

United States Court of Appeals For the First Circuit

No. 15-1897

PIERO ANVERSA and ANNAROSA LERI,

Plaintiffs, Appellants,

v.

PARTNERS HEALTHCARE SYSTEM, INC., ET AL.,

Defendants, Appellees.

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

[Hon. Denise J. Casper, U.S. District Judge]

Before

Thompson, Selya and Kayatta,
Circuit Judges.

Tracy A. Miner, with whom Megan A. Siddall and Demeo LLP were on brief, for appellants.

Roberto M. Braceras, with whom Jennifer L. Chunias and Goodwin Procter LLP were on brief, for appellees Harvard Medical School and Gretchen Brodnicki.

Geoffrey M. Raux, with whom Michael J. Tuteur and Foley & Lardner LLP were on brief, for remaining appellees.

August 30, 2016

SELYA, Circuit Judge. There is a time for every action, cf. Ecclesiastes 3:1 ("To every thing there is a season, and a time to every purpose"), including the bringing of suit. This case breathes life into that axiom.

The context is the high-stakes world of academic medical research. The questions before us have their genesis in allegations that the plaintiffs (prominent medical researchers) used manipulated research data in articles reporting on studies supported by government funds. Responding to those allegations, the institutional defendants (including a medical school and a teaching hospital) triggered a unique federal statutory and regulatory scheme. Things did not go smoothly and, after some time elapsed, the plaintiffs repaired to the federal courts in search of relief (without awaiting the outcome of the administrative proceedings).

Concluding that the suit was premature because the plaintiffs had not exhausted their administrative remedies, the district court dismissed the action. See Anversa v. Partners Healthcare Sys., Inc., 116 F. Supp. 3d 22, 34-35 (D. Mass. 2015). The plaintiffs appeal. Their appeal raises novel questions at the federal appellate level concerning the interrelationship between the statutory and regulatory scheme and state-law causes of action touching upon its implementation. Answering those questions, we affirm the district court's application of the doctrine of

administrative exhaustion but modify the judgment to ensure that the suit receives a full airing at the appropriate time.

I. STATUTORY AND REGULATORY FRAMEWORK

We begin with a description of the unique and highly detailed statutory and regulatory scheme that underlies this appeal. The federal government provides substantial funding for path breaking medical research. Fearful that these funds could be misused by researchers who might fabricate, falsify, or otherwise doctor research outcomes, Congress envisioned a need to establish procedures to address complaints of research misconduct. To this end, Congress created the Office of Research Integrity (ORI) within the Department of Health and Human Services (HHS), see 42 U.S.C. § 289b(a)(1), and tasked ORI with responsibility for carrying out regulations to be promulgated by the Secretary of HHS (the Secretary) for the investigation of research misconduct allegations, see id. § 289b(a)(2), (b)-(e).

Among other things, the statute obligates the Secretary to promulgate regulations that define "research misconduct," id. § 289b(a)(3)(A); to ensure that institutions receiving funds have a compliant "administrative process to review reports of research misconduct," id. § 289b(b)(1); and to create a process for ORI itself to receive allegations of and reports about research misconduct, to carry out its own investigations as needed, and to take necessary remedial action, see id. § 289b(c). Relatedly,

Congress tasked the Secretary with fashioning regulations that would facilitate ORI's oversight of institutional compliance with the research misconduct regulations. See id. § 289b(d). Congress also authorized the Secretary to appoint ORI's director, who must "be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct." Id. § 289b(a)(2).

The Secretary has responded to this statutory mandate by promulgating an elaborate regulatory mosaic. In that mosaic, "research misconduct" is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." 42 C.F.R. § 93.103. Establishing research misconduct requires a showing, by a preponderance of the evidence, of "a significant departure from accepted practices of the relevant research community" that is "committed intentionally, knowingly, or recklessly." Id. § 93.104.

