

1 UNITED STATES COURT OF APPEALS

2
3 FOR THE SECOND CIRCUIT

4
5
6
7 August Term, 2010

8
9 (Argued: March 15, 2011 Decided: March 23, 2011)

10
11 Docket No. 10-4630-cv

12
13
14 ANGELINE CACCHILLO,

15
16 *Plaintiff-Appellant,*

17
18 -v.-

19
20 INSMED, INC.,

21
22 *Defendant-Appellee.*

23
24
25
26 Before:

27 WESLEY, CHIN, and LOHIER, JR., *Circuit Judges.*

28
29 Appeal from an order of the United States District
30 Court for the Northern District of New York (McAvoy, J.)
31 entered on October 22, 2010, denying Plaintiff-Appellant
32 Angeline Cacchillo's motion for a preliminary injunction.

33
34 AFFIRMED.

35
36
37
38 KEVIN A. LUIBRAND, Albany, N.Y., *for Plaintiff-*
39 *Appellant.*

40
41 ROBERT P. CHARROW (Laura Metcoff Klaus, Cynthia E.

1 The Food and Drug Administration ("FDA") has not
2 approved IPLEX for general use. As a result, Cacchillo
3 cannot resume IPLEX treatment unless she receives a special
4 authorization - known as a "compassionate use" exception -
5 from the FDA. Cacchillo contends that before she may file a
6 compassionate use application, Insmmed - as the manufacturer
7 of IPLEX - must provide her with a form to be forwarded to
8 the FDA stating that Insmmed will provide Cacchillo with
9 IPLEX in the event her application is approved. Insmmed has
10 refused to participate in this process. Further
11 complicating matters, IPLEX is no longer produced, only
12 limited stores of IPLEX remain and, according to Insmmed, all
13 remaining IPLEX has been committed to patients with
14 amyotrophic lateral sclerosis ("ALS").

15 Cacchillo asserts that Insmmed agreed to support her FDA
16 compassionate use application and is now in breach of that
17 agreement. Cacchillo commenced this action asserting claims
18 pursuant to 42 U.S.C. § 1983 and New York State common law
19 challenging Insmmed's refusal to support her application.
20 Cacchillo moved for a preliminary injunction requiring
21 Insmmed to:

22

1 (1) "provide to Angeline Cacchillo a
2 written statement directed to the United
3 States Food and Drug Administration . . .
4 in a form customary for such submissions
5 supporting the 'compassionate use' of . . .
6 . IPLEX for Angeline Cacchillo, stating
7 that Insmmed, Inc. will, without
8 reservation, provide Angeline Cacchillo
9 the medication IPLEX at cost upon the
10 granting of her compassionate use
11 application by the FDA;" and (2)
12 "directing Insmmed, Inc., in the event
13 that Angeline Cacchillo's application is
14 granted by the FDA, to provide Angeline
15 Cacchillo IPLEX"
16

17 Insmmed opposed the motion, arguing, among other things,
18 that Cacchillo lacked standing to pursue a preliminary
19 injunction because her injury cannot be redressed when the
20 remaining stores of IPLEX have already been committed to ALS
21 patients. The district court agreed and denied Cacchillo's
22 motion.

23 On appeal, Insmmed contends that Cacchillo cannot
24 establish either standing or ripeness to pursue a
25 preliminary injunction. We disagree, but nevertheless
26 affirm the district court's opinion on the ground that
27 Cacchillo has not shown that she is likely to succeed on the
28 merits.¹

¹ Cacchillo's standing to pursue her additional claims and pleas for relief has not yet been considered by the district court and is not before us on appeal. See 28 U.S.C. § 1291.

