United States Court of Appeals
For the First Circuit

No. 15-1446

ANITA HOCHENDONER ET AL.,

Plaintiffs, Appellants,

v.

GENZYME CORPORATION,

Defendant, Appellee.

No. 15-1447

PHILIP ADAMO ET AL.,

Plaintiffs, Appellants,

v.

GENZYME CORPORATION,

Defendant, Appellee.

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

[Hon. Douglas P. Woodlock, U.S. District Judge]

Before

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

Matthew L. Kurzweg, with whom Kurzweg Law Offices was on brief, for appellants.

Robert G. Jones, with whom Justin Florence, Mark S. Gaioni, Cassandra Bolaños, and Ropes & Gray LLP were on brief, for appellee.

May 23, 2016

SELYA, Circuit Judge. These consolidated actions stand on the cutting edge of modern medicine. In the end, however, they reduce mainly to a question of standing. Though we affirm the order of dismissal (with one small exception), our reasoning differs from that of the district court: we dismiss for lack of Article III standing. Because a dismissal for lack of standing is functionally equivalent to a dismissal for lack of jurisdiction, the resulting judgment will (unlike a judgment on the merits) operate without prejudice. The tale follows.

I. BACKGROUND

Because these appeals follow the granting of a motion to dismiss, we rehearse the facts as they appear in the plaintiffs' complaints (including documents incorporated by reference therein). See Katz v. Pershing, LLC, 672 F.3d 64, 69 (1st Cir. 2012).

Fabry Disease (Fabry) is a rare genetic disorder that leaves afflicted persons unable to synthesize a key enzyme that helps the body break down fats. Left untreated, Fabry patients will suffer a variety of progressively more severe symptoms, including pain in their extremities, gastrointestinal issues, vision and hearing losses, stroke, and heart and kidney failure, eventually leading to premature death. Researchers at the Mt. Sinai School of Medicine (Mt. Sinai) developed a method for producing a replacement enzyme, which effectively treats (but does

not cure) Fabry. After patenting this method, Mt. Sinai granted an exclusive license to defendant-appellee Genzyme Corporation (Genzyme). Genzyme thus became the sole producer of the replacement enzyme. Dubbed "Fabrazyme," it is the only enzyme replacement therapy approved by the federal Food and Drug Administration (FDA) for the treatment of Fabry.

Fabrazyme received FDA approval in April of 2003. That approval was based on a dose of one milligram of Fabrazyme for each kilogram of body weight taken intravenously every two weeks. Genzyme provided the drug steadily to Fabry patients until June of 2009, after a virus was discovered in improperly cleaned equipment at the company's Allston, Massachusetts manufacturing facility. This discovery compelled Genzyme to reduce production, leading to a shortage of Fabrazyme.

In response, the company initiated a rationing plan, providing Fabry patients with a reduced dose of Fabrazyme in order to stretch the available supply during the shortage. It also organized a group of doctors and other stakeholders to work on supply management guidance.

In November of 2009, Genzyme's efforts to restore a full supply of Fabrazyme met a roadblock in the form of the discovery of particulate steel, glass, and rubber in a recently produced batch of Fabrazyme. Later, another adulterated lot of Fabrazyme was spotted and destroyed prior to any distribution. A bad

situation grew worse: shortages in the United States were exacerbated in 2011 when Genzyme diverted some Fabrazyme to the European market. The complaints aver that this diversion was part of a pattern of favoring European patients due to competition Genzyme faced from an alternative enzyme replacement therapy approved only in Europe.

Although the company had been able, beginning in January of 2010, to provide Fabry patients with 50% of their FDA-approved doses, even this reduced supply was subject to intermittent interruptions. The supply dried up entirely in August of 2011, leaving Fabry patients in the United States unable to obtain Fabrazyme at all for a brief period. It was not until some time in 2012 that Genzyme succeeded in restoring fully supplies of Fabrazyme.

This sustained shortage sparked a proliferation of lawsuits, including the two actions that are before us. The first of these actions (Hochendoner) was filed in the United States District Court for the Western District of Pennsylvania in March of 2011 on behalf of the named plaintiffs and a putative class comprising all Fabry patients in the United States. The Hochendoner complaint was amended the following month and, shortly thereafter, the district court transferred the case to the District of Massachusetts. After the defendants moved to dismiss, the

Hochendoner plaintiffs obtained leave of court and filed a second amended complaint (the operative pleading for present purposes).

