

United States Court of Appeals For the First Circuit

No. 21-1951

CONFORMIS, INC.,
Plaintiff, Appellant,
v.

AETNA, INC. and AETNA LIFE INSURANCE COMPANY,
Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Indira Talwani, U.S. District Judge]

Before

Barron, Chief Judge,
Selya and Lipez, Circuit Judges.

Anthony P. La Rocco, with whom Jeffrey S. King, Adam R.D. Paine, Robert F. Pawlowski, and K&L Gates LLP were on brief, for appellant.

Sarah M. Harris, with whom Whitney D. Hermandorfer, Mihir Khetarpal, Williams & Connolly LLP, Stephen LaRose, Kierstan Schultz, and Nixon Peabody LLP were on brief, for appellees.

January 23, 2023

SELYA, Circuit Judge. An epigram, popular among children in the last century, teaches that "[s]ticks and stones will break my bones, but words will never harm me." G.F. Northall, *Folk-Phrases of Four Counties* 23 (1894). That folk wisdom, though, has scant purchase in the commercial world. This case, in which the plaintiff advances claims for product disparagement and related torts, illustrates the point.

The district court, ruling on a motion filed pursuant to Federal Rule of Civil Procedure 12(b)(6), dismissed the plaintiff's amended complaint for failure to state a claim upon which relief could be granted. The plaintiff appeals. Concluding, as we do, that some of the plaintiff's claims are sufficiently plausible to warrant further proceedings, we affirm in part and reverse in part.

I

We briefly rehearse the relevant facts and travel of the case. As this appeal follows the allowance of a motion to dismiss under Rule 12(b)(6), we draw the facts from the amended complaint and its attachments. See Lanza v. Fin. Indus. Regul. Auth., 953 F.3d 159, 161 (1st Cir. 2020).

Plaintiff-appellant Conformis, Inc. (Conformis) is a medical device company that designs and manufactures customized hip and knee replacements, including the Conformis iTotal Knee Replacement System (the Conformis system). The Conformis system

is a customized total knee replacement (TKR) designed to improve upon the limitations of uniform, off-the-shelf knee replacements.

The Conformis system received clearance from the federal Food and Drug Administration (FDA) in February of 2011, through the premarket notification process elaborated in 21 U.S.C. § 360(k). Over 100,000 patients have received the Conformis system, and it is covered by over 90% of commercial payors as well as the Centers for Medicare and Medicaid Services (CMS).

Various clinical studies have concluded that customized TKRs in general, and the Conformis system in particular, exhibit favorable patient outcomes when compared to off-the-shelf TKRs. Studies also suggest that although customized TKRs may be more expensive than off-the-shelf models on the front end, the total cost may be lower due to fewer complications. The Conformis system has been endorsed by the American Association of Hip and Knee Surgeons (AAHKS). It also has a 5A rating from the Orthopaedic Data Evaluation Panel in the United Kingdom – a rating that indicates strong evidence of favorable outcomes assessed against national clinical best practice guidelines.

Defendant-appellee Aetna, Inc., together with its wholly owned subsidiary, Aetna Life Insurance Company (collectively, Aetna), is one of the leading providers of health insurance and third-party health plan administration in the United States. Aetna's plans provided coverage (and, thus, reimbursement) for the

Conformis system from 2011 until September of 2018, when Aetna released a revised policy for "Unicompartmental, Bicompartmental, and Bi-unicompartmental Knee Arthroplasties" (Policy 0660 or the Policy). The Policy recharacterized Aetna's view of customized TKRs, taking the position that "Aetna considers customized [TKRs] experimental and investigational because [their] effectiveness has not been established." The Policy did not explain the reason for recharacterization, although the Policy's background section included summaries of certain studies evaluating different types of TKRs.

Separately, Aetna's website provides a glossary of terms, which defines "experimental services or procedures" and "investigational services" as "newer drugs, treatments or tests. They are not yet accepted by doctors or by insurance plans as standard treatment. They may not be proven as effective or safe for most people."

Aetna's unexplained recharacterization of the Conformis system had profound financial consequences. Aetna does not either cover or reimburse for treatments that it characterizes as "experimental and investigational" except in instances marked by special circumstances.

Conformis has contracts with more than 2,100 healthcare providers (including hospitals, group purchasing organizations, and integrated delivery networks). It also maintains

relationships with other healthcare providers who have, according to the complaint, "routinely prescribed or otherwise provided the Conformis System." After Aetna reversed course and changed its position through the issuance of Policy 0660, Conformis saw a significant reduction in the number of Aetna-covered patients receiving the Conformis system. Some orthopedic surgeons have stopped ordering the Conformis system for patients covered by Aetna. And to avoid uncertainty about reimbursement, some orthopedic surgeons have stopped ordering the Conformis system for a wider universe of patients, including those covered under other insurance plans.

The pleadings contain a vivid example of the Policy in practice. The Conformis system was prescribed for one patient, John Michael Schaub, but Aetna denied coverage only days before Schaub's scheduled surgery. At the time, Schaub had health insurance through an employer-sponsored plan administered by Aetna (which contracts with eviCore Healthcare to handle patient claims). Following the denial of coverage, an eviCore surgeon explained to Schaub's surgeon that, while he considered the Conformis system very effective, his "hands were tied by Aetna's Policy." Various representatives of Aetna confirmed to Schaub in subsequent telephone calls that it was Aetna's policy to no longer

afford reimbursement for the Conformis system. Schaub went ahead with the procedure despite Aetna's denial of coverage.¹

Conformis sent Aetna a letter in April of 2019, requesting that Aetna reconsider its policy revision. Conformis provided additional studies in support of the Conformis system's efficacy and widespread acceptance. In response, Aetna released a policy supplement, which included summaries of some of the additional studies, noting instances in which the authors had recommended further research.

The president of AAHKS also wrote to Aetna after the policy change to express his "concern . . . because the custom implants in question are FDA approved, have been in use for many years and have peer-reviewed published studies that should support their continued use." That concern was heightened because some of the scientific literature cited in the Policy's background section as relating to customized TKRs did not involve the assessment of customized TKRs at all. But Aetna dug in its heels.

