United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 12, 2010 Decided June 25, 2010

No. 09-5374

JAMES L. SHERLEY, ET AL.,
APPELLANTS

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:09-cv-01575-RCL)

Thomas G. Hungar argued the cause for appellants. With him on the briefs were *Bradley J. Lingo*, *Ryan J. Watson*, *Blaine H. Evanson*, *Samuel B. Casey*, and *Steven H. Aden*.

Stephanie R. Marcus, Attorney, U.S. Department of Justice, argued the cause for appellees. On the brief were *Mark B. Stern*, *Alisa B. Klein*, and *Abby C. Wright*, Attorneys. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Before: GINSBURG, BROWN, and KAVANAUGH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* GINSBURG.

GINSBURG, *Circuit Judge*: An array of variously situated plaintiffs sued the Department and the Secretary of Health and Human Services and the National Institutes of Health and its Director, challenging newly promulgated guidelines that authorize the NIH to fund more research projects involving human embryonic stem cells than it had previously done. The district court dismissed the suit for want of a plaintiff with standing and dismissed as moot the plaintiffs' motion for a preliminary injunction. All the plaintiffs appeal those rulings, but they defend the standing of only two of their number, Drs. James Sherley and Theresa Deisher.

We conclude the two Doctors have standing. Therefore, we reverse the order of the district court insofar as it dismissed their claims and we reinstate the motion for a preliminary injunction.

I. Background

Because a stem cell can develop into any one of many specialized cells in the human body, it can be used in the treatment of a variety of diseases. There are two basic kinds of mammalian stem cells relevant to this case: embryonic stem cells (ESCs), which are found in human embryos, and adult stem cells (ASCs), which are found in the human body and in tissues discarded after birth.

Scientists, often with financial support from the NIH, have done research involving ASCs for about 50 years. They have done research involving ESCs only since 1998, and the

NIH did not fund such research until 2001, when President Bush authorized it to do so subject to the limitation that only ESCs derived from then-extant stem cell lines be used.

In 2009 President Obama removed that limitation, directing the "Secretary of Health and Human Services ... through the Director of NIH, [to] support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law" and to "issue new NIH guidance on such research that is consistent with this order." Exec. Order No. 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 9, 2009). Pursuant to the resulting Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170 (July 7, 2009), the NIH may now fund more projects involving ESCs than was previously possible.

The plaintiffs alleged the issuance of the Guidelines violated the Administrative Procedure Act because, among other reasons, the "promulgation and implementation of the Guidelines are not in accordance with law," Compl. ¶ 67; *see* 5 U.S.C. § 706(2)(A), to wit, the Dickey-Wicker Amendment, which the Congress has attached every year since 1996 to the Acts appropriating money for the DHHS and which prohibits federal funding of research in which a human embryo is to be harmed or destroyed, *e.g.*, Omnibus Appropriations Act of 2009, Pub. L. No. 111-8, div. F, Title V, § 509(a)(2), 123 Stat. 524. The defendants moved to dismiss the case on the ground that none of the plaintiffs had standing to challenge the issuance of the Guidelines. *Sherley v. Sebelius*, 686 F. Supp. 2d 1 (D.D.C. 2009).

The plaintiffs whose standing is at issue here are Drs. Sherley and Deisher, both of whom "specialize in adult stem cell research" and who, respectively, have received and plan to seek NIH grants for research involving ASCs. *Id.* at 3.

They claimed to have "competitor standing" because the Guidelines would "result in increased competition for limited federal funding and [would] thereby injure [their] ability to successfully compete for ... NIH stem cell research funds." *Id.* at 4. The district court rejected that contention. First, relying upon *Hardin v. Kentucky Utilities Co.*, 390 U.S. 1, 6 (1968), the court reasoned that a party may assert competitor standing only when the "particular statutory provision ... invoked" reflects a purpose "to protect a competitive interest" and that the Doctors had not shown they had a protected interest in receiving research funds from the NIH. *Sherley*, 686 F. Supp. 2d at 6. The court further concluded the cases upon which the Doctors relied established only that competitor standing applies to participants in "strictly regulated economic markets," whereas the Doctors were "applicants for research grants." *Id.* at 7. Finally, the court opined that even if the Doctors qualify as "competitors," they would still lack standing because the "application process to receive NIH funding is [already] extremely competitive," *id.*, *i.e.*, the additional competition made possible by the Guidelines would "not 'almost surely cause [them] to lose' funding," *id.* (quoting *El Paso Natural Gas Co. v. FERC*, 50 F.3d 23, 27 (D.C. Cir. 1995)).

The district court also held none of the other plaintiffs had standing. On appeal, those plaintiffs make no argument to the contrary, wherefore we take their lack of standing as conceded. *See, e.g.*, *Sitka Sound Seafoods, Inc. v. NLRB*, 206 F.3d 1175, 1181 (D.C. Cir. 2000) (argument not raised in opening brief on appeal is forfeited).