The second of the two actions (Adamo) was brought directly in the District of Massachusetts. That action was filed in June of 2013 by another group of Fabry patients on behalf of themselves and a putative class. After motions to dismiss were served, the Adamo complaint was amended as of right in September of 2013. That amended complaint is the operative pleading for present purposes. The district court thereafter consolidated the two cases.

Each complaint named Genzyme and Mt. Sinai as defendants and laid out a laundry list of claims. Those claims rest on a variety of theories, implicating alleged statutory violations (federal and state), torts, breaches of warranty, breaches of contract, and losses of consortium (brought by spouses of Fabry patients). By stipulation, Mt. Sinai has been dropped as a party, and the cases are proceeding against Genzyme alone.

After a hearing on Genzyme's motions to dismiss for failure to state any actionable claims, see Fed. R. Civ. P. 12(b)(6), the court below dismissed both actions, see Hochendoner v. Genzyme Corp., 95 F. Supp. 3d 15, 35 (D. Mass. 2015). The court's reasoning warrants some elaboration.

Faced with a matched set of rambling complaints, the court identified three potential injuries, bound up with three

potential causal chains. The first such cause and effect pairing involved the return of Fabry symptoms and the progression of the disease previously prevented by full doses of Fabrazyme. See id. at 24. The second pairing drew upon assertions in the complaints that patients "not only had a return of life threatening symptoms but also an accelerated course of deterioration on the lowered dose" (emphasis in original). On this second theory, the reduced Fabrazyme doses caused affirmative harm rather than merely permitting the return of the normal progression of Fabry symptoms. See id. at 24-25. The final pairing involved the plaintiffs' claims of harm attributable to the receipt of Fabrazyme tainted with particulate matter. See id. at 25-26.

After titrating the complaints into these three types of claims — the progression claims, the acceleration claims, and the contaminant claims — the court rejected them all. See id. at 35. The court concluded that the acceleration and contaminant claims did not comport with the requirements of Federal Rule of Civil Procedure 8(a) because they did not provide sufficient notice to Genzyme of which plaintiffs, if any, suffered the harms alleged under those theories. See id. at 25-26. While the court found that the progression claims did provide sufficient notice — after all, the complaints alleged that every plaintiff had suffered disease progression as a result of the Fabrazyme shortage — it nonetheless found the panorama of common-law and statutory causes

of action underlying the progression claims to be impuissant. Many of them were ineffective due to reliance on the notion, debunked by the district court, that Genzyme had a duty to supply the market with Fabrazyme. See, e.g., id. at 30-31.

On appeal, the parties embrace the district court's tripartite taxonomy as a means of channeling the plaintiffs' claims. The progression claims need not concern us: the plaintiffs do not challenge the district court's thorough evaluation and ultimate dismissal of those claims. Nor do they challenge the court's conclusion that Genzyme had no free-standing duty to supply the market with Fabrazyme. Their appeals challenge only the district court's disposition of the acceleration and contaminant claims.

II. ANALYSIS

Federal courts are courts of limited jurisdiction and, thus, we must begin by ensuring that we have jurisdiction to reach the questions presented by these appeals. This brings front and center Genzyme's asseveration that the plaintiffs lack standing to advance claims based on either the acceleration or contaminant theories. Though Genzyme did not challenge the plaintiffs' standing below, we nonetheless must address its asseveration here: because standing is a prerequisite to a federal court's subject matter jurisdiction, the absence of standing may be raised at any stage of a case. See P.R. Tel. Co. v. T-Mobile P.R. LLC, 678 F.3d

49, 57 (1st Cir. 2012). Since no class was certified below, we focus on the standing vel non of the named plaintiffs, individually. See Katz, 672 F.3d at 71.