Conformis sent a second letter in January of 2020, demanding that Aetna, among other things, cease and desist from treating the Conformis system as experimental and investigational.

¹ Schaub was an additional plaintiff in this suit, pressing claims against Aetna under the Employee Retirement Income Security Act. See 29 U.S.C. §§ 1132(a)(1)(B), (a)(3), 1133. Schaub's claims were settled and the parties stipulated to their dismissal with prejudice. See Fed. R. Civ. P. 41(a)(1)(A)(ii).

Conformis also demanded that Aetna re-authorize its approval of the Conformis system. Aetna acknowledged receipt of the letter but did not furnish any substantive response.

Conformis then repaired to the United States District Court for the District of Massachusetts and sued Aetna, alleging state common-law claims for product disparagement and tortious interference with both contractual and advantageous relations, as well as unfair trade practices in violation of Mass. Gen. Laws chapter 93A. Conformis subsequently filed an amended complaint containing similar allegations. See Fed. R. Civ. P. 15(a)(1) (allowing amendment of complaint as of right within twenty-one days after service of motion under Rule 12(b)). Aetna moved to dismiss the amended complaint for failure to state a claim. See id. 12(b)(6). Following a hearing, the district court granted the motion to dismiss. See Conformis, Inc. v. Aetna, Inc., 2021 WL 1210293, at *10 (D. Mass. Mar. 31, 2021). This timely appeal ensued.

II

We review de novo a district court's dismissal of a complaint for failure to state a claim. See Alston v. Spiegel, 988 F.3d 564, 571 (1st Cir. 2021). In conducting that tamisage, we accept as true all well-pleaded facts set forth in the complaint and draw all reasonable inferences therefrom to the pleader's

behoof. See SEC v. Tambone, 597 F.3d 436, 441 (1st Cir. 2010) (en banc).

To ward off dismissal, "the plaintiff need not demonstrate that [it] is likely to prevail, but [its] claim must suggest 'more than a sheer possibility that a defendant has acted unlawfully.'" García-Catalán v. United States, 734 F.3d 100, 102-103 (1st Cir. 2013) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In other words, the complaint must be "plausible on its face." Iqbal, 556 U.S. at 678 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The hunt for plausibility requires that we separate factual allegations from conclusory ones and then evaluate whether the factual allegations support a "reasonable inference that the defendant is liable for the misconduct alleged." Id. at 678-79.

This inquiry does not demand a plentitude of factual content. See Grajales v. P.R. Ports Auth., 682 F.3d 40, 47 (1st Cir. 2012). Even so, the pleader must put some meat on the bones. Thus, the complaint "must contain more than a rote recital of the elements of a cause of action." Rodríguez-Reyes v. Molina-Rodríguez, 711 F.3d 49, 53 (1st Cir. 2013). It need not show, however, "a one-to-one relationship between any single allegation and a necessary element of the cause of action." Id. at 55. "For pleading purposes, circumstantial evidence often suffices to clarify 'a protean issue such as an actor's motive or intent.'"

Id. at 56 (quoting Anthony v. Sundlun, 952 F.2d 603, 605 (1st Cir. 1991)).

Because this case is in a federal court by virtue of diversity jurisdiction, see 28 U.S.C. § 1332(a), state law supplies the substantive rules of decision, see Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938). Here, the parties agree that Massachusetts law controls. That is a reasonable choice under the circumstances, and we accept it. See Borden v. Paul Revere Life Ins. Co., 935 F.2d 370, 375 (1st Cir. 1991) (holding that "a federal court sitting in diversity is free, if it chooses, to forgo independent analysis and accept the parties' agreement" as to what law controls).

A

We begin with the claim for product disparagement. This tort has many different guises: it is also variously known as, among other cognomens, commercial disparagement, trade libel, or injurious falsehood. See HipSaver, Inc. v. Kiel, 984 N.E.2d 755, 759 n.1 (Mass. 2013).

Conformis alleges that three particular statements are actionably disparaging. The first, excerpted from the Policy, declares that "Aetna considers customized [TKRs] experimental and investigational because [their] effectiveness has not been established." For ease in exposition, we refer to this statement as "the Policy statement." The other two statements come from the

definitions of "experimental services and procedures" and "investigational services" contained in a glossary available on Aetna's website. Such services and procedures, the glossary definitions each explain, "are not yet accepted by doctors or by insurance plans as standard treatment" and "may not be proven as effective or safe for most people." We refer to these statements as "the glossary statements."

To make out a claim for product disparagement, a plaintiff must plausibly allege that the defendant "(1) published a false statement to a person other than the plaintiff; (2) 'of and concerning' the plaintiff's products or services; (3) with knowledge of the statement's falsity or with reckless disregard of its truth or falsity; (4) where pecuniary harm to the plaintiff's interests was intended or foreseeable; and (5) such publication resulted in special damages in the form of pecuniary loss." HipSaver, 984 N.E.2d at 763; see Dulgarian v. Stone, 652 N.E.2d 603, 609 (Mass. 1995) (adopting Restatement (Second) of Torts § 623A (Am. L. Inst. 1977)). Product disparagement is similar to defamation but lacks a reputational harm element and makes greater demands as to the "falsity of the statement[s], fault of the defendant and proof of damage." HipSaver, 984 N.E.2d at 762, 763 n.7 (quoting Restatement (Second) of Torts, supra at § 623A cmt. g).

