was an employee of Premier, that Chiesi hired Premier to conduct the study, and that all three physician defendants had served as consultants to Chiesi.

Plaintiff's primary objection to the substance of the article's scientific methodology is that the authors omitted any mention of the length-of-stay data, despite the fact that they had presented such data at the October 2007 conference. Because an important determinant of mortality rate is the pre-treatment health of the infants in the sample, plaintiff contends that the omission of length-of-stay data was intentional and designed to mask the fact that the neonatal infants treated with Curosurf had a greater ex ante chance of survival than did the group treated with Infasurf. If the length-of-stay data had been included, plaintiff alleges, "it would be obvious to readers that the differences in the results were a result of differences in the groups of patients treated, not of any differences in the effect of the particular lung surfactant administered." Appellant's Br. at 14. Plaintiff also objects to the authors' failure to cite articles with different primary conclusions, although such contradictory authority was known to them, and to the use of retrospective data, which was allegedly improper because it rendered the data subject to "selective distortion." *Id.* at 10. Finally, plaintiff contends that Chiesi and Cornerstone paid Premier to collect data that supported their own product's effectiveness.

After the article's publication, Chiesi and Cornerstone issued a press release touting its conclusions and distributed promotional materials that cited the article's findings. Since the article's publication, meanwhile, plaintiff has, through its corporate

officers – themselves pediatricians – written letters to the Journal of Perinatology rebutting the article’s conclusions, objecting to its methods, and asking that it be retracted. We take judicial notice of the fact that several of those letters were eventually published by the journal, although they did not appear in print until after the district court dismissed the complaint. See J.J. Cummings, Is There Evidence for a Mortality Difference Between Natural Surfactants?, 33 J. Perinatology 161 (2013) (originally published online, Feb. 16, 2012); see also E.A. Egan, In Response to Mortality in Preterm Infants with Respiratory Distress Syndrome Treated with Poractant Alfa, Calfactant or Beractant: A Retrospective Study, 33 J. Perinatology 165 (2013). The authors were given, and took, the opportunity to respond to those letters. See R. Ramanathan et al., Response to Dr. Egan’s Letter, 33 J. Perinatology 166 (2013).

On December 2, 2011, plaintiff filed a complaint seeking damages and injunctive relief in the United States District Court for the Western District of New York. The complaint alleged violations of the Lanham Act and New York General Business Law § 349, as well as claims for injurious falsehood and tortious interference with prospective economic advantage.⁴ Defendants moved to dismiss the complaint in its entirety; plaintiff

⁴ Although plaintiff originally pled its tortious interference claim as interference with existing contracts, it admitted before the district court that the complaint did not plead interference with any particular contract, and did not seek leave to amend these allegations. The district court therefore treated this claim as one alleging tortious interference with prospective economic advantage. We adopt the same approach.

cross-moved to amend its complaint and proposed an amended complaint. The district court (William M. Skretny, *Chief Judge*) granted the motion to dismiss and denied as futile plaintiff's cross-motion to amend. Judgment was entered on May 21, 2012, and plaintiff timely appealed.

DISCUSSION

We review a district court's dismissal of a complaint for failure to state a claim de novo. Sarmiento v. United States, 678 F.3d 147, 152 (2d Cir. 2012). We accept as true all factual allegations contained in the complaint. Id. We also review a district court's interpretation of a statute or state common law de novo. Roach v. Morse, 440 F.3d 53, 56 (2d Cir. 2006); Reilly v. NatWest Mkts. Grp. Inc., 181 F.3d 253, 262 (2d Cir. 1999).

I. Claims Arising out of the Article's Publication

The Lanham Act generally prohibits false advertising. In particular, it provides a civil cause of action against "any person" who, in interstate commerce, "uses . . . any . . . false or misleading description of fact, or false or misleading representation of fact." 15 U.S.C. § 1125(a)(1). Because the Act proscribes conduct that, but for its false or misleading character, would be protected by the First Amendment, free speech principles inform our interpretation of the Act. Indeed, "we have been careful not to permit overextension of the Lanham Act to intrude on First Amendment values." Boule v. Hutton, 328 F.3d 84, 91 (2d Cir. 2003) (internal quotation marks omitted). We have been especially careful when applying defamation and related causes of action to academic

works, because academic freedom is “a special concern of the First Amendment.”

Keyishian v. Bd. of Regents of the Univ. of the State of N.Y., 385 U.S. 589, 603 (1967).

