

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 08-3575

JACOB GUNVALSON; CHERI AND JOHN GUNVALSON, AS GUARDIANS FOR
JACOB GUNVALSON; CHERI AND JOHN GUNVALSON INDIVIDUALLY

v.

PTC THERAPEUTICS INC,

Appellant

Appeal from the United States District Court
for the District of New Jersey
(Civil No. 2-08-cv-03559)
District Judge: Honorable William J. Martini

Argued: December 11, 2008

Before: McKEE and SMITH, and
ROTH, *Circuit Judges*

(Opinion filed: December 16, 2008)

JOHN G. HUTCHINSON, ESQ. (Argued)
JOHN J. LAVELLE, ESQ.
ELIZABETH M. ZITO, ESQ.
Sidley Austin LLP
787 Seventh Avenue
New York, New York 10019
KENNETH R. MEYER, ESQ.
Porzio, Bromberg & Newman, P.C.
100 Southgate Parkway
P.O. Box 1997

Morristown, New Jersey 07962
ROBERT C. HEIM, ESQ.
JOHN S. GHOSE, ESQ.
Dechert LLP
2929 Arch Street
Philadelphia, Pennsylvania 19104
Attorneys for Appellant

MARC E. WOLIN, ESQ. (Argued)
JAKOB B. HAPLERN, ESQ.
Saiber LLC
One Gateway Center
Newark, New Jersey 07102
Attorneys for Appellees

OPINION

McKEE, Circuit Judge:

PTC Therapeutics, Inc. (PTC) appeals from the district court's grant of the Gunvalson's motion for preliminary injunction.¹ We assume the parties' familiarity with the facts and the record of prior proceedings, which we refer to only as necessary to explain our decision. For the reasons that follow, we will now vacate the district court's order and remand for further proceedings.²

¹ The court ordered PTC to provide the information Jacob's physician needs to apply for a single-use investigational new use drug application (IND) with the FDA, and, if the FDA denies this application, ordered PTC to submit a treatment protocol to the FDA for a protocol exception to the Phase 2a extension trial.

² This Court will reverse a district court's grant of preliminary injunction "only if the court abused its discretion, committed an obvious error in applying the law, or made a serious mistake in considering the proof." *Loretangeli v. Critelli*, 853 F.2d 186, 193 (3d Cir. 1988).

I.

In granting the Gunvalsons' motion for preliminary injunction, the district court found the Gunvalsons had a reasonable probability of success on the merits of their promissory estoppel claim.³ We disagree with this finding and conclude the district court abused its discretion.

To succeed on the merits of their promissory estoppel claim under New Jersey law, the Gunvalsons must plead facts establishing: "1) a clear and definite promise; 2) made with the expectation that the promisee will rely upon it; 3) reasonable reliance upon the promise; 4) which results in definite and substantial detriment." *Commerce Bancorp, Inc. v. BK Int'l Ins. Brokers, LTD.*, 490 F. Supp. 2d 556, 561 (D.N.J. 2007) (quoting *Lobiondo v. O'Callaghan*, 815 A.2d 1013, 1020 (N.J. Super. Ct. App. Div. 2003)). The Gunvalsons have failed to adequately plead two of the requirements – a clear and definite promise and reasonable reliance.⁴

The district court erred in finding the Gunvalsons adequately alleged PTC and its officers made clear and definite promises that Jacob would get PTC124 outside of the

³ Moveants for preliminary injunction must demonstrate: (1) a "reasonable probability of eventual success" on the merits; (2) they "will be irreparably injured pendente lite" if injunctive relief is denied; (3) "the possibility of harm to other interested persons from the grant or denial of the injunction"; and (4) that "the public interest" favors the relief. *Bennington Foods LLC v. St. Croix Renaissance Group, LLP*, 528 F.3d 176, 179 (3d Cir. 2008) (internal citations omitted). The district court focused its determination on the first prong of the preliminary injunction standard. We will do the same here.

⁴ Failing to demonstrate any one of the elements is fatal to their case.

clinical trials. The promises the Gunvalsons assert that PTC and its officers made to them lack the requisite specificity and clarity required to succeed under the theory of promissory estoppel. The district court focused on that statement of Claudia Hirawat, PTC's Vice President, to Mrs. Gunvalson that Jacob's non-enrollment in Phase 2a trials would not by itself preclude him from participating in all of PTC's anticipated future clinical trials for PTC124. This statement and other alleged statements by PTC officers fail as a clear and definite promise because it asserts nothing conclusive about Jacob's participation in future trials or his access to PTC124.

Moreover, the district court erred in finding the Gunvalsons reasonably relied on the purported promises of PTC in not attempting to enroll Jacob in the Phase 2a trial. The district court erred in its analysis by failing to recognize the Gunvalsons did not enroll Jacob in the Phase 2a trial because Dr. Finkel, the principal investigator for the Philadelphia area clinical trial, ruled Jacob ineligible based on the medical records Mrs. Gunvalson provided him, and not because the Gunvalsons had been promised PTC124 via some other means. The records showed Jacob's longstanding diagnosis with BMD, rather than DMD.⁵ The records also showed impaired kidney function and evidence of cardiac problems, which alone would have foreclosed his participation in the trial. Accordingly, the Gunvalsons could not rely on any statements of PTC officers to decide

⁵ A diagnosis of DMD was a prerequisite for the Phase 2a trials. Dr. Brenda Wong, primary investigator for the Cincinnati trials, subsequently found Jacob did have DMD, but this determination is of no consequence to the Gunvalsons' decision at that time to enroll Jacob in the trial.

not to enroll Jacob in the Phase 2a trials because they had no decision to make.⁶

II.

As we explained in open court following oral argument, we are sympathetic to the plight of Jacob and his family. Similarly, we are moved by the Gunvalsons' heroic efforts on behalf of their son and others afflicted with this devastating disease. Nevertheless, we are constrained by the law to conclude that the Gunvalsons cannot demonstrate either a clear and definite promise or detrimental reliance, requirements for a promissory estoppel claim. Accordingly, because the Gunvalsons have not shown a reasonable probability of success on the merits, the district court abused its discretion in granting the preliminary injunction. We will, therefore, vacate the order granting the preliminary injunction and remand for further proceedings.

⁶ It is apparent from the record this is the real reason she did not attempt to enroll Jacob in the Phase 2a trial, as Mrs. Gunvalson e-mailed a number of parties reporting her disappointment upon hearing of his ineligibility.

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JUDGMENT

This cause came to be considered on the record from the United States District Court for the District of New Jersey and was argued on December 11, 2008.

On consideration whereof, it is hereby ORDERED that the order of the district

court entered August 21, 2008, granting a preliminary injunction is vacated and the case is remanded for further proceedings.

Attest:

/s/Marcia M. Waldron
Clerk

DATED: December 16, 2008