1

To narrow the scope of our inquiry, we leap-frog ahead and start by analyzing the second element of a product disparagement claim. That element requires that each of the challenged statements be "of and concerning" the complaining party's products or services. A plaintiff may show that a statement is "of and concerning" it by proving either "(1) that the defendant intended the words to refer to the plaintiff and that they were so understood or (2) that persons could reasonably interpret the defendant's words to refer to the plaintiff and that the defendant was negligent in publishing them in such a way that they could be so understood." HipSaver, 984 N.E.2d at 766 (quoting ELM Med. Lab'y, Inc. v. RKO Gen., Inc., 532 N.E.2d 675, 679 (Mass. 1989), abrogated on other grounds by United Truck Leasing Corp. v. Geltman, 551 N.E.2d 20, 23 (Mass. 1990)); see Eyal v. Helen Broad. Corp., 583 N.E.2d 228, 231 (Mass. 1991) (emphasizing disjunctive character of standard). Conformis relies mainly on the first modality – a modality that has been described as "subjective." Eyal, 583 N.E.2d at 231.

We first come to grips with the Policy statement. Admittedly, that statement does not refer to Conformis by name. Instead, it refers only to "customized [TKRs]." But a common-sense reading of the Policy is required, and such a reading leaves

little doubt that Aetna intended the words to refer to Conformis's product. We explain briefly.

Conformis has been a leading producer of customized TKRs for many years – and Aetna knew as much. In point of fact, Aetna provided coverage for those implants for many years. But – immediately upon the publication of the Policy – Aetna stopped providing that coverage. What is more, representatives of Aetna confirmed to Schaub that Aetna no longer covered the Conformis system once the Policy was issued. And, finally, while the Policy statement does not mention the Conformis system, the background section of the Policy contains a subsection dedicated to the "ConforMIS Knee Implant." These alleged facts suffice plausibly to show that Aetna intended the statement to refer to the Conformis system.

To satisfy the first modality of the "of and concerning" test, Conformis also must allege facts demonstrating that the Policy statement was understood by third parties to refer to the Conformis system. See HipSaver, 984 N.E.2d at 766. Here, Conformis alleges facts sufficient to satisfy that obligation. For instance, Conformis alleges that the eviCore surgeon who reviewed Schaub's claim understood the statement in the Policy to refer to the Conformis system and to foreclose coverage for it. So, too, Conformis alleges that numerous orthopedic surgeons have told its sales team that they would no longer prescribe the

Conformis system because of concerns that it would not be covered under the Policy.

Still more is needed to demonstrate that the statement is "of and concerning" the plaintiff when a statement is directed at a group. Such is the case here: the Policy statement refers to all customized TKRs generally, rather than to the Conformis system specifically. A member of the group may recover for defamation only if "the group or class is so small that the matter can reasonably be understood to refer to the member, or . . . the circumstances of publication reasonably give rise to the conclusion that there is particular reference to the member." Eyal, 583 N.E.2d at 230 n.6 (alteration in original) (quoting Restatement (Second) of Torts, supra at § 564A); see Arcand v. Evening Call Pub. Co., 567 F.2d 1163, 1164-65 (1st Cir. 1977). Whether the circumstances of publication reasonably give rise to the conclusion that there is particular reference to the plaintiff is determined by what a reasonable reader would understand. See Restatement (Second) of Torts, supra at § 564A cmt. D, illus. 5.

Although the Policy statement itself does not mention Conformis, there is (as we previously have noted) a subsection dedicated to the "ConforMIS Knee Implant" in the background section of the Policy. The Conformis system is the only customized TKR singled out with its own subsection. A reasonable reader could

conclude, based on those circumstances, that the Policy statement made particular reference to Conformis.

That ends this phase of our inquiry. We hold that Conformis has plausibly alleged facts sufficient to show that the Policy statement is a statement "of and concerning" Conformis.

The glossary statements are a different matter. Conformis has not provided any convincing explanation as to how those statements, standing alone, can be regarded as "of and concerning" the Conformis system. There is no indication that Aetna intended the glossary statements to refer to the Conformis system, nor that they were so understood by third parties. See HipSaver, 984 N.E.2d at 766. And we do not believe that anyone reading the glossary statements would reasonably interpret them, standing alone, as referring to the Conformis system. See id.

The bottom line is that the Policy statement is potentially actionable under the product disparagement rubric but the glossary statements are not. The relevance of the latter statements, if any, is merely as an aid in understanding the Policy statement. See infra Part II(A)(2)(a).

2

Having established which statement is at issue, we turn to the first element of product disparagement: the requirement that a plaintiff show that the challenged statement is false. See HipSaver, 984 N.E.2d at 763. For a statement to be false, though,

it would need first to be factual. In the context of claims for defamation, for example, non-factual statements – commonly called "opinions" – are not actionable because they cannot be proven false. See Lyons v. Globe Newspaper Co., 612 N.E.2d 1158, 1161 (Mass. 1993); King v. Globe Newspaper Co., 512 N.E.2d 241, 243 (Mass. 1987).

The Massachusetts Supreme Judicial Court (the SJC) has yet to address whether the same analysis extends to a claim for product disparagement. See HipSaver, 984 N.E.2d at 765 n.11 (declining to resolve whether "mere opinions that imply no misstatement of objectively verifiable fact" can qualify as product disparagement (quoting W.L. Prosser & W.P. Keeton, Torts § 128, at 967 (5th ed. 1984))). We must, therefore, "endeavor to predict how [the SJC] would likely decide the question." In re PHC, Inc. S'holder Litig., 894 F.3d 419, 428 (1st Cir. 2018) (quoting Butler v. Balolia, 736 F.3d 609, 613 (1st Cir. 2013)).

We draw on the permissible sources that customarily inform such a prediction. See id.; Blinzler v. Marriott Int'l, Inc., 81 F.3d 1148, 1151 (1st Cir. 1996). We are persuaded that the striking similarity between product disparagement and defamation, see HipSaver, 984 N.E.2d at 762, and the First Amendment considerations that circumscribe both torts, see Restatement (Second) of Torts, supra at § 623A cmts. c-e, would cause the SJC to apply, in product disparagement cases, the same

analytic modality that it has used in defamation cases. Other courts that have considered the question have reached the same conclusion. See, e.g., Advanced Tech. Corp. v. Instron, Inc., 66 F. Supp. 3d 263, 269 (D. Mass. 2014); Dulgarian v. Stone, 1994 WL 879631, at *4 (Mass. Super. Ct. Feb. 3, 1994).

a

This means, of course, that a statement of fact can be actionable as product disparagement, but a statement of opinion cannot. Accordingly, we must address the threshold question of whether the Policy statement is fact or opinion before determining whether it is false. The determination of whether a statement is fact or opinion is a question of law "if the statement unambiguously constitutes either fact or opinion," but a question of fact "if the statement reasonably can be understood both ways." Scholz v. Delp, 41 N.E.3d 38, 45 (Mass. 2015) (quoting King, 512 N.E.2d at 244). At the pleading stage, then, a statement that can reasonably be understood as either fact or opinion is sufficient to survive a motion to dismiss.