These standards inform a protocol which, mirroring congressional intent, creates a two-level process for review of research misconduct allegations. The first level occurs at the funded institution. An inquiry "is warranted" when the institution is made aware of "sufficiently credible and specific" allegations of research misconduct. Id. § 93.307(a)(3). Such an inquiry comprises "an initial review of the evidence to determine whether to conduct an investigation." Id. § 93.307(c). The institution

generally "must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period," and it must document the reasons for any delays in completing the inquiry. Id. § 93.307(g). The inquiry culminates in a written report – a report on which the target of the inquiry (the respondent) has the opportunity to comment. See id. § 93.307(e)-(f).

If the inquiry finds a "reasonable basis for concluding" that some research misconduct involving federal funds has taken place, id. § 93.307(d)(1), and that particularized allegations of research misconduct "may have substance," id. § 93.307(d)(2), the institution must notify ORI of the inquiry results within 30 days, sending along a copy of the inquiry report, see id. § 93.309(a). It must also give the respondent notice of the allegations that the investigation will explore. See id. § 93.310(c).

From that point forward, the institution is obliged to conduct a "thorough and sufficiently documented" investigation, which "includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations." Id. § 93.310(e). The institution is expected to interview all relevant witnesses, see id. § 93.310(g), and to "[p]ursue diligently all significant issues and leads discovered that are determined relevant to the investigation . . . and continue the investigation to completion," id. § 93.310(h). As with the earlier

inquiry, the investigation culminates in a written report, on which the respondent has the opportunity to comment. See id. §§ 93.312(a), 93.313(g). This phase of the regulatory framework has its own temporal limitation: it provides that "[a]n institution must complete all aspects of an investigation within 120 days," id. § 93.311(a), unless it requests and receives an extension from ORI, see id. § 93.311(b). Regardless of whether the investigation concludes that research misconduct occurred, the report, its findings and conclusions, all the relevant evidence, and any information about actions taken or pending by the institution must be forwarded to ORI. See id. § 93.315.

Once ORI receives the investigation report and the related materials, it conducts its own assessment of the allegations. ORI has the authority to obtain additional input from virtually any source, supplement the evidence, and develop its own analysis. See id. § 93.403(d)-(e). Moreover, ORI may make independent findings as to whether research misconduct was committed and if so, by whom. See id. § 93.403(f). It also may recommend appropriate administrative action, which can range from the relatively mild (say, a letter of reprimand) to the relatively severe (say, debarment from eligibility to receive federal research funding). See id. § 93.407(a).

Even beyond the notice requirements, opportunities for comment, and time limits described above, the regulatory framework

contains protections for researchers facing investigation. For example, the regulations offer assurances of confidentiality, limiting disclosure of information about an ongoing proceeding "to the extent possible, to those who need to know." Id. § 93.108(a). So, too, the regulations require institutions to "[t]ake reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable." Id. § 93.310(f). In this regard, institutions must ensure that those participating in the investigation have the "appropriate scientific expertise" and are not affected by "personal, professional, or financial conflicts of interest." Id.

Should ORI find research misconduct, a respondent has access to an additional safety valve: a right to appeal that finding and any resulting administrative action to an administrative law judge (ALJ). See id. § 93.500(b). The ALJ's review of both ORI's finding and its proposed administrative action is de novo. See id. § 93.517(b). Withal, the ALJ "does not review the institution's procedures or misconduct findings." Id. When issued, the ALJ's decision serves as a recommendation to the Assistant Secretary for Health in HHS, who may affirm, modify, or reject it entirely. See id. § 93.523(b). In making those determinations, the Assistant Secretary uses familiar standards of review, such as whether particular findings are clearly erroneous or whether the decision (or any part of it) is arbitrary or

capricious. See id. The Assistant Secretary's decision constitutes final agency action for most purposes,¹ subject to review in the federal courts under the Administrative Procedure Act (APA). See 5 U.S.C. § 701-706.

Three other features of this statutory/regulatory scheme deserve mention. First, although ORI examines the institution's handiwork in determining whether to carry out its own investigation, see 42 C.F.R. § 93.403(c), there is no formal process for a respondent to prefer charges that an institution has violated the regulations in the course of either the inquiry or the first-tier investigation. The regulations do, however, provide a process by which ORI may, on its own initiative, probe an institution's compliance with the regulations and take appropriate enforcement action. See id. §§ 93.412-.413.