Although review of a Rule 12(b)(6) dismissal for failure to state a claim and review to ensure the existence of standing are conceptually distinct, the same basic principles apply in both situations. See id. at 70-71. Appellate review is de novo, see P.R. Tel., 678 F.3d at 57, and the court of appeals must take the complaint's well-pleaded facts as true and indulge all reasonable inferences in the pleader's favor, see Kerin v. Titeflex Corp., 770 F.3d 978, 981 (1st Cir. 2014). We are not wedded to the district court's reasoning but, rather, may affirm the order of dismissal on any basis that is apparent from the record. See id.

The parallelism between the threshold requirements needed to satisfy Rule 12(b)(6) and the threshold showing necessary for standing extends beyond the standard of review. Just as the plaintiff bears the burden of plausibly alleging a viable cause of action, see, e.g., Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009), so too the plaintiff bears the burden of pleading facts necessary to demonstrate standing, see FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 231 (1990). Each element of standing "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." Lujan v.

Defs. of Wildlife, 504 U.S. 555, 561 (1992). Taking this cue, we — like the majority of our sister circuits — have applied the plausibility standard applicable under Rule 12(b)(6) to standing determinations at the pleading stage. See Van Wagner Bos., LLC v. Davey, 770 F.3d 33, 40 (1st Cir. 2014); Katz, 672 F.3d at 77-78; see also Silha v. ACT, Inc., 807 F.3d 169, 173-74 (7th Cir. 2015); In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 243-44 (3d Cir. 2012); Amidax Trading Grp. v. S.W.I.F.T. SCRL, 671 F.3d 140, 145 (2d Cir. 2011) (per curiam); White v. United States, 601 F.3d 545, 551-52 (6th Cir. 2010).

In the interest of clarity, we make explicit today what our cases have implied and what the near-uniform precedent in other circuits has established: at the pleading stage, the plaintiff bears the burden of establishing sufficient factual matter to plausibly demonstrate his standing to bring the action. Neither conclusory assertions nor unfounded speculation can supply the necessary heft. See Iqbal, 556 U.S. at 678-79; Blum v. Holder, 744 F.3d 790, 795 (1st Cir.), cert. denied, 135 S. Ct. 477 (2014).

With this backdrop in place, we divide our ensuing discussion into four segments. First, we turn to the allegations made by the plaintiffs in support of the acceleration and contaminant claims.[1] Second, we discuss the unique situation of

[1] From this point forward, we use the term "the plaintiffs" to refer to all of the named plaintiffs except for James Mooney and

two of the named plaintiffs — James Mooney and his wife, Laura Kurtz-Mooney — whose allegations do satisfy the prerequisites for standing. Third, we address the plaintiffs' contention that the district court should have permitted further amendment of the complaints. Finally, we explain why the district court must modify the dismissal of the acceleration and contaminant claims to operate without prejudice.

A. Standing.

Standing doctrine assures respect for the Constitution's limitation of "[t]he judicial Power" to "Cases" and "Controversies." U.S. Const. art. III, § 2, cl. 1. At bottom, that doctrine reflects "concern about the proper — and properly limited — role of the courts in a democratic society." Warth v. Seldin, 422 U.S. 490, 498 (1975). The heartland of constitutional standing is composed of the familiar amalgam of injury in fact, causation, and redressability. See Lujan, 504 U.S. at 560-61.

In our view, the case at hand hinges on the presence or absence of a plausibly pleaded injury in fact. Such an injury "must be both 'concrete and particularized and actual or imminent, not conjectural or hypothetical.'" Van Wagner Bos., 770 F.3d at

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his wife, Laura Kurtz-Mooney. For reasons to which we shall return, see infra Part II(B), we treat the Mooney claims separately.

37 (quoting Susan B. Anthony List v. Driehaus, 134 S. Ct. 2334, 2341 (2014)).

The Supreme Court recently has emphasized that concreteness and particularization are distinct requirements. An injury is concrete only if it "actually exist[s]." Spokeo, Inc. v. Robins, ___ S. Ct. ___, ___ (2016) [No. 13-1339, slip op. at 8]. For example, when an alleged injury is nothing more than "a bare procedural violation," there may be no cognizable harm to the plaintiff and thus no concreteness. Id. at ___ [slip op. at 9]. The particularization requirement is a different matter: it necessitates that a plaintiff has been affected "in a personal and individual way" by the injurious conduct. Id. at ___ [slip op. at 7] (quoting Lujan, 504 U.S. at 560 n.1).