Whether a statement is fact or opinion is determined by whether the statement would be understood by a reasonable reader as containing "objectively verifiable facts." Id. at 45 (quoting Levinsky's, Inc. v. Wal-Mart Stores, Inc., 127 F.3d 122, 131 (1st Cir. 1997)); see Lyons, 612 N.E.2d at 1162. That approach requires us to "examine the statement in its totality in the context in

which it was uttered or published." Scholz, 41 N.E.3d at 45-46 (quoting Cole v. Westinghouse Broad. Co., 435 N.E.2d 1021, 1025 (Mass. 1982)). The factors to be considered comprise "all of the circumstances surrounding the statement, including the medium by which the statement is disseminated and the audience to which it is published"; "all the words used, not merely a particular phrase or sentence"; and any "cautionary terms" employed. Lyons, 612 N.E.2d at 1162 (quoting Fleming v. Benzaquin, 454 N.E.2d 95, 100 (Mass. 1983)).

The district court concluded that a reasonable reader could interpret the Policy statement as either fact or opinion. See Conformis, 2021 WL 1210293, at *8. We agree that the statement could plausibly be read as either an expression of fact or as an opinion. A reasonable reader could interpret this statement as a statement of fact because such a reader could interpret it as a verifiable assertion that the Conformis system is "not clinically effective and not accepted by doctors and insurance providers as a standard treatment." Our reasoning follows.

Whether a statement is fact or opinion depends on whether "in a given context it reasonably can be understood as having an easily ascertainable and objectively verifiable meaning." Levinsky's, 127 F.3d at 129. Put another way, the inquiry turns on whether the statement has a meaning capable of being proven or

rebutted by objective evidence. See id. at 131; Scholz, 41 N.E.3d at 45.

With respect to verifiability, Conformis and Aetna advance different approaches for deducing the meaning of the Policy statement. Conformis asserts that the glossary definitions can shed light on the meaning of "experimental and investigational." Aetna takes a different view: it asserts that there is no reason to incorporate the definitions of "experimental" and "investigational" found in the glossary because the Policy itself defines those terms (stating that a customized TKR system is "experimental and investigational because its effectiveness has not been established").

When a text contains a specific definition for a term, courts normally eschew reliance on an external definition. See In re Blinds to Go Share Purchase Litig., 443 F.3d 1, 6 (1st Cir. 2006) (explaining that when contract provides specific definition for term, courts should not rely on general usage). Here, however, the Policy – fairly read – does not contain a specific definition for either "experimental" or "investigational." We do not think it clear, as Aetna maintains, that the word "because" that connects the two clauses in the Policy statement transmogrifies the second clause into a definition of the first. And in the absence of a specific definition within the text, it is appropriate to consult outside sources to understand how a reasonable reader would define

the disputed terms. See Piccone v. Bartels, 785 F.3d 766, 772 (1st Cir. 2015) (considering dictionary definitions to define allegedly defamatory term); Levinsky's, 127 F.3d at 129 (reviewing various literary and legal uses to define allegedly defamatory term).

In this instance, it seems logical that a reasonable reader would likely consult the definitions found in Aetna's own glossary to define the allegedly disparaging terms. We hold, therefore, that the glossary definitions are relevant to our inquiry.

With this understanding in place, we return to the question of whether the Policy statement could reasonably be understood as having a verifiable meaning. In that statement, Aetna characterizes customized TKRs as "experimental" and "investigational." And, as described, the glossary defines "experimental" and "investigational" services as treatments that "are not yet accepted by doctors or by insurance plans as standard treatment" and which "may not be proven as effective or safe for most people." A reasonable reader plausibly could understand those statements, taken together, as conveying verifiable facts: whether a treatment has been accepted by insurers and medical professionals as "standard treatment" and whether it is safe or medically effective are questions that suggest an appraisal of

that treatment against objective professional or scientific standards.

To be sure, statements to the effect that a procedure is "experimental" or "investigational" may not, under all circumstances, convey verifiable facts. In cases where an objective standard is lacking or cannot be ascertained, the disputed statements may not be actionable. See Piccone, 785 F.3d at 772 (explaining that disputed term conveyed opinion in context even though same term could refer to sufficiently objective standard in another context). But given the context supplied by the glossary statements, a reasonable reader could interpret the assertion that the Conformis system is "experimental and investigational" as a verifiable statement that could be proved or disproved by objective criteria agreed upon by the insurance industry and medical professionals. This proof could be measured (as the glossary statements suggest) by whether the treatment was widely prescribed by doctors and covered by insurers as standard practice.

