

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 19-13381

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D.C. Docket No. 0:18-cv-61047-UU

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

JAN AITKEN,  
CAROL BARROWS,  
DAVID H. BUCKLES,  
et al.,

Intervenors - Appellants,

versus

US STEM CELL CLINIC, LLC,  
a Florida limited liability company,  
US STEM CELL, INC.,  
a Florida profit corporation,  
KRISTIN C. COMELLA,  
individually,  
THEODORE GRADEL,  
individually,

Defendants - Appellees.

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Appeals from the United States District Court  
for the Southern District of Florida

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(February 11, 2021)

Before JORDAN, MARCUS, and GINSBURG,\* Circuit Judges.

GINSBURG, Circuit Judge:

Two groups of patients who deposited tissue in a stem-cell “bank” appeal the denial of their respective motions to intervene pursuant to Federal Rule of Civil Procedure 24 in a suit between the corporation running the bank and the United States Food and Drug Administration. The district court did not reach the question whether the patients met the requirements for intervention. Instead, it found their motions were premature and denied them without prejudice. Because the district court’s order was not a “final decision” within the meaning of 28 U.S.C. § 1291, we lack jurisdiction to consider the patients’ appeal.

**I.**

US Stem Cell, Inc. (the Corporation), is a Florida-based company that offers stem-cell therapies that purportedly treat a host of diseases and conditions.

US Stem Cell Clinic, LLC, a subsidiary of the Corporation, provides the

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\* Honorable Douglas H. Ginsburg, United States Court of Appeals for the District of Columbia Circuit, sitting by designation.

treatments. Separately, the Corporation operates a stem-cell bank where patients can store stem cells for later use in treating chronic conditions. The patient-appellants have each deposited stem cells in the bank.

In 2018 the FDA sued the Corporation, the Clinic, and an individual associated with both companies. It alleged the defendants' operations at the Clinic amounted to the misbranding and adulteration of drugs in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. In June 2019 the district court granted summary judgment for the FDA, *United States v. US Stem Cell Clinic, LLC*, 403 F. Supp. 3d 1279 (S.D. Fla. 2019), and issued a permanent injunction requiring, among other things, that the defendants: (1) refrain from distributing any stem-cell products until they obtain approval from the FDA, D.E. 83 ¶ 7, and (2) destroy all stem cells in their possession within 30 days, D.E. 83 ¶ 10. The court stayed the destruction provision pending a potential appeal by the defendants.

In July 2019 the patients moved to intervene either as-of-right or permissively. The patients also sought to extend the stay of the destruction provision in the district court's order. If permitted to intervene, the patients would ask the district court to declare either that their stem cells at the bank are outside

the scope of the injunction or that destruction of their stem cells would violate their rights under the Fifth Amendment to the Constitution of the United States.

The district court denied the motions without prejudice in an omnibus order, explaining:

[B]oth the relief requested by the putative intervenors and the appropriate forum for their intervention is entirely dependent upon whether Defendants appeal .... As such the Court is unable to rule on the [m]otions at this time.

*United States v. US Stem Cell Clinic, LLC*, No. 0:18-cv-61047, 2019 WL 4647746, at \*1 (S.D. Fla. July 31, 2019).

Shortly thereafter the defendants filed a timely notice of appeal, which is pending in this court. As such, the stay of the destruction provision of the injunction remains in place.

## II.

The patients argue we have jurisdiction to hear their appeal from the omnibus order under this circuit’s “anomalous rule.”\* Where that rule applies, we exercise “provisional jurisdiction” to determine whether a district court erred in denying intervention as of right under Rule 24(a), or clearly abused its discretion in

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\* Alternatively the patients contend they are appealing either the injunction itself or the district court’s implicit denial of their requests to stay the injunction. Initial Br. for Aitken Intervenors 1-2. Unless and until they successfully intervene, however, the patients remain non-parties and may not appeal any order except one denying intervention. See *Brotherhood of R.R. Trainmen v. Balt. & O.R. Co.*, 331 U.S. 519, 524 (1947); 7C C. Wright, A. Miller, & M. Kane, *Federal Practice & Procedure* § 1923 (3d Ed. 2020).

denying permissive intervention under Rule 24(b). *E.g.*, *Fox v. Tyson Foods, Inc.*, 519 F.3d 1298, 1301 (11th Cir. 2008). If we discover no reason to reverse the district court, then “our jurisdiction evaporates” and we dismiss the appeal. *Id.*

In the past, we have applied the anomalous rule in cases where a motion to intervene was considered on its merits and denied with prejudice. We have explained that “such a determination is a ‘final decision’ under 28 U.S.C. § 1291 that ‘ends the litigation on the merits’ for the intervenor.” *Meek v. Metro. Dade Cty.*, 985 F.2d 1471, 1476 (11th Cir. 1993) (citations omitted), *abrogated on other grounds*, *Dillard v. Chilton Cty. Comm’n*, 495 F.3d 1324 (11th Cir. 2007). This case is different. Here, the district court did not reject the patients’ arguments under Rule 24 or otherwise determine the patients were not entitled to intervene. Rather, it merely stated it was “unable to rule on the motions at this time.” The anomalous rule does not reach this situation because the patients’ motions were not denied. *Cf. Smith v. SEECO, Inc.*, 865 F.3d 1021, 1025 (8th Cir. 2017) (holding denial of a motion to intervene was not appealable where the district court did not make a “final determination,” but instead deferred consideration until “a more appropriate stage in the litigation”); *Grilli v. Metro. Life Ins. Co.*, 78 F.3d 1533, 1538 (11th Cir. 1996) (holding an order was not final in part because the district court “anticipated further proceedings with respect to the issues raised”).

This disposition does not prejudice the patients. They are free to return to the district court and renew their motions. The district court seemed to contemplate they would do so after the defendants filed their notice of appeal or after the defendants' appeal was resolved. The patients' motions are presumably no less timely now than they were in July 2019. *Cf. McDonald v. E.J. Lavino Co.*, 430 F.2d 1065, 1074 (5th Cir. 1970) (explaining the flexible nature of the timeliness inquiry).\*\*

In their reply brief the patients argue they were prejudiced by the district court's decision because it "effectively denied their right to access and use their [stem cells] now." Reply Br. for Aitken Intervenors 5-6. The patients did not, however, request this relief in their motions before the district court: They sought to stay only the destruction of their stem cells; they did not ask the district court to stay other parts of the injunction and they did not otherwise request immediate access to their stem cells. The district court cannot be faulted for failing to grant relief not requested.

### III.

The patients' appeal is **DISMISSED** for lack of appellate jurisdiction.

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\*\* We have adopted all decisions of the Fifth Circuit issued prior to October 1, 1981 as binding precedent. *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981).