Generally, statements of pure opinion – that is, statements incapable of being proven false – are protected under the First Amendment. Milkovich v. Lorain Journal Co., 497 U.S. 1, 19-20 (1990); see also Groden v. Random House, Inc., 61 F.3d 1045, 1051-52 (2d Cir. 1995). But the line between fact and opinion is not always a clear one. In Milkovich, the Supreme Court declined to carve out an absolute privilege for statements of opinion and reaffirmed that the test for whether a statement is actionable does not simply boil down to whether a statement is falsifiable. 497 U.S. at 18. To illustrate the difficulty, the Court provided the example of a statement of fact phrased as a statement of opinion: stating that “in my opinion John Jones is a liar” is no different from merely asserting that John Jones is a liar. Id. at 18-19. Thus, the question of whether a statement is actionable admits of few easy distinctions.

In this case, plaintiff claims that the article made statements about scientific findings that were intentionally deceptive and misleading, and that it therefore constituted false advertising. Plaintiff’s theory is that scientific claims made in print purport to be statements of fact that are falsifiable, and such statements can be defamatory or represent false advertising if known to be false when made. Plaintiff argues that the district court based its conclusion that the article’s statements were non-actionable solely on its determination that the assertions were statements of opinion, without conducting the more

fine-grained analysis required by Milkovich. According to plaintiff, dismissal prior to discovery under such circumstances was error.

Scientific academic discourse poses several problems for the fact-opinion paradigm of First Amendment jurisprudence. Most conclusions contained in a scientific journal article are, in principle, “capable of verification or refutation by means of objective proof,” Phantom Touring, Inc. v. Affiliated Publ’ns, 953 F.2d 724, 728 n.7 (1st Cir. 1992). Indeed, it is the very premise of the scientific enterprise that it engages with empirically verifiable facts about the universe. At the same time, however, it is the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation. Importantly, those conclusions are presented in publications directed to the relevant scientific community, ideally in peer-reviewed academic journals that warrant that research approved for publication demonstrates at least some degree of basic scientific competence. These conclusions are then available to other scientists who may respond by attempting to replicate the described experiments, conducting their own experiments, or analyzing or refuting the soundness of the experimental design or the validity of the inferences drawn from the results. In a sufficiently novel area of research, propositions of empirical “fact” advanced in the literature may be highly controversial and subject to rigorous debate by qualified experts. Needless to say, courts are ill-equipped to undertake to referee such

controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury.

In other cases involving “matters of argument” appearing in print, we have been reluctant to recognize causes of action grounded on statements of fact that are best evaluated by an informed reader. In Groden, we concluded that “statements made to summarize an argument or opinion within a book” are “to be accepted or rejected by those who read the book,” even when such statements are made in advertisements. 61 F.3d at 1052. The Seventh Circuit has also declined to allow suits based on claims of false conclusions in matters of scientific controversy to proceed. See Underwager v. Salter, 22 F.3d 730, 736 (7th Cir. 1994) (“Scientific controversies must be settled by the methods of science rather than by the methods of litigation. . . . More papers, more discussion, better data, and more satisfactory models – not larger awards of damages – mark the path toward superior understanding of the world around us.”). District courts presented with controversial scientific questions have also declined to find them actionable. See Arthur v. Offit, No. 01:09-cv-1398, 2010 WL 883745, at *6 (E.D. Va. March 10, 2010) (“Plaintiff’s claim . . . threatens to ensnare the Court in [a] thorny and extremely contentious debate over . . . which side of this debate has ‘truth’ on their side. That is hardly the sort of issue that would be subject to verification based upon a core of objective evidence.” (internal quotation marks omitted)); cf. Padnes v. Scios Nova Inc., No C 95-1693, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996) (“Medical researchers may

well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols. The securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal.” (internal citation omitted)).

Where, as here, a statement is made as part of an ongoing scientific discourse about which there is considerable disagreement, the traditional dividing line between fact and opinion is not entirely helpful. It is clear to us, however, that while statements about contested and contestable scientific hypotheses constitute assertions about the world that are in principle matters of verifiable “fact,” for purposes of the First Amendment and the laws relating to fair competition and defamation, they are more closely akin to matters of opinion, and are so understood by the relevant scientific communities. In that regard, it is relevant that plaintiff does not allege that the data presented in the article were fabricated or fraudulently created. If the data were falsified, the fraud would not be easily detectable by even the most informed members of the relevant scientific community. Rather, plaintiff alleges that the inferences drawn from those data were the wrong ones, and that competent scientists would have included variables that were available to the defendant authors but that were not taken into account in their analysis. But when the conclusions reached by experiments are presented alongside an accurate description of the data taken into account and the methods used, the validity of the authors’ conclusions may be assessed on their face by other members of the relevant discipline or specialty.