Second, it is manifest that neither the statute nor the regulations contemplate enforcement by private parties. Instead, enforcement is left to the Secretary, acting through ORI and the Assistant Secretary for Health.

Finally, the statute itself contains no explicit exhaustion requirement. While the district court found an

¹ We say "for most purposes" because a recommendation for debarment or suspension from receiving federal research funds only becomes final after ratification by a different official. See 42 C.F.R. § 93.523(c).

exhaustion requirement to be implicit in the statutory scheme, see Anversa, 116 F. Supp. 3d at 31-32, it is unnecessary (for reasons to which we shortly shall return) for us to pass upon this aspect of the district court's decision – and we do not do so. Instead, we resolve this appeal on the basis of the district court's alternate holding (its administrative exhaustion ruling).

II. FACTUAL OVERVIEW

The raw facts, outlined in the complaint, are essentially undisputed for present purposes. The plaintiffs are two high-profile medical researchers, Dr. Piero Anversa and Dr. Annarosa Leri. At the time of the underlying events, both of them held faculty appointments at Harvard Medical School (Harvard).² In addition to their teaching roles, both plaintiffs were intimately involved with a cardiac stem cell research laboratory at Brigham and Women's Hospital (the Brigham): Dr. Anversa led the lab, and Dr. Leri toiled as a principal investigator there. The Brigham, it should be noted, is not only a Harvard teaching hospital but also a founding member of the Partners HealthCare System (Partners).

In 2012, questions arose about the authenticity of data that appeared in an article co-authored by the plaintiffs and other

² At oral argument in this court, plaintiffs' counsel reported that both of her clients have left Harvard and are now working in Switzerland.

scientists, including a researcher at Lawrence Livermore National Laboratory (LLNL). Shortly after the publication of this paper in the journal "Circulation," the LLNL researcher reported to the plaintiffs that discrepancies existed between the data LLNL had provided and the data presented in the paper. Dr. Anversa asserts that he repeatedly asked the Brigham lab member who received the LLNL data if the presentation in the paper was accurate and received assurances that everything was in order. But LLNL persisted; it reported the discrepancies to Gretchen Brodnicki, Harvard's Dean for Faculty and Research Integrity.

On January 10, 2013, Dean Brodnicki informed the plaintiffs that Harvard and the Brigham were going to begin a joint inquiry into allegations of research misconduct. These allegations related not only to the "Circulation" paper but also to an article co-authored by the plaintiffs and other collaborators that had appeared in another journal, "The Lancet," in 2011.

The inquiry took substantially longer than the 60 days allotted in the regulations. One reason was that (as Dean Brodnicki told the plaintiffs in March of 2013) the inquiry was expanded to encompass yet another allegation relating to an unpublished manuscript submitted in 2013 to "The Lancet" and the journal "Science." The inquiry panel did not submit a draft report to the plaintiffs for their comments until January 8, 2014. The final panel inquiry report was issued on February 28, 2014. The

plaintiffs allege that the report recommended retraction of the 2011 "Lancet" and 2012 "Circulation" papers, that the lab be evaluated for its appropriateness as a training ground for budding researchers, and that the inquiry proceed to a full-blown investigation. The plaintiffs further allege that "[t]he inquiry panel found no evidence that [the plaintiffs] ever participated in falsifying or fabricating research data or results, or that they even knew of any research misconduct at the time it occurred," but nonetheless recommended proceeding to an investigation "on the theory that Dr. Anversa should be held responsible for arguably negligent failure to investigate" research misconduct.