The particularization element of the injury-in-fact inquiry reflects the commonsense notion that the party asserting standing must not only allege injurious conduct attributable to the defendant but also must allege that he, himself, is among the persons injured by that conduct. See Lujan, 504 U.S. at 563. The requirement that a plaintiff must adduce facts demonstrating that he himself is adversely affected guarantees that "the decision as to whether review will be sought [is] in the hands of those who have a direct stake in the outcome," Sierra Club v. Morton, 405 U.S. 727, 740 (1972), and ensures that disputes are settled "in a concrete factual context conducive to a realistic appreciation of

the consequences of judicial action," Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc., 454 U.S. 464, 472 (1982).

With respect to both the acceleration and contaminant claims, the plaintiffs here have failed to satisfy this abecedarian requirement. The sum total of the relevant portions of the complaints is easily summarized. The complaints, taken collectively, list each plaintiff's name and place of residence and proceed to allege that each plaintiff is a Fabry sufferer (or the spouse of a Fabry sufferer). The complaints proceed to set forth general information about each plaintiff's history of taking Fabrazyme, typically in the form of an assertion that, prior to 2009, the particular plaintiff received a full dose of Fabrazyme but thereafter was limited to a reduced dose (due to the shortage).[2] The Adamo complaint further avers that many plaintiffs were "forced to be injected with non FDA-approved doses of Fabrazyme under Defendants' threat to place [each such] Plaintiff at the end of a secret waiting list for access to Fabrazyme during its shortage if the unapproved and untested dose was refused."

[2] Our generalized description masks some idiosyncrasies among Fabrazyme recipients that are not relevant to the standing inquiry. For example, some plaintiffs are alleged not to have begun taking Fabrazyme until after the shortage began, while at least one other plaintiff alleges that she stopped taking Fabrazyme during the shortage.

Tellingly, no specific information is provided regarding the harm, if any, that has befallen each individual plaintiff. Instead, the complaints offer only scattered descriptions of generalized harms. They state, in nearly identical language, that "[a]s a direct result" of Fabrazyme rationing, "denial of access," "dilution," "change in dosing schedules," and "sale of adulterated [Fabrazyme]," Fabry patients in the United States "have had a return of symptoms, accelerated disease development, injury, and otherwise preventable disease progression" or "have died from these injuries." Under the heading of the first substantive count, each complaint alleges that the "Plaintiffs have sustained, or are at imminent risk of sustaining, the following serious injuries." A list of horribles then appears, including heart and kidney failure, pain, vision and hearing impairments, and premature death. Utterly absent, however, is any allegation linking the alleged acceleration and contaminant injuries to any specific plaintiff.

This gap is most apparent with respect to the contaminant theory. There is simply no assertion at any point in the complaints that any specific plaintiff took or received a dose contaminated with particulate matter. Rather, the allegation is only that Genzyme produced a batch of Fabrazyme contaminated with particulate matter — not that contaminated doses were ever shipped or administered to any named Fabry patients. Upon close scrutiny,

the same gap is evident in the acceleration claims: there is no allegation that any named plaintiff has suffered accelerated disease progression (as opposed to the natural progression of the disease) as a result of taking a reduced dose of Fabrazyme.[3]

The plaintiffs rail against this characterization. They say that the complaints allege that every named Fabry patient has been injured. Specifically, the plaintiffs say that they "have unambiguously averred that Genzyme produced a defective drug, the [plaintiffs] took that drug, and as a result they have sustained, or are at imminent risk of sustaining, enumerated specific harms." But this gloss on the complaints is insupportable. It ignores the settled rule that "standing is not dispensed in gross." Lewis v. Casey, 518 U.S. 343, 358 n.6 (1996). The appropriate inquiry must be "whether each particular plaintiff is entitled to have a federal court adjudicate each particular claim that he asserts." Pagán v.