We therefore conclude that, to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act. Here, ONY has alleged false advertising not because any of the data presented were incorrect but because the way they were presented and the conclusions drawn from them were allegedly misleading. Even if the conclusions authors draw from the results of their data could be actionable, such claims would be weakest when, as here, the authors readily disclosed the potential shortcomings of their methodology and their potential conflicts of interest.⁵

Our conclusion that the article's contents are not actionable under the Lanham Act also leads us to conclude that the statements are not actionable under New York's General Business Law § 349 or New York state common law. In determining the extent of its defamation and consumer protection laws, New York follows the same facts-and-circumstances approach laid out by the Supreme Court in Milkovich. See Immuno AG. v. Moor-Jankowski, 77 N.Y.2d 235, 240, 244-45 (1991) (dismissing a libel suit against the

⁵ To the extent plaintiff alleges harm arising from the relationship between the authors and Chiesi and Cornerstone, we agree with the district court that the disclosure of a conflict of interest, which was included in the article's original publication, suffices to put a reasonable reader on notice that the article's conclusions may have been influenced by the authors' professional associations.

editor of a scientific journal, in light of Milkovich, because the allegedly libelous statements were protected opinion). Our conclusion that what is non-actionable opinion under the Lanham Act is also non-actionable as a New York tort or under General Business Law § 349 is buttressed by the Court of Appeals’s statement that “the protection afforded by the guarantees of free press and speech in the New York Constitution is often broader than the minimum required by the Federal Constitution.” Id. at 249 (internal quotation marks omitted). In other words, New York law is, if anything, more protective of free speech interests and less expansive in permitting causes of action based on speech, than federal law. There is thus no reason to believe that the New York Court of Appeals would interpret state law to provide for more expansive liability than does the Lanham Act.

We therefore conclude that the contents of the article are non-actionable scientific conclusions to which neither the Lanham Act, New York General Business Law § 349, nor New York’s common law tort of injurious falsehood apply. Because our decision rests entirely on our conclusion about the non-actionability of the article’s contents, we need not reach the district court’s independent holding that it lacked personal jurisdiction over the physician defendants.⁶

⁶ Although we traditionally treat personal jurisdiction as a threshold question to be addressed prior to consideration of the merits of a claim, see In re Rationis Enters., Inc. of Pan., 261 F.3d 264, 267-68 (2d Cir. 2001), that practice is prudential and does not reflect a restriction on the power of the courts to address legal issues. In cases involving

II. Claims Arising out of the Distribution of the Article's Conclusions

Plaintiff separately alleges that, by touting and distributing the article's findings for promotional purposes, Chiesi and Cornerstone tortiously interfered with its prospective economic advantage in contracting with hospitals and other health-care providers. It is important to note that plaintiff does not allege, nor did it at any point during the proceedings before the district court seek to amend its complaint to allege, that the promotional materials misstated the article's conclusions. Thus, plaintiff's objection is not that Chiesi and Cornerstone distorted the article's findings; rather, its theory is that by presenting accurately the article's allegedly inaccurate conclusions, Chiesi and Cornerstone committed a separate tort, for which plaintiff is entitled to relief.

We are therefore presented with a much easier case than we would be if a plaintiff alleged that a defendant distorted an article's findings in its promotional materials. On these facts, we conclude that the district court did not err in dismissing plaintiff's tortious interference claim with prejudice in light of its correct conclusions that (a) the article

“multiple defendants – over some of whom the court indisputably has personal jurisdiction – in which all defendants collectively challenge the legal sufficiency of the plaintiff's cause of action,” we have proceeded directly to the merits on a motion to dismiss, Chevron Corp. v. Naranjo, 667 F.3d 232, 246 n.17 (2d Cir. 2012), and we do so here. We have noted that this course of action is particularly appropriate where, as here, “the personal jurisdictional challenges are based on factual allegations that are, in this early posture, still under development.” Id.

itself was not actionable and (b) the tortious interference claim did not separately allege any additional misleading statements.

CONCLUSION

For the foregoing reasons, the judgment of the district court is hereby **AFFIRMED**.