Simultaneous with their receipt of the final panel inquiry report, the plaintiffs were notified that Harvard and the Brigham intended to commence an investigation. The three scientists who composed the inquiry panel were appointed to serve on the investigation panel, and a fourth member was added a few weeks later. On three separate occasions – twice in 2014 and once in 2015 (after suit had been commenced) – the investigation was expanded to include additional research papers beyond those identified in the panel inquiry report. Betimes, Harvard and the Brigham have sought – and ORI has granted – multiple extensions to the 120-day investigatory period.³

³ At oral argument in this court, counsel for Harvard reported that the deadline for completing the investigation authorized by

III. TRAVEL OF THE CASE

In December of 2014 – while the investigation was still in progress – the plaintiffs sued Partners, the Brigham, Harvard, Dean Brodnicki, and Dr. Elizabeth Nabel (the Brigham's president). Their complaint limned claims under Massachusetts law for tortious interference with business relations, invasion of privacy, and unfair and deceptive business practices. The complaint also charged Partners, the Brigham, and Harvard with breach of contract based on a claim that the ORI regulations are incorporated into their employment contracts with those institutions.

The plaintiffs alleged that both the completed inquiry and the ongoing investigation failed to comply with pertinent regulations. Specifically, they alleged that the inquiry panel applied the wrong standard in recommending an investigation and that its report was riddled with other errors. See id. § 93.104(b). They also ascribed a host of failings to the investigation panel, claiming (for example) that some of its members lacked the requisite scientific expertise and that some were either biased due to their participation in the flawed inquiry or labored under conflicts of interest. See id. § 93.310(f). The plaintiffs further lamented that both the inquiry and the

the most recent ORI extension is November 1, 2016. The investigation panel, we were told, is in the process of drafting its report.

investigation have been subject to egregious and unwarranted delays. See id. §§ 93.307(g), .311(b). Finally, the plaintiffs alleged that Dr. Steven Gygi (a member of both the inquiry and investigation panels), Dean Brodnicki, and Dr. Nabel separately transgressed confidentiality obligations imposed by the regulations.⁴ See id. § 93.108.

The plaintiffs seek money damages and unspecified declaratory relief. With respect to damages, they say that the manifold failures that occurred during the inquiry and the investigation caused them harm. They claim, for instance, that they missed out on a number of promising employment and other professional opportunities, and lost a lucrative offer for the purchase of Dr. Anversa's company. They also claim that Dr. Leri's promotion to a full professorship at Harvard was delayed and that they have suffered reputational injury.

The defendants moved to dismiss. See Fed. R. Civ. P. 12(b)(1), (6). They contended, inter alia, that the plaintiffs should be required to exhaust administrative remedies before bringing suit. The district court agreed and dismissed the complaint without prejudice. See Anversa, 116 F. Supp. 3d at 35. The court held that the statutory scheme governing research

⁴ The plaintiffs allege that Dr. Gygi resigned from the investigation panel in September of 2014, acknowledging that he had discussed the investigation with a colleague.

misconduct investigations mandated exhaustion. See id. at 32. Alternatively, the court held that common-law principles of administrative exhaustion militated in favor of dismissal. See id. at 34. This timely appeal followed.

IV. ANALYSIS

Given the structure of the district court's disposition, an issue of jurisdictional priority looms. Even though the doctrines of statutory and administrative exhaustion have a common objective - delaying a plaintiff's day in court while administrative proceedings run their course - the two doctrines rest on different foundations. The question whether a statutory scheme requires the channeling of claims through the administrative process implicates the jurisdiction of the district court. See, e.g., Free Enter. Fund v. Pub. Co. Accounting Oversight Bd., 561 U.S. 477, 489-91 (2010); Thunder Basin Coal Co. v. Reich, 510 U.S. 200, 207-09 (1994). By contrast, administrative exhaustion applies "where Congress has not clearly required exhaustion," and cedes discretion to a district court to decline the exercise of jurisdiction and await the conclusion of administrative proceedings. See McCarthy v. Madigan, 503 U.S. 140, 144 (1992).

Here, the district court's ruling consists of two alternative holdings. Taken together, these holdings amount to a double-barreled conclusion that the statutory structure forbade

the district court's exercise of jurisdiction over the action and – even if it had jurisdiction – it would decline to exercise that jurisdiction for prudential reasons.