1 successive stages of the litigation." *Id.* When a
2 preliminary injunction is sought, a plaintiff's burden to
3 demonstrate standing "will normally be no less than that
4 required on a motion for summary judgment." *Lujan v. Nat'l*
5 *Wildlife Fed'n (Lujan I)*, 497 U.S. 871, 907 n.8 (1990).
6 Accordingly, to establish standing for a preliminary
7 injunction, a plaintiff cannot "rest on such 'mere
8 allegations,' [as would be appropriate at the pleading
9 stage] but must 'set forth' by affidavit or other evidence
10 'specific facts,' which for purposes of the summary judgment
11 motion will be taken to be true." *Lujan*, 504 U.S. at 561
12 (internal citation omitted).

13 Here, Cacchillo's injury in fact is that in breach of
14 an alleged agreement between herself and Insmmed, she has not
15 received Insmmed's support in preparing her compassionate use
16 application. As set forth in Cacchillo's affidavit, this
17 injury is concrete and particularized: Cacchillo seeks a
18 specific document from Insmmed that she contends is required
19 for her compassionate use application. This injury is
20 actual, and not conjectural or hypothetical, because
21 Cacchillo does not have the document to which she currently
22 claims entitlement. Insmmed's lack of support is no less an

1 injury because Cacchillo additionally hopes to receive both
2 Insmmed's support and, ultimately, FDA approval.

3 Cacchillo's injury is unquestionably caused by Insmmed.
4 Cacchillo does not have a document from Insmmed because
5 Insmmed has declined to provide it.

6 Finally, Cacchillo's injury is redressable because she
7 seeks relief directly from Insmmed that is within the court's
8 authority to order. *See Sprint Commc'ns Co. v. APCC Servs.,*
9 *Inc.*, 554 U.S. 269, 273-74 (2008) (defining redressability
10 as an inquiry asking whether "it is 'likely' and not 'merely
11 speculative' that the plaintiff's injury will be remedied by
12 the relief plaintiff seeks in bringing suit" (some internal
13 quotation marks omitted)). *Cf. Allen v. Wright*, 468 U.S.
14 737, 758 (1984) (finding redressability lacking where it was
15 "entirely speculative" whether respondents' desired remedy -
16 an injunction against the IRS - would remedy their alleged
17 injury - failure of their children to receive a desegregated
18 public education). Here, the court could redress
19 Cacchillo's injury directly by ordering specific performance
20 on the alleged underlying contract. That is, the court
21 could redress Cacchillo's failure to receive the document
22 from Insmmed by ordering Insmmed to provide her with the
23 document.

1 In opposition, Insmmed argues that Cacchillo's injury is
2 not redressable because the court cannot order Insmmed to
3 provide Cacchillo with a document stating that Insmmed will
4 provide her with IPLEX when all of the remaining IPLEX has
5 already been promised to ALS patients. Yet, whether Insmmed
6 has any unallocated IPLEX or whether Cacchillo's claim to
7 IPLEX supercedes that of the ALS patients are both questions
8 that go to the merits of Cacchillo's claims, not her
9 standing to bring those claims. If we accepted Insmmed's
10 invitation to view the alleged unavailability of IPLEX as a
11 barrier to redressability, then Insmmed's mere assertion that
12 it cannot supply IPLEX would deprive the court of
13 jurisdiction to assess the validity of Insmmed's defenses.
14 Redressability does not permit us to wade so deeply into the
15 merits. See *Steel Co. v. Citizens for a Better Env't*, 523
16 U.S. 83, 89 (1998) (explaining that the "nonexistence of a
17 cause of action [is not a] proper basis for a jurisdictional
18 dismissal").

19 Based on the foregoing, Cacchillo has standing to
20 pursue her motion for a preliminary injunction.

21 **B. Ripeness**

22 Insmmed also contends that Cacchillo's claims are not
23 ripe. We disagree.

1 Ripeness "is peculiarly a question of timing." *Thomas*
2 *v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580
3 (1985). A claim is not ripe if it depends upon "contingent
4 future events that may not occur as anticipated, or indeed
5 may not occur at all." *Id.* at 580-81.