II. Analysis

In reviewing *de novo* the district court's decision to dismiss this suit on the ground that the Doctors lack standing

to sue, *Young Am.'s Found. v. Gates*, 573 F.3d 797, 799 (D.C. Cir. 2009), we "accept[] as true all of the factual allegations contained in the complaint and draw[] all inferences in favor of the nonmoving party," *City of Harper Woods Employees' Ret. Sys. v. Olver*, 589 F.3d 1292, 1298 (D.C. Cir. 2009). The Doctors' burden is to show they have standing not only under Article III of the Constitution of the United States but also under our doctrine of prudential standing. *See Shays v. FEC*, 414 F.3d 76, 83 (D.C. Cir. 2005).

A. Article III Standing

In order to establish their Article III standing, the Doctors must both identify an "injury in fact" that is "actual or imminent" and "fairly ... trace[able] to the challenged action of the defendant," and show it is "likely, as opposed to merely speculative, that [their] injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks omitted). The doctrine of competitor standing addresses the first requirement by recognizing that economic actors "suffer [an] injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition" against them. *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998); *accord New World Radio, Inc. v. FCC*, 294 F.3d 164, 172 (D.C. Cir. 2002) ("basic law of economics" that increased competition leads to actual injury); *see also Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319, 1332 (Fed. Cir. 2008) (doctrine of competitor standing "relies on economic logic to conclude that a plaintiff will likely suffer an injury-in-fact when the government acts in a way that increases competition or aids the plaintiff's competitors"). The form of that injury may vary; for example, a seller facing increased competition may lose sales to rivals, or be forced to lower its price or to expend more resources to achieve the

same sales, all to the detriment of its bottom line. Because increased competition almost surely injures a seller in one form or another, he need not wait until "allegedly illegal transactions ... hurt [him] competitively" before challenging the regulatory (or, for that matter, the deregulatory) governmental decision that increases competition. *La. Energy*, 141 F.3d at 367.

In considering whether the Doctors have Article III standing, we address only the question whether they allege a legally adequate injury-in-fact. That is the only element of constitutional standing upon which the parties focus, for it is clear the alleged injury is traceable to the Guidelines and redressable by the court.

We do not agree with the district court's suggestion that only a "participant[] in [a] strictly regulated economic market[]" may assert competitor standing. *Sherley*, 686 F. Supp. 2d at 7. We see no reason any one competing for a governmental benefit should not be able to assert competitor standing when the Government takes a step that benefits his rival and therefore injures him economically. In this vein, we have applied the doctrine of competitor standing to the political "market," holding incumbent congressmen had standing to challenge new campaign finance regulations that made it easier for rival candidates to compete against them for election. *Shays*, 414 F.3d at 87.

The district court also concluded the doctrine of competitor standing applies only where the "particular statutory provision ... invoked" reflects a purpose "to protect a competitive interest." *Sherley*, 686 F. Supp. 2d at 6 (quoting *Hardin*, 390 U.S. at 6). The requirement of a protected competitive interest, however, "goes to the merits" of a plaintiff's claim, not to his Article III standing. *See Ass'n of*

Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153 (1970).

In order to bring themselves within the scope of the doctrine of competitor standing, the Doctors invoke our holding in *Associated Gas Distributors v. FERC*, 899 F.2d 1250 (1990), and similar holdings in other cases, that plaintiffs may "establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales," *id*. at 1259, and argue they are injured because "[a]s a result of the new Guidelines, [they] now face more competition for [NIH] research grants than they did before." For context, we note it is uncontested that, at least in the short run, the amount of money available from NIH for research grants is fixed notwithstanding the greater range of stem cell research projects made eligible for funding by the Guidelines.

The Government has two responses. First, it maintains the Doctors have not shown "an increase in funding for embryonic stem cell research ... require[s] a diminution in funding for adult stem cell research." To that we say: Nor need they do so. The Doctors need show only that they themselves will suffer some competitive injury, not that the NIH will spend less overall to fund projects involving ASCs.

Second, the Government argues the specific process by which the NIH awards grants makes it "entirely conjectural" whether the Doctors will face increased competition for funding. Each funding cycle proceeds in two stages. In the first, a peer-review committee assigns a preliminary score to each grant application. Each application with a score above the median then goes to one or more of the 24 Institutes and Centers (ICs) at the NIH. Each such component has its own

budget and awards grants to projects that address its particular mission; for instance, the National Cancer Institute funds research relating to cancer. In the second stage of the process, each IC decides which grant applications to fund.

The Government reasons that the Guidelines will not cause an increase in competition at the first stage because the NIH will always pass along to the ICs half the applications it receives. Therefore, each application, regardless how many there are, will still have a 50% chance of reaching the second stage of the process.

At the second stage, moreover, "it is ... entirely conjectural whether an application submitted by [one of the plaintiffs] would actually 'compete' with proposals involving [ESCs]" because the doctor's project would both have to "be ranked low enough to fall below the [IC's] funding capacity and be outranked by an [ESC] project." In other words, according to the Government, there is no certainty that an application for research involving ESCs will arrive at an IC in the same funding cycle as an application from one of the Doctors; even if the two applications do compete in the same funding cycle, there is no guarantee the one for research involving ESCs will get funding that would otherwise have gone to one of the Doctors. This mere possibility of injury does not establish competitor standing, argues the Government, which, as did the district court, reads our cases to require that a plaintiff asserting competitor standing show a challenged agency action will "almost surely cause [him] to lose business." *El Paso*, 50 F.3d at 27.