In the ordinary course, questions about the existence of subject matter jurisdiction take precedence in our analysis of a case.⁵ See Acosta-Ramírez v. Banco Popular de P.R., 712 F.3d 14, 18 (1st Cir. 2013). This approach is consistent with the Supreme Court's admonition that a court "may not rule on the merits of a case without first determining that it has jurisdiction over the category of claim in suit." Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp., 549 U.S. 422, 430-31 (2007). But the two exhaustion doctrines at issue here do not implicate this principle: they are simply alternative "threshold grounds for denying

⁵ The parties have not contested the existence of Article III jurisdiction, and the district court did not consider that question. Nevertheless, we have an obligation to assure ourselves of our own jurisdiction. See Watchtower Bible & Tract Soc'y of N.Y., Inc. v. Colombani, 712 F.3d 6, 10 (1st Cir. 2013). In keeping with that obligation, we note that Article III jurisdiction exists in this case notwithstanding that the controversy is between non-diverse parties and asserts exclusively state-law claims. Federal question jurisdiction under 28 U.S.C. § 1331 encompasses a narrow swath of cases in which "a state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 314 (2005). Given that all of the plaintiffs' claims turn on the interpretation of the federal regulations governing research misconduct investigations and the importance of those regulations to the Congressional scheme, this case plainly falls within the narrow swath of cases described in Grable.

audience to a case on the merits." Ruhrgas AG v. Marathon Oil Co., 526 U.S. 574, 585 (1999). In comparable situations, the Supreme Court has made pellucid that a nonjurisdictional threshold reason for preterminating a merits determination – such as a decision not to exercise pendent jurisdiction over state-law claims, dismissal on the basis of forum non conveniens, or Younger abstention – may be applied without first resolving a difficult jurisdictional question. See Sinochem Int'l, 549 U.S. at 431-32.

Such an approach – bypassing the jurisdictional inquiry – is preferable here. The statutory exhaustion analysis is complex and uncertain, and its outcome would have no bearing on the ultimate result: as we explain below, the district court acted well within its discretion in insisting upon administrative exhaustion. Thus, we proceed directly to the merits of the district court's administrative exhaustion ruling.

Administrative exhaustion is governed by "sound judicial discretion." McCarthy, 503 U.S. at 144. Consequently, the customary practice among the circuits has been to review a district court's decision to compel the exhaustion of administrative remedies, in the absence of a statute directing exhaustion, for abuse of discretion. See, e.g., Koch v. White, 744 F.3d 162, 164-65 (D.C. Cir. 2014); Thermal Sci., Inc. v. U.S. Nuclear Regulatory Comm'n, 184 F.3d 803, 805 n.3 (8th Cir. 1999) (per curiam). Although we have never explicitly stated the standard in this

manner, we have recognized that application of the administrative exhaustion doctrine is a matter of discretion, guided by the factors identified in McCarthy. See Portela-Gonzalez v. Sec'y of the Navy, 109 F.3d 74, 77 (1st Cir. 1997). We hold, therefore, that appellate review of a district court's decision to require administrative exhaustion should be for abuse of discretion.

Generally, aggrieved parties are required to exhaust available federal administrative remedies before bringing suit in federal court. See Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50-51, 51 n.9 (1938); Portela-Gonzalez, 109 F.3d at 77. This principle rests on solid foundations: exhaustion normally "serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency." McCarthy, 503 U.S. at 145. Preserving agency authority is particularly important insofar as "the action under review involves exercise of the agency's discretionary power or when the agency proceedings in question allow the agency to apply its special expertise." Id. Insisting upon exhaustion not only gives an agency the first opportunity to apply that expertise and correct possible errors, but also respects congressional prerogative by "prevent[ing] litigants from bypassing Congress' carefully crafted remedial scheme." Irizarry v. United States, 427 F.3d 76, 79 (1st Cir. 2005). So, too, insisting upon exhaustion promotes judicial efficiency both by obviating the need for review in cases in which

the agency provides appropriate redress, see Portela-Gonzalez, 109 F.3d at 79, and by creating "a useful record for subsequent judicial consideration, especially in a complex or technical factual context," McCarthy, 503 U.S. at 145.