The second half of the Policy statement ("its effectiveness has not been established") mirrors the second glossary statement. With respect to that portion of the Policy statement, standard dictionaries generally define "effective" as producing an intended effect. See, e.g., Merriam-Webster's Collegiate Dictionary 367 (10th ed. 2001) (defining "effective" as

"producing a decided, decisive, or desired effect"); The American Heritage Dictionary of the English Language 587 (3d ed. 1992) (defining "effective" as "[h]aving an intended or expected effect"). Conformis asserts that the Conformis system's intended effect logically refers to its clinical effect. We agree with this assertion and, thus, the question reduces to the extent to which the system's clinical effect could reasonably be understood as verifiable.²

Aetna posits that effectiveness in this context is not verifiable because there is no single, recognized threshold at which there is sufficient scientific evidence to permit the conclusion that the Conformis system is clinically effective. In support, Aetna relies primarily on the decision in TMJ Implants, Inc. v. Aetna, Inc., 498 F.3d 1175 (10th Cir. 2007), in which the Tenth Circuit concluded that an assertion that one medical product "has not been shown to be as effective as" another was non-actionable opinion under Colorado defamation law because it was "not provably false," id. at 1195. The court reasoned that "[d]ifferent people will make different judgments on whether a product 'has been shown to be as effective as' another." Id. It

² We reject the district court's suggestion that "effectiveness" refers to "cost effective[ness]." Conformis, 2021 WL 1210293, at *8. Nothing in the policy, the glossary definitions, or Aetna's submissions supports this imaginative reading.

explained that, "[s]ome may require only one study; others may require the gold standard of a double-blind study, or even multiple such studies." Id. The threshold at which scientific evidence was sufficient to render a product "effective" was therefore found to be "a matter of individual taste," leading to the conclusion that the clinical effectiveness of a given medical product was not susceptible to objective verification. Id.

In our view, TMJ Implants overlooked a significant and plausible alternative: that in some circumstances, there may already be a consensus within relevant scientific and medical circles that a product or procedure produces or fails to produce its intended clinical effect. When that is the case, the effectiveness of such a product or procedure would be objectively verifiable. And here, Conformis has plausibly alleged that a consensus exists in the relevant scientific and medical communities – a consensus holding that the Conformis system is clinically effective. At the motion-to-dismiss stage, this plausible assertion suffices to show verifiability.

In a further effort to blunt the force of this reasoning, Aetna seizes upon two of our prior decisions. First, it brandishes our decision in Piccone, 785 F.3d 766. There, the plaintiffs sued for defamation when the defendant called them "unprofessional." Id. at 772. We upheld the district court's rejection of their suit, noting that even though the definition of "unprofessional"

might include reference to a particular "standard," the "[p]laintiffs [had] not allege[d] that [the] [d]efendant accused them of violating any technical, ethical, or commonly-understood standard." Id. But we also explained that the same statement, in a different context, might refer to a "sufficiently objective standard of conduct" as to make the statement verifiable. Id.

Seen in this light, Piccone is of no help to Aetna. The case at hand is far different: the statement as set forth in the complaint could be susceptible to an objective scientific standard – which Conformis alleges the Conformis system meets.

Aetna also flaunts our decision in Cheng v. Neumann, 51 F.4th 438 (1st Cir. 2022). There, we concluded that the terms "right-wing," "far-right," and "conspiracy theorist" in an online article were "unprovable as false" and, thus, were not actionable. Id. at 446. In the context of political discourse, we determined that those statements would be read as "rhetorical hyperbole" and expressions of the author's opinion. Id. (quoting Pan Am Sys., Inc. v. Atl. Ne. Rails & Ports, Inc., 804 F.3d 59, 65 (1st Cir. 2015)).

Cheng is at a considerable distance from the case at hand. Here – in the context of an insurer's policy and its intended audience – we think that the statement "Aetna considers [the Conformis system] experimental and investigational because its effectiveness has not been established" could reasonably be read

as a statement of verifiable fact. That is all that is required at this early stage of the proceedings.

Aetna has yet another rejoinder: it suggests that the Policy statement should be protected as opinion because it forms part of a scientific debate. For support, Aetna turns to ONY, Inc. v. Cornerstone Therapeutics, Inc., 720 F.3d 490 (2d Cir. 2013), in which the Second Circuit rejected a defamation claim based on conclusions presented in a scientific article. There, the court held that a statement "made as part of an ongoing scientific discourse about which there is considerable disagreement" and presented in a journal intended for experts "alongside an accurate description of the data taken into account" should be treated as a non-actionable opinion. Id. at 497-98.

Although this suggestion has some force, it does not take Aetna where it wants to go. After all, we must take into account the statement's context, including the medium in which the statement was published and the audience to which it was presented. See Lyons, 612 N.E.2d at 1162.

The medium in this case is an explanatory document issued by Aetna in aid of its insurance plans and policies. That medium is designed to help communicate Aetna's coverage determinations. Unlike a medical journal, it is not a medium meant to communicate insights into matters of scientific debate. See HipSaver, 984 N.E.2d at 769; ONY, 720 F.3d at 497.

The audience consists primarily of prospective patients and healthcare providers. That audience, of course, includes laypeople seeking to determine whether a certain procedure is covered by their medical insurance. It also includes physicians and other healthcare professionals seeking to determine whether reimbursement will be forthcoming for a given procedure. The purpose of the statement is to inform that audience as to what financial support may be expected – not to "mark the path toward superior understanding of the world around us." HipSaver, 984 N.E.2d at 769 (quoting Underwager v. Salter, 22 F.3d 730, 736 (7th Cir. 1994)). The upshot, then, is that Aetna cannot take refuge in the hallowed halls of scientific debate for purposes of this case.

Aetna has one more shot in its sling. A statement of opinion may be actionable if it implies the existence of undisclosed defamatory facts. See Lyons, 612 N.E.2d at 1161. But the converse is equally true: an opinion is not actionable if it merely draws a conclusion from disclosed non-defamatory facts. See id.; see also Restatement (Second) of Torts, supra at § 566. Such a rule creates a safe harbor for an opinion that reveals its basis even if the same statement – standing alone – would be actionable because it implies knowledge of a defamatory fact. See Nat'l Ass'n of Gov't Emps. v. Cent. Broad. Corp., 396 N.E.2d 996, 1000-01 (Mass. 1979). Aetna claims that the Policy statement is

not actionable because it is an opinion that discloses the non-defamatory facts on which it is based: scientific studies cited in the Policy.

In order to reach this safe harbor, though, "a challenged statement first must qualify as an expression of opinion." Lyons, 612 N.E.2d at 1162. And as we have just explained, the statement challenged here – taken in the light most favorable to the plaintiff, as required by the motion-to-dismiss standard – does not so qualify.