6 In addition to requiring a commitment from Insmad to
7 supply her with IPLEX if her compassionate care application
8 is approved, Cacchillo's compassionate care application
9 requires a physician to agree to act as Cacchillo's sponsor
10 and investigator. See 21 C.F.R. §§ 312.3 (defining
11 "sponsor" and "investigator"), 312.305 (setting forth the
12 current requirements for a compassionate use application).
13 Insmad argues that Cacchillo's claim is not ripe because she
14 does not have a sponsor or investigator. Yet, Cacchillo
15 avers in her Complaint that two doctors are "ready and eager
16 to commence and support [her] compassionate use
17 application." Insmad has produced no evidence to the
18 contrary. As a result, Cacchillo's claim for a preliminary
19 injunction is ripe for our consideration.

20 **C. Merits Analysis**

21 Although the district court denied Cacchillo's motion

1 for lack of standing, we may affirm its decision "on any
2 ground supported by the record."² *NXIVM Corp. v. Ross*
3 *Inst.*, 364 F.3d 471, 476 (2d Cir. 2004).

4 A party seeking a preliminary injunction must show "(a)
5 irreparable harm and (b) either (1) likelihood of success on
6 the merits or (2) sufficiently serious questions going to
7 the merits to make them a fair ground for litigation and a
8 balance of hardships tipping decidedly toward the party
9 requesting the preliminary relief." *Citigroup Global Mkts.,*
10 *Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d
11 30, 35 (2d Cir. 2010). The burden is even higher on a party
12 like Cacchillo that seeks "a mandatory preliminary
13 injunction that alters the status quo by commanding some
14 positive act, as opposed to a prohibitory injunction seeking
15 only to maintain the status quo." *Id.* at 35 n.4 (internal
16 quotation marks omitted). A mandatory preliminary
17 injunction "should issue only upon a clear showing that the
18 moving party is entitled to the relief requested, or where

² In light of the unusual facts of this case, the parties pressed the Court at oral argument to consider Cacchillo's entitlement to a preliminary injunction rather than remand the case to the district court.

1 extreme or very serious damage will result from a denial of
2 preliminary relief." *Id.* (internal quotation marks
3 omitted).

4 Here, even assuming Cacchillo has established that she
5 will suffer irreparable harm, she has not met her burden to
6 show that she has a likelihood of success on the merits.
7 Cacchillo's claims hinge on Insmmed's alleged promise to
8 support Cacchillo's compassionate care application. Yet,
9 Cacchillo has no evidence that such an agreement existed
10 beyond her own vague recollection. Cacchillo has not
11 described in any detail what exactly Insmmed allegedly
12 promised her; Cacchillo asserts only that (1) on its
13 webpage, "Insmmed stated that it supported clinical trial
14 subjects' compassionate use applications;" and (2) a
15 clinical research coordinator not employed by Insmmed "told
16 [Cacchillo] that Insmmed would support [Cacchillo's]
17 application."

18 Cacchillo's description of the alleged agreement is
19 problematic for at least three reasons. First, Cacchillo's
20 recollection of the contents of Insmmed's website is belied
21 by Insmmed's exhibits showing that its website contained no

1 such statements. Second, Cacchillo offers no theory of
2 agency by which the clinical research coordinator's alleged
3 statement would be binding upon Insmmed. See Restatement
4 (Second) of Agency § 27 cmt. b (explaining that only a
5 principal's acts - and not those of an agent - may create
6 apparent authority). Third, Cacchillo's vague descriptions
7 of the alleged agreement, without more, strongly suggest
8 that Cacchillo is not likely to establish that Insmmed agreed
9 to support her compassionate use application even if, as
10 happened in the present case, Insmmed concluded that the drug
11 at stake is ineffective and better allocated to other
12 patients.

13 Based on the foregoing, Cacchillo has not met her
14 burden to establish that she is entitled to a mandatory
15 preliminary injunction.

16 **Conclusion**

17 For the foregoing reasons, the order of the district
18 court is hereby **AFFIRMED**.