Where, as here, Congress has not mandated exhaustion, federal courts have some leeway to relax this requirement. See Swirsky v. Nat'l Ass'n of Sec. Dealers, 124 F.3d 59, 63 (1st Cir. 1997). That leeway is built into the common-law doctrine of administrative exhaustion. In considering whether to exercise it, "courts must balance the interest of the individual in retaining prompt access to a federal judicial forum against countervailing institutional interests favoring exhaustion." McCarthy, 503 U.S. at 146. This analysis is "'intensely practical,' because attention is directed to both the nature of the claim presented and the characteristics of the particular administrative procedure provided." Id. (internal citations omitted) (quoting Bowen v. City of New York, 476 U.S. 467, 484 (1986)).

In discussing how to construct this balance, the Supreme Court described three "sets of circumstances in which the interests of the individual weigh heavily against requiring administrative exhaustion." Id. These situations arise when "requiring resort to the administrative remedy may occasion undue prejudice to subsequent assertion of a court action," id. at 146-47; when an administrative remedy may be insufficient because the agency is

powerless to grant effective relief or incompetent to adjudicate the claims at issue, see id. at 147-48; or when the administrative body is clearly biased, see id. at 148-49.

The plaintiffs asseverate that their case falls within two of these categories. In their view, the administrative process cannot grant them appropriate relief and, moreover, they face an indefinite (and, therefore, unreasonable) timeline. These drawbacks, they say, more than outweigh whatever may be gained by exhaustion because – in this instance – exhaustion will neither preserve agency authority nor promote judicial economy.

We start our inquiry into the district court's application of administrative exhaustion with the plaintiffs' suggestion that completion of the administrative process in this case will not advance the interests that exhaustion exists to protect. We do not agree. To begin, the plaintiffs vastly understate the ongoing importance of ORI's expertise to the administrative proceedings. They similarly understate the degree to which ORI's expertise already has played a valuable role in the institutional investigation. The issues raised by the plaintiffs' suit are in many respects the very kind of issues that call for the exercise of ORI's special insights. We explain briefly.

The enabling statute requires that ORI be led by a professional experienced in research misconduct investigations, and the regulations envision that ORI's oversight of the

institutional investigation process will allow it to apply that expertise. This know-how is reflected, for example, in ORI's ability to grant extensions to an institution to complete an investigation and to conduct a review of the institution's investigation before issuing findings of research misconduct. What is more, ORI – in the course of its review – may well comment on the interpretation of key components of the regulations undergirding the plaintiffs' claims, such as the appropriate standard for initiating an investigation, the scope of confidentiality obligations, and the qualifications needed for panel members.

Permitting the agency to apply its expertise in the first instance is especially important because it protects ORI's authority even if the plaintiffs' state-law claims are not themselves adjudicated in the agency-supervised proceeding. The statutory structure contemplates that the first tier of review in research misconduct cases will take place at the institutional level with ORI oversight. Respect for Congress's judgment in this area counsels in favor of allowing the agency to exercise that oversight authority before a federal court intervenes. ORI's authority would be severely undermined if, for example, we were to permit a jury to decide whether an ongoing investigation, with extension requests reviewed and approved by ORI, had dragged on so

long as to amount to a breach of contract based on the very rules that ORI is tasked with administering.

The plaintiffs' countervailing interests in immediate review do not outweigh these substantial advantages to exhaustion. Arguing to the contrary, they assert that the administrative process cannot provide them with appropriate relief. In support, they note that ORI lacks any mechanism to review state-law claims and has no authority to award money damages (the primary form of relief demanded in their suit). Although they acknowledge ORI's oversight role, they observe that they will not be parties to any enforcement action taken by ORI against the institutions. Furthermore, even if they were to challenge a hypothetical future finding of research misconduct before an ALJ, the ALJ would not have the authority to consider the institution's conduct of either the inquiry or the investigation. There is some truth in what the plaintiffs say – but we conclude that neither the unavailability of a monetary remedy in agency proceedings nor the agency's lack of capacity to adjudicate the state-law claims at issue is dispositive.