No more need be said at this stage. We recognize that Conformis's allegations are far from conclusive. But in this early chapter of the litigation, we must construe ambiguities in the record in favor of the non-moving party (here, Conformis). See Vázquez-Ramos v. Triple-S Salud, Inc., 55 F.4th 286, 299 (1st Cir. 2022); see also Lyons v. New Mass Media, Inc., 453 N.E.2d 451, 457 (Mass. 1983) (explaining that when "allegedly libelous remarks could have been understood by the average reader [as either fact or opinion], the issue must be left to the jury's determination"). Consistent with this obligation, we conclude that because the Policy statement reasonably could be understood as either fact or opinion, Aetna's contention that the claim should be dismissed as one based on a non-actionable opinion cannot prevail.

b

This conclusion brings us back to the claimed falsity of the challenged statement. Conformis alleges that over 90% of commercial payors, as well as CMS, cover the Conformis system – and in the insurance context, coverage is powerful evidence that the payors view the system as accepted as standard treatment. Conformis also alleges that the system is approved by the AAHKS and has a 5A rating from the Orthopaedic Data Evaluation Panel in the United Kingdom (which assesses the performance of a procedure against national clinical best practice guidelines). Those facts justify a plausible inference that Aetna's recharacterization of the Conformis system as experimental and investigational, defined as "not yet accepted by doctors or by insurance plans as standard treatment," is false.

As for the remainder of the statement – declaring that the Conformis system's "effectiveness has not been established" – one plausible interpretation is that its truth can be verified by showing that a consensus of scientific journals and experts agree that the system produces its intended effect. See supra Part II(A) (2) (a). Conformis plausibly alleges that such a consensus exists here, pointing to the array of studies that it submitted to Aetna. To buttress that plausible allegation, it notes that AAHKS and the Orthopaedic Data Evaluation Panel have endorsed the system.

Those averments are sufficient to make out a showing of falsity for pleading purposes.³

3

The next element of product disparagement is that the defendant "knows that the statement is false or acts in reckless disregard of its truth or falsity." HipSaver, 984 N.E.2d at 768 (quoting Restatement (Second) of Torts, supra at § 623A). This element "mirrors what has been termed 'actual malice' in the defamation context," without regard to whether the plaintiff is a public figure. Id. at 767, 768 n.14. A defendant acts in reckless disregard if it "entertained serious doubts as to the truth of [its] publication." Id. at 767-68 (quoting St. Amant v. Thompson, 390 U.S. 727, 731 (1968)).

Because "direct evidence of actual malice is rare," it may be shown through inference and circumstantial evidence. Sindi v. El-Moslimany, 896 F.3d 1, 16 (1st Cir. 2018) (quoting Levesque v. Doocy, 560 F.3d 82, 90 (1st Cir. 2009)). By way of example, actual malice "may be found where a publisher fabricates an account, makes inherently improbable allegations, relies on a

³ It is less clear that the Conformis system's FDA clearance demonstrates that its effectiveness has been established. The FDA clearance process evaluates the similarity of a new device to a relevant existing device, and the resulting assessment is, therefore, "focused on equivalence, not safety" or, presumably, effectiveness. Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (emphasis in original) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996)).

source where there is an obvious reason to doubt its veracity, or deliberately ignores evidence that calls into question his published statements." Id. (quoting Levesque, 560 F.3d at 90). Essentially the same standard applies in product disparagement cases. See HipSaver, 984 N.E.2d at 767-68.

Conformis alleges that Aetna did not consider the Conformis system experimental and investigational for many years before recharacterizing it in Policy 0660, and then provided no explanation for its sudden about-face. Aetna's support for the recharacterization consists generally of the listed studies and their language suggesting areas ripe for further inquiry – language that Conformis plausibly claims is boilerplate. Conformis also plausibly alleges that Aetna deliberately ignored the compelling evidence of established effectiveness and widespread use of customized TKRs provided by the AAHKS president in his February 2019 letter, explaining that the studies Aetna cited to support the recharacterization did not warrant that conclusion and that relevant medical literature "[did] not appear to have been considered."

Separating wheat from chaff, we conclude that Conformis plausibly alleges that Aetna ignored credible evidence presented to it that called its statement into serious question. See Sindi, 896 F.3d at 16. And Aetna's abrupt change in policy, without any explanation at all as to why a previously covered device had

suddenly become "experimental and investigational," forms the basis for a plausible inference that Aetna must have known that assertion was false.

Aetna responds that the product disparagement claim nonetheless must fail because Conformis does not allege that Aetna "specifically intended [the defamatory] meaning," as required by Howard v. Antilla, 294 F.3d 244, 252 (1st Cir. 2002). But Howard is factually distinct. There, we concluded that an article that presented evidence for and against a rumor that the plaintiff was not who he said he was – but which ultimately disclaimed "evaluating the truth or falsity of any party's account" – could not be read to express a "harmful implication." Id. The defendant could not be said to have serious doubts about the veracity of an implication that she had expressly disavowed. See id. at 253-54.

Unlike in Howard, this is not a case in which Conformis seeks to ascribe an allegedly disparaging meaning that Aetna's statement expressly disavows. Nor is this a case that depends on a negative implication derived from the disputed statement; rather, Conformis alleges that the statement itself is injurious.

At this nascent stage, it is enough that Conformis has plausibly alleged facts from which a jury reasonably could infer that Aetna "entertained serious doubts as to the truth of [its] publication." HipSaver, 984 N.E.2d at 768 (quoting St. Amant, 390 U.S. at 731). Conformis has carried this burden: it has plausibly

alleged that Aetna acted with reckless disregard for both the truth of whether the Conformis system was experimental and investigational and the truth of whether its effectiveness had been established.