[3] On this point, the plaintiffs rely heavily on a report from the European Medicines Agency, attached to the complaints. This report includes a statement that the observed "pattern of adverse events" in Fabry patients who received reduced dosages of Fabrazyme during the shortage period "resembles the natural, but accelerated, course of Fabry's disease" (emphasis omitted). Even accepting arguendo the plaintiffs' assertion that this report bolsters the theory behind the acceleration claims, the report provides no basis for concluding that every Fabry patient on the reduced dose suffered an acceleration. Thus, the report does not justify the conclusion that every Fabry patient in the plaintiffs' shoes has standing to assert acceleration-theory claims. See Hochendoner, 95 F. Supp. 3d at 25.

Calderón, 448 F.3d 16, 26 (1st Cir. 2006); accord DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006).

Here, the progression, acceleration, and contaminant theories allege different injuries and causal chains. Consequently, the plaintiff-by-plaintiff and claim-by-claim analysis required by standing doctrine demands allegations linking each plaintiff to each of these injuries. Suffering one species of injury does not confer standing on a plaintiff to press claims based on another species of injury, even if the injuries share a common genus. See Blum v. Yaretsky, 457 U.S. 991, 999 (1982) ("Nor does a plaintiff who has been subject to injurious conduct of one kind possess by virtue of that injury the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject.").

It follows that, even assuming for argument's sake that the complaints make out a showing of harm sufficient to ground the progression claims, that showing does not confer standing with respect to either the acceleration or contaminant claims. The progression claims may be characterized as sufficient to plead an injury because the complaints (read in the most forgiving manner) allege that every named Fabry patient suffered a progression of his or her disease due to a lack of Fabrazyme during the period of the shortage. However, no comparable allegation pertains to either

the acceleration or contaminant claims,[4] and the complaints are wholly lacking in assertions that any named plaintiff suffered either an acceleration or contaminant injury in fact.

The plaintiffs have one last string to their bow. In support of their professed standing, they point to the complaints' generalized assertion that Genzyme forced patients in the United States to forgo doses, resulting "in an increased risk and severity of acute adverse reactions due to inconsistent infusion schedules." Though this injury does not fall neatly into either the progression or acceleration category, it need not detain us: what matters is that none of the plaintiffs (other than Mooney, see supra note 1) is alleged actually to have suffered an adverse reaction as a result of taking a diminished dose. Nor is any ongoing risk of harm apparent: the plaintiffs concede, and the incorporated documents show, that the Fabrazyme shortage has long since ended and that all Fabry patients are now able to receive full doses of the drug. The plaintiffs thus lack standing to advance claims based on their averments concerning reactions to the drug.

We add a coda. Although the same pleading standards apply both to standing determinations and Rule 12(b)(6)

[4] At least with respect to the Adamo complaint, any such allegation would fly in the face of specifically pleaded facts. That complaint asserts that one of the named plaintiffs, Adam Dible, never took Fabrazyme during the period of the shortage.

determinations, the two inquiries remain fundamentally distinct: "standing in no way depends on the merits of the plaintiff's contention that particular conduct is illegal." Warth, 422 U.S. at 500; accord Ariz. State Legislature v. Ariz. Indep. Redistricting Comm'n, 135 S. Ct. 2652, 2663 (2015). An individual's plausible allegations of a personal injury will generally suffice to plead an injury in fact, even if the claim is ultimately lacking on the merits. See, e.g., Chaudhry v. City of Los Angeles, 751 F.3d 1096, 1109 (9th Cir.), cert. denied, 135 S. Ct. 295 (2014); Katz, 672 F.3d at 72; Carver v. City of New York, 621 F.3d 221, 225-26 (2d Cir. 2010); Muir v. Navy Fed. Credit Union, 529 F.3d 1100, 1105-07 (D.C. Cir. 2008). It follows that, in conducting our inquiry into standing, we have not considered the validity of any of the plaintiffs' claims as a matter of law or the adequacy of their pleading to state a claim under Rule 12(b)(6). Mindful of the bedrock proposition that a plaintiff must "be himself among the injured," Lujan, 504 U.S. at 563 (quoting Sierra Club, 405 U.S. at 735), we conclude that the utter failure of any plaintiff (other than Mooney) to plausibly allege that he or she suffered an injury in fact as a result of accelerated disease progression or receipt of a contaminated drug means that none of the plaintiffs has standing to assert claims based on those theories of injury.