With respect to the unavailability of money damages, the plaintiffs rely on the McCarthy Court's statement that "the uncertainty of the administrative agency's authority to award [monetary] relief counsels against requiring exhaustion." Id. at 155. But the McCarthy Court mentioned the unavailability of a

specific form of relief merely as one factor in the exhaustion calculus. Other circumstances (such as the agency's lack of interest in exhaustion, the fact that the claim at issue did not call for the application of agency expertise, and the fact that record development before the agency would provide only minimal assistance to future judicial review) combined to make exhaustion unnecessary. See id. at 155-56. Because no comparable mix of factors is present here, the unavailability of monetary relief through ORI does not relieve us of the duty to carry out the intensely practical analysis required by McCarthy. See Munsell v. Dep't of Agric., 509 F.3d 572, 592 (D.C. Cir. 2007) ("The rationale for requiring exhaustion does not depend on the existence of money damages as a remedy. So long as the administrative process offers the possibility of some redress . . . the administrative process can serve its proper function.").

We add, moreover, that there are significant institutional advantages in compelling exhaustion here. Addressing a similar claim in an analogous context, we recognized that "[e]xhaustion is beneficial regardless of whether the administrative process offers the specific form of remediation sought by a particular plaintiff" because "the administrative process facilitates the compilation of a fully developed record," which "is an invaluable resource for a state or federal court required to adjudicate a subsequent civil action covering the same

terrain." Frazier v. Fairhaven Sch. Comm., 276 F.3d 52, 61 (1st Cir. 2002).

So it is here. Although ORI will not adjudicate the plaintiffs' state-law claims as such, the district court's eventual disposition of those claims would benefit greatly from any legal interpretations or factual findings made by ORI in the course of its review.⁶ Indeed, the shape of the plaintiffs' claims may well change based on the outcome of the institutional investigation. The regulations specifically require institutions to make "[a]ll reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made." 42 C.F.R. § 93.304(k). Insofar as the complaint seeks to remedy "[l]ong-term injury to [the plaintiffs'] professional reputations and careers," the outcome of the institutional investigation and any subsequent action under this provision may reconfigure the contours of the

⁶ It is worth noting that this is not a case in which self-sufficient state-law claims merely run parallel to administrative regulations. Rather, the plaintiffs invoke the federal court's subject matter jurisdiction only by advancing claims that turn on the answers to embedded federal questions concerning the meaning and application of the very federal regulations that ORI exists to enforce. To allow the case to proceed to judgment and run the risk of having ORI's ongoing oversight thereafter arrive at conclusions that conflict with that judgment makes little practical sense.

controversy by the time it is ripe for district court consideration.

Our review of the record persuades us that the district court made the "intensely practical" assessment that the McCarthy Court required. We think that the totality of the circumstances – particularly the unique characteristics of this two-tiered investigatory system, Congress's manifest desire to ensure that ORI is able to use its expertise to guide and evaluate an initial round of investigation at the institutional level, and the significant advantages that exhaustion could bring – warrants a finding that the district court did not abuse its discretion in applying the doctrine of administrative exhaustion. In the circumstances at hand, neither the unavailability of a monetary remedy in the administrative proceeding nor the agency's inability to adjudicate state-law claims demands a different result.

The plaintiffs have a fallback position. They press the notion that forcing them to delay their suit will cause undue prejudice to its subsequent prosecution because they face an indefinite timeframe for administrative action. They emphasize the length of the inquiry to date and the several extensions to the investigation (which has entered its third year). This problem is exacerbated, they say, by the institutions' lackadaisical approach to the matter and by the repeated widening of the scope of the investigation. In their view, these developments show that

the time limits in the regulations are effectively meaningless and that ORI has abdicated its responsibility to superintend the investigation.