4

The remaining elements of a product disparagement claim are inextricably intertwined. In combination, they require a showing that "pecuniary harm to the plaintiff's interests was intended or foreseeable" and that the disparagement "resulted in special damages in the form of pecuniary loss." HipSaver, 984 N.E.2d at 763. The special damages requirement limits a plaintiff's recovery to the "'pecuniary loss that results directly and immediately from the effect of the conduct of third persons' acting in response to the alleged disparagement." Id. at 772 (quoting Restatement (Second) of Torts, supra at § 633(1)(a)). In the product disparagement context, a plaintiff typically establishes those damages by identifying "a specific loss of sales to identifiable customers." Id. But where, as here, the disparaging statement has been "widely disseminated," the plaintiff may show by circumstantial evidence "that the loss [of the market] has in fact occurred" and that no other factor caused that loss. Id. at 772-73 (alteration in original) (quoting Restatement (Second) of Torts, supra at § 633 cmt. h).

The district court determined that the plaintiff had adequately alleged these intertwined elements. Conformis, 2021 WL 1210293, at *8. We agree with that determination. To this end, Conformis alleges that orthopedic surgeons told its sales team that they would no longer prescribe the Conformis system due to Aetna's shift in policy. For pleading purposes, those reports indicate lost sales to identifiable customers. So, too, Conformis plausibly alleges that the "widespread dissemination" of the Policy caused its sales to suffer a "significant dropoff." Given Aetna's prominent position within the health insurance market, it was foreseeable that Aetna's recharacterization of the Conformis system as "experimental and investigational" and, thus, ineligible for coverage, would result in a plummeting sales curve. In light of these averments, Conformis has plausibly alleged the pecuniary harm and special damages elements.

That ends this aspect of the matter. We hold that Conformis has plausibly alleged a claim for product disparagement as to the Policy statement. For pleading purposes, Conformis's allegations suffice to "remove the possibility of relief from the realm of mere conjecture." Hamann v. Carpenter, 937 F.3d 86, 92 (1st Cir. 2019) (quoting Tambone, 597 F.3d at 442). It follows that the district court erred in granting Aetna's motion to dismiss the product disparagement claim.

B

We turn next to the claims of tortious interference with contractual and advantageous relations. We treat these claims separately.

1

To defeat a motion to dismiss a claim for tortious interference with contractual relations, a plaintiff must plausibly allege that "(1) [it] had a contract with a third party; (2) the defendant knowingly induced the third party to break that contract; (3) the defendant's interference, in addition to being intentional, was improper in motive or means; and (4) the plaintiff was harmed by the defendant's actions." Psy-Ed Corp. v. Klein, 947 N.E.2d 520, 536 (Mass. 2011) (quoting G.S. Enters., Inc. v. Falmouth Marine, Inc., 571 N.E.2d 1363, 1369 (Mass. 1991)).

In an effort to satisfy the first element, Conformis alleges that it "has contracts with more than 2,100 healthcare providers (e.g., hospitals, group purchasing organizations, and integrated delivery networks) under which Conformis supplies the Conformis System." It is not necessary at the pleading stage to furnish "a high degree of factual specificity," Grajales, 682 F.3d at 47, so Conformis's allegations may be sufficient to satisfy the first element of tortious interference with contractual relations — that the plaintiff had a contract with a third party.

But Conformis stumbles at the next step: it fails to provide any further details about those contracts. Even under the lenient plausibility standard, a plaintiff must furnish enough detail about the obligations of the alleged contracts to allow a reasoned determination as to whether the second element – breach of contract – is alleged. Cf. Tel. Answering Serv. of Bos., Inc. v. New Eng. Tel. & Tel. Co., 267 N.E.2d 918, 918-19 (Mass. 1971) ("Where the gist of the action, whatever its form and however stated, is failure to perform a duty arising out of a contract, . . . it is essential to state with substantial certainty the facts showing the existence of the contract and the legal effect thereof" (internal alteration and quotation marks omitted) (quoting Pollock v. New Eng. Tel. & Tel. Co., 194 N.E. 133, 136 (Mass. 1935))). Conformis's claim for tortious interference with contractual relations, as pleaded, does not satisfy this requirement. Thus, we uphold the district court's dismissal of that claim.

2

Conformis's parallel claim for tortious interference with advantageous relations (sometimes described as business relations) stands on a different footing. To defeat a motion to dismiss such a claim, a plaintiff must plausibly allege that "(1) [it] had an advantageous relationship with a third party (e.g., a present or prospective contract or [business] relationship); (2)

the defendant knowingly induced a breaking of the relationship; (3) the defendant's interference with the relationship, in addition to being intentional, was improper in motive or means; and (4) the plaintiff was harmed by the defendant's actions." Hamann, 937 F.3d at 93 (second alteration in original) (quoting Blackstone v. Cashman, 860 N.E.2d 7, 12-13 (Mass. 2007)). In connection with such a claim, plausible allegations of a "probable future business relationship anticipating a reasonable expectancy of financial benefit will suffice" to satisfy the first element. Am. Priv. Line Servs., Inc. v. E. Microwave, Inc., 980 F.2d 33, 36 (1st Cir. 1992).

With respect to this claim – as with respect to its claim for tortious interference with contractual relations – Conformis alleges the existence of "contracts with more than 2,100 healthcare providers," as well as relationships with "non-contracted healthcare providers [who] have routinely prescribed or otherwise provided the Conformis System since it received FDA clearance in 2011." The question, then, is whether these allegations suffice, for pleading purposes, to satisfy the first element of the advantageous relations tort.

Aetna says that we should answer this question in the negative. It labors to draw comparisons between this case and the decisions in Singh v. Blue Cross/Blue Shield of Massachusetts and

Laser Labs, Inc. v. ETL Testing Laboratories, Inc. We think that these comparisons are strained and, ultimately, unhelpful.

In Singh, we held that the allegation that unspecified patients either left or failed to sign up for the plaintiff's medical practice was too "speculat[ive]" and non-specific to withstand a motion for summary judgment. 308 F.3d 25, 48 (1st Cir. 2002). In Laser Labs, the district court held that merely alleging business relationships with "several" unspecified customers was insufficient to withstand summary judgment. 29 F. Supp. 2d 21, 23 (D. Mass. 1998). The case at hand, though, differs both in its procedural posture and in substance.