B. The Mooney Claims.

This leaves only the excepted claims, which relate to James Mooney (one of the named plaintiffs in Adamo).[5] The district court did not single out these claims in any way. Mooney argues that his claims were overlooked and, in all events, stand on a different footing. Genzyme, though, suggests that the differences do not matter and that separate consideration was unnecessary.

In Genzyme's view, Mooney's alleged injury is that he is no longer able to take Fabrazyme after experiencing a severe reaction to the drug and, thus, his untreated Fabry is progressing. Genzyme sees this as old wine in a new bottle: the notion that Genzyme had a duty to supply the market with Fabrazyme, thus preventing the progression of untreated Fabry, was rejected by the district court and is not pursued on appeal.

Genzyme's analysis misreads the gravamen of Mooney's claims. To be sure, the Adamo complaint states that Mooney, like other Fabry patients, was placed on a reduced Fabrazyme regimen beginning in June of 2009. But the complaint goes on to provide

[5] Under this rubric, we include, albeit without further reference, the allegations and claims of Mooney's wife, Laura Kurtz-Mooney (who is also a named plaintiff in Adamo). For the reasons given as to Mooney himself, we hold that Kurtz-Mooney's allegations, like her husband's, are sufficient to plead an injury in fact and, thus, are adequate to ground standing for her derivative loss-of-consortium claims. See generally Bowen v. Kil-Kare, Inc., 585 N.E.2d 384, 391-92 (Ohio 1992) (discussing derivative spousal consortium claims under Ohio law).

specific and unique details about Mooney's alleged injury: "In March 2012, when Genzyme finally permitted Mr. Mooney to resume receiving FDA approved doses . . . he experienced anaphylactic treatment reactions from the development of antibodies to the diluted Fabrazyme" that he earlier had received. This statement, combined with the other information in the complaint, establishes Mooney's standing: he alleges that he was injured through an allergic reaction attributable to his exposure to a reduced dose of Fabrazyme at Genzyme's behest. Monetary damages would redress this injury, even if imperfectly.

Properly understood, Mooney's alleged injury is the anaphylactic reaction suffered when he returned to a full dose of Fabrazyme, not his inability to receive full doses of Fabrazyme. Although Genzyme may have had no duty to provide Mooney with a drug to treat his Fabry, it may still be responsible for taking care to make sure that any drug it did supply was safe for use. Mooney's central contention — that a reduced Fabrazyme dose led to his anaphylactic reaction when the full dose was resumed — does not depend in any way on a duty to supply the market.

As a fallback, Genzyme suggests that alternative grounds exist for affirming the dismissal of the Mooney claims. It argues that the claims fail to adumbrate causes of action under the law of Ohio (the jurisdiction in which Mooney resides) and are bereft

of the full complement of plausible factual allegations necessary to state actionable claims under that law.

As a general matter, federal courts of appeals, engaged in appellate review, are understandably reluctant to consider issues that were not passed upon below. See Singleton v. Wulff, 428 U.S. 106, 120 (1976). While this reluctance is not a straitjacket — we have loosened it, for example, when the result is obvious or when failure to address the issue immediately would work an injustice, see id. at 121; Town of Barnstable v. O'Connor, 786 F.3d 130, 141 (1st Cir. 2015) — there is no reason to loosen it here. This is especially so since the district court's rescript passes over the Mooney claims without any discussion, and the viability of those claims under Ohio law is neither well-briefed nor readily discernable. We conclude, therefore, that we should adhere to the usual praxis, vacate the dismissal of the Mooney claims, and remand them for consideration by the district court in the first instance.

C. Leave to Amend.

The plaintiffs insist that their claims should be returned to the district court to allow amendment. We do not agree.

Some further background is helpful to put this aspect of the appeals into perspective. After the last set of motions to dismiss was filed, the plaintiffs did not move for leave to amend.

But at the hearing on the motions to dismiss, they suggested that they could provide information about the specific harms suffered by each plaintiff. Even then, however, no motion to amend was made.