Although we understand the plaintiffs' frustration with the pace of the proceedings, we do not believe that matters have reached the tipping point. The duration of administrative proceedings, without more, cannot suffice to demonstrate that an agency's actions are unreasonable. Rather, determining whether a timeframe for agency action is unreasonable involves more than a matter of simple arithmetic. Cf. Telecomms. Research & Action Ctr. v. FCC, 750 F.2d 70, 80 (D.C. Cir. 1984) (listing range of factors for evaluating the reasonableness of agency delay). An inquiring court must pay close attention to the specific regulatory framework and its relationship to the claims presented. See McCarthy, 503 U.S. at 146.

Here, the district court fulfilled that responsibility. The features of the ongoing process are every bit as consistent with a conclusion that the investigation is proceeding apace through a complex area of medical research as with an inference of indefiniteness. Virtually by definition, research misconduct is a complicated area; and the regulations specifically envision that research misconduct inquiries and investigations may take longer than the time limits spelled out in the regulations. Both the inquiry process and (with ORI's consent) the investigatory process

can be extended when circumstances warrant. See 42 C.F.R. §§ 93.307(g), 93.311(b). Such flexibility is crucial, given the regulatory imperative that institutions must "[p]ursue diligently all significant issues and leads discovered that are determined relevant to the investigation." Id. § 93.310(h).

In the case at hand, all indications are that the investigation is being actively pursued, and the repeated expansions of its scope suggest compliance with the mandate to explore "any evidence of additional instances of possible research misconduct" that comes to light during the investigation. Id. Against this backdrop, we discern no principled basis for viewing this timeframe, at present, as unreasonable.

The plaintiffs advance one other strain of this argument. They submit that the duration of the investigation and subsequent ORI review could cause the statute of limitations to expire on some or all of their state-law claims. See, e.g., Mass. Gen. Laws ch. 260, § 2A (establishing three-year statute of limitations for tort claims). This is a legitimate concern: the running of the statute of limitations could well "occasion undue prejudice to subsequent assertion" of the plaintiffs' claims. McCarthy, 503 U.S. at 146. At least some of the plaintiffs' claims already may have accrued, and the district court's order of dismissal without prejudice will be of little consolation should those claims become time-barred.

This concern, however, does not demand the solution that the plaintiffs urge. In light of the strong interests in exhaustion that are extant here, permitting this action to go forward in parallel to the administrative proceedings is not the most salutary way to guard against a potential limitations problem. In the context of state habeas proceedings (which present similar temporal snares), federal appellate courts have acknowledged that district courts may stay a petition filed within the statute of limitations until state remedies have been exhausted. See, e.g., Pace v. DiGuglielmo, 544 U.S. 408, 416 (2005); Rhines v. Weber, 544 U.S. 269, 274-78 (2005); Neverson v. Bissonnette, 261 F.3d 120, 126 n.3 (1st Cir. 2001); see also Dolis v. Chambers, 454 F.3d 721, 725 (7th Cir. 2006) (collecting cases). Such a prophylactic approach is well-suited to administrative exhaustion cases because it protects agency authority while administrative proceedings are ongoing yet ensures that limitations concerns will not bar the ultimate consideration of the plaintiffs' claims.

For these reasons, we hold that, as a matter of practice, a district court ordinarily should stay, rather than dismiss, an action when it finds that principles of administrative exhaustion require it to act. We apply that prescription here: though upholding the district court's determination that administrative exhaustion is warranted, we think it appropriate to direct that its order of dismissal be converted to a stay of judicial

proceedings pending the timely resolution of the administrative proceedings.

V. CONCLUSION

The defendants have raised a gallimaufry of other grounds for dismissing this action, but we need go no further. Thus, we take no view of these other grounds. Suffice it to say that we affirm the district court's decision, based on the common-law doctrine of administrative exhaustion, and the plaintiffs must exhaust their administrative remedies before proceeding with their suit. However, we direct that the district court, on remand, convert its order of dismissal to an order staying the case pending the timely resolution of administrative proceedings.

Affirmed as modified. All parties shall bear their own costs.