In Singh and Laser Labs, bare allegations of advantageous relations were deemed insufficient to withstand summary judgment. See Singh, 308 F.3d at 48; Laser Labs, 29 F. Supp. 2d at 23. A plaintiff is held to a less demanding standard at the motion to dismiss stage, "with a record yet to be fleshed out with evidence." Vázquez-Ramos, 55 F.4th at 297. It need not establish the existence of a genuine issue of material fact but, rather, may rest on allegations as long as those allegations "create a reasonable expectation that discovery may yield evidence of [the defendant's] allegedly tortious [interference]." Hamann, 937 F.3d at 92 (second alteration in original) (quoting García-Catalán, 734 F.3d at 103).

Conformis has made this modest showing. It alleges the existence of sustained relationships, contractual and non-contractual, with a constituency of healthcare providers during the extended period of time that the Conformis system has been on the market. Such allegations are plausible, and we deem them sufficient to show the existence of business relationships "anticipating a reasonable expectancy of financial benefit." Am. Priv. Line Servs., Inc., 980 F.2d at 36.

Of course, the plaintiff also must plausibly allege that the defendant knew of the advantageous relations and intentionally interfered with them, causing economic harm. See Hamann, 937 F.3d at 93; see also Sindi, 896 F.3d at 26; Ayash v. Dana-Farber Cancer Inst., 822 N.E.2d 667, 690 (Mass. 2005). In this context, intentionality requires that the defendant "either desired to bring about the harm to the plaintiff or [] kn[ew] that this result was substantially certain to be produced by his conduct." Restatement (Second) of Torts ch. 37, intro. note (Am. L. Inst. 1979). Here, Conformis plausibly alleges that its leading position in the market for customized knee replacements, its letters to Aetna urging reconsideration of the Policy, the articles Aetna reviewed, and the claims submitted on behalf of Aetna's subscribers combine to ground a reasonable inference that Aetna not only knew of the existence of Conformis's advantageous relations but also must have known that its interference – the recharacterization of

the Conformis system as experimental and investigational and therefore ineligible for coverage – was virtually certain to result in economic harm.

We think these allegations are sufficient to lift this claim above the realm of mere speculation. Giving due weight to the "cumulative effect" of Conformis's factual averments, Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 14 (1st Cir. 2011), it is nose-on-the-face plain that Aetna must have been aware that Conformis had advantageous relations that were almost certain to be disrupted by Aetna's recharacterization of the Conformis system. It would be too much to demand – at the pleading stage – that Conformis allege more specific facts about Aetna's knowledge and intent. See Rodríguez-Reyes, 711 F.3d at 56 ("For pleading purposes, circumstantial evidence often suffices to clarify 'a protean issue such as an actor's motive or intent.'" (quoting Anthony, 952 F.2d at 605)). We hold, therefore, that Conformis's allegations with respect to this element of its advantageous relations claim are plausible.

Last – but far from least – Conformis must plausibly allege that Aetna's interference with its advantageous relations "was improper in motive or means." Hamann, 937 F.3d at 93 (quoting Blackstone, 860 N.E.2d at 13). We agree with Aetna that no improper motive has been proffered. After all, it is settled that purely financial motives will not normally sink to the necessary

level of impropriety. See id. at 90; King v. Driscoll, 638 N.E.2d 488, 495 (Mass. 1994). And here, Conformis's complaint explicitly states that "Aetna's motive for excluding coverage for the Conformis System . . . was purely financial."

But the failure plausibly to show an improper motive does not sound the death knell for Conformis's claim of tortious interference with advantageous relations. Conformis may still carry its pleading burden on this element of the tort by plausibly alleging improper means. See Geltman, 551 N.E.2d at 23-24. In this context, improper means refers to whether the defendant "violated a statute or a rule of common law[,] . . . used threats, misrepresented any facts, defamed anyone, or used any other improper means" in interfering with the business relationship. Id. at 24.

The allegations of the complaint plausibly allege improper means. In considering whether Conformis has plausibly alleged improper means, the decisive data point is that Conformis – as we have explained, see supra Part II(A) – has pleaded a plausible claim for product disparagement. This same showing does double duty, serving to satisfy the "improper means" element. See Geltman, 551 N.E.2d at 24.

3

We summarize succinctly. Although we uphold the district court's dismissal of Conformis's claim for tortious

interference with contractual relations, we reverse its dismissal of Conformis's claim for tortious interference with advantageous relations. Conformis has plausibly alleged the necessary elements of the latter claim.

C

This brings us to Conformis's challenge to the dismissal of its claim for unfair or deceptive trade practices. See Mass. Gen. Laws ch. 93A. To state a claim for unfair or deceptive trade practices under chapter 93A, a commercial plaintiff must plausibly allege "1) that the defendant engaged in an unfair method of competition or committed an unfair or deceptive act or practice, as defined by [Mass. Gen. Laws ch.] 93A, § 2, or the regulations promulgated thereunder; 2) a loss of money or property suffered as a result; and 3) a causal connection between the loss suffered and the defendant's unfair or deceptive method, act, or practice." Auto Flat Car Crushers, Inc. v. Hanover Ins. Co., 17 N.E.3d 1066, 1074-75 (Mass. 2014). The plaintiff's allegations must plausibly show that the defendant's actions fell "within at least the penumbra of some common-law, statutory, or other established concept of unfairness" or were "immoral, unethical, oppressive, or unscrupulous." Ruiz v. Bally Total Fitness Holding Corp., 496 F.3d 1, 11 (1st Cir. 2007) (quoting PMP Assocs., Inc. v. Globe Newspaper Co., 321 N.E.2d 915, 917 (Mass. 1975)).

The parties agree that the viability of this claim at the motion-to-dismiss stage depends on the viability of the claims for product disparagement and tortious interference. Because we have determined that some of those claims survive Aetna's motion to dismiss, see supra Parts II(A), (B)(2), we reverse the district court's dismissal of Conformis's chapter 93A claim.

III

We need go no further. For the reasons elucidated above, the judgment of the district court is

Affirmed in part and reversed in part. No costs.