In the absence of exceptional circumstances, a district court is under no obligation to offer a party leave to amend when such leave has not been requested by motion. See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 241-42, 241 n.30 (1st Cir. 2004); Emerito Estrada Rivera-Isuzu de P.R., Inc. v. Consumer's Union of U.S., Inc., 233 F.3d 24, 30-31 (1st Cir. 2000). Although the standard of review for a district court's failure to offer a sua sponte opportunity to amend is uncertain, see Karvelas, 360 F.3d at 242 n.32 (collecting cases and identifying abuse of discretion, plain error, and interests of justice as three standards this circuit has applied), we discern no infirmity on this record under any standard. The short of it is that there is a complete absence of exceptional circumstances. The plaintiffs had (and used) several previous opportunities to amend. Moreover, the concern that the injuries to the plaintiffs were insufficiently pleaded was apparent from the outset: that concern was thoroughly briefed and argued by the parties, and the district court pointedly observed that it had given the plaintiffs "an extended opportunity to draft a complaint" that would survive a Rule 12(b)(6) motion.

The plaintiffs' importuning that they "reasonably and strategically opted not to amend their Complaints in an effort to cure deficiencies that they believed non-existent" does not tip the scale. The liberal disposition of the Civil Rules toward amendments, see Fed. R. Civ. P. 15(a), cannot be exploited to avoid the predictable consequences of a litigant's strategic choices, see Fisher v. Kadant, Inc., 589 F.3d 505, 510 (1st Cir. 2009). We thus find no fault with the district court's failure to invite the plaintiffs, sua sponte, to further amend their complaints. See Emerito Estrada, 233 F.3d at 30-31.

D. Effect of Dismissal for Lack of Standing.

There is one loose end. The plaintiffs rail against the prejudicial effect of the district court's order of dismissal. There is good reason for this concern: although the district court's order does not specify whether it is to operate with or without prejudice, the normal presumption is that a Rule 12(b)(6) dismissal is with prejudice. See Fed. R. Civ. P. 41(b); Karvelas, 360 F.3d at 241. After all, such a judgment constitutes "a final decision on the merits." Karvelas, 360 F.3d at 241.

By contrast, a dismissal for lack of subject matter jurisdiction normally operates without prejudice. See Torres-Fuentes v. Motorambar, Inc., 396 F.3d 474, 475 (1st Cir. 2005). This approach makes eminently good sense since a want of jurisdiction deprives a court of the authority to enter a judgment

on the merits of the claims sub judice. See Mills v. Harmon Law Offices, P.C., 344 F.3d 42, 45-46 (1st Cir. 2003); Christopher v. Stanley-Bostitch, Inc., 240 F.3d 95, 100 (1st Cir. 2001) (per curiam). Courts routinely apply this principle to dismissals for lack of Article III standing. See, e.g., S. Walk at Broadlands Homeowner's Ass'n, Inc. v. OpenBand at Broadlands, LLC, 713 F.3d 175, 185 (4th Cir. 2013); Stalley ex rel. United States v. Orlando Reg'l Healthcare Sys., Inc., 524 F.3d 1229, 1232, 1234-35 (11th Cir. 2008) (per curiam); Brereton v. Bountiful City Corp., 434 F.3d 1213, 1216 (10th Cir. 2006); County of Mille Lacs v. Benjamin, 361 F.3d 460, 464-65 (8th Cir. 2004). Following this line of authority, we hold that a dismissal for lack of Article III standing must operate without prejudice.

Consequently, we will direct the district court, on remand, to clarify its judgment to reflect that the judgment is to operate without prejudice as to claims based on the acceleration and contaminant injuries. The judgment shall continue to operate with prejudice, however, as to claims based on the progression theory. Those claims were disposed of below under Rule 12(b)(6) and are not pursued on appeal.

III. CONCLUSION

We need go no further. The Mooneys alone have plausibly alleged facts sufficient to demonstrate Article III standing. We thus affirm the dismissal of the complaints as to all the other

plaintiffs based on their lack of Article III standing. However, we direct the district court, on remand, to clarify the judgment so that it will operate without prejudice as to claims based on the alleged acceleration and contaminant injuries. At the same time, we vacate the dismissal of the Mooneys' claims and remand the Adamo action for further proceedings consistent with this opinion. All parties shall bear their own costs.

So Ordered.