As the parties' arguments demonstrate, our cases addressing competitor standing have articulated various formulations of the standard for determining whether a plaintiff asserting competitor standing has been injured.

Regardless how we have phrased the standard in any particular case, however, the basic requirement common to all our cases is that the complainant show an actual or imminent increase in competition, which increase we recognize will almost certainly cause an injury in fact.

For instance, in *Louisiana Energy*, we held one seller of electric energy had standing to challenge a decision of the FERC that allowed a current competitor to sell energy at market-based rates. 141 F.3d at 366. We recognized the petitioner would "be injured by increased price competition" and that such injury was "imminent." *Id.* at 367 (explaining "parties suffer constitutional injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition"). In contrast, in *DEK Energy Co. v. FERC*, we held the plaintiff, a supplier of natural gas in Northern California, did not have competitor standing to challenge a decision of the FERC that would have allowed another company to ship a quantity of natural gas to Oregon and to sell it at a lower price than that at which DEK could sell its gas. 248 F.3d 1192, 1196 (2001). Although increased competition from lower-priced gas would likely cause DEK "to lose business or drop its prices," we concluded that increased competition was not imminent; there was only "some vague probability that any gas" sold by DEK's competitor would "actually reach [the] market" in which DEK sold its gas. *Id.* (noting decision of the FERC will not "almost surely" cause DEK "to lose business").

The Doctors have met the basic requirement for competitor standing. This is not a situation like that in *El Paso*, in which it was uncertain whether a new seller would enter the market. 50 F.3d at 27. There can be no doubt the Guidelines will elicit an increase in the number of grant applications involving ESCs; indeed, the Government never

suggests otherwise. Because the Guidelines have intensified the competition for a share in a fixed amount of money, the plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury.

The Doctors will suffer an additional injury whenever a project involving ESCs receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs. They are more likely to lose funding to projects involving ESCs than are researchers who do not work with stem cells because ASCs and ESCs are substitutes in some uses. The Doctors illustrated this point in a post-argument letter in which they report Dr. Sherley recently submitted a grant for a project in which ASCs will be used to create a surrogate for a human liver and suggest his "chief competitor" will be a company that "engages in similar research using [ESCs]." Although no one can say exactly how likely the Doctors are to lose funding to projects involving ESCs, having been put into competition with those projects, the Doctors face a substantial enough probability to deem the injury to them imminent. *See, e.g., DEK Energy Co.*, 248 F.3d at 1195 ("substantial (if unquantifiable) probability of injury" shifts injury from "conjectural" to "imminent").

B. Prudential Standing

Parties "claiming standing under the APA must show ... their claims fall 'arguably within the zone of interests to be protected or regulated by the statute in question.'" *Shays*, 414 F.3d at 83 (quoting *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 488 (1998)). This requirement "is not meant to be especially demanding" and there "need be no indication of congressional purpose to

benefit the would-be plaintiff"; it excludes "only those parties whose interests are not consistent with the purposes of the statute in question." *Amgen, Inc. v. Smith*, 357 F.3d 103, 108–09 (D.C. Cir. 2004) (internal quotation marks omitted).

Here the parties disagree about whether the injury the Doctors assert lies within the zone of interests protected by the Dickey-Wicker Amendment. The Doctors argue that pursuit of their interests furthers the purposes of that Amendment, which they say are "to fund permissible research, such as the adult stem cell research for which [they] seek funding, and ... [to] provide[] that federal funds could not be used for [ESC] research." The Government responds that the Amendment "was intended to protect [not] the financial interests of researchers engaging in adult stem cell research ... [but rather] society's interest in not funding 'research in which a human embryo ... [is] destroyed."

We conclude the Doctors have prudential standing. The Dickey-Wicker Amendment clearly limits the funding of research involving human embryos. Because the Act can plausibly be interpreted to limit research involving ESCs, the Doctors' interest in preventing the NIH from funding such research is not inconsistent with the purposes of the Amendment. Under the standard of *Amgen*, quoted above, that is all that matters.

III. Conclusion

We reverse the order of the district court dismissing the plaintiffs' claims for lack of standing insofar as it applies to the Doctors and affirm that order in all other respects. As a result, we also reverse the order dismissing as moot the plaintiffs' motion for a preliminary injunction.

The Doctors ask us to consider the merits of their motion, but it is not the usual practice of this court to grant a motion for a preliminary injunction that the district court denied without having considered its merits. "It falls to the district court in the first instance ... to balance the four factors [of the test for a preliminary injunction] in order to decide whether" the motion should be granted. *Belbacha v. Bush*, 520 F.3d 452, 459 (D.C. Cir. 2008).

This matter is remanded to the district court for further proceedings consistent with the foregoing opinion.

So ordered.