

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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

Plaintiffs,

v.

PTC THERAPEUTICS, INC.,

Defendant.

Civil Action No. 08-3559 (WJM) (MF)

ORDER

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WHEREAS THIS MATTER was opened to the Court by the motion of plaintiffs Jacob Gunvalson, Cheri and John Gunvalson, as guardians for Jacob Gunvalson, and Cheri and John Gunvalson, individually (collectively, "Plaintiffs") for a Preliminary Injunction, and the Court has considered Plaintiffs' Brief and other papers in support thereof, as well as the Verified Complaint; and the Court has further considered any papers filed in opposition thereto by defendant PTC Therapeutics, Inc. ("Defendant"); and the Court has further considered any papers submitted by Plaintiffs in reply thereto; and the Court further has considered the pleadings of record in this matter; and the Court further has considered oral argument on August 19, 2008, wherein Plaintiffs were represented by Marc Wolin and Jakob Halpern of Saiber LLC and Michael Hatch of Blackwell Burke, P.A., and Defendant was represented by Kenneth Meyer of Porzio, Bromberg & Newman, P.C. and John Hutchinson, John Lavelle and Elizabeth Zito of

Sidley Austin LLP; and for other and good cause shown; and

WHEREAS, it appears to the Court that Jacob Gunvalson has satisfied the criteria for treatment use of PTC124 pursuant to 21 C.F.R. §312.34:

IT IS on this 21st day of August, 2008,

ORDERED that Plaintiffs' Motion for a Preliminary Injunction be and the same is hereby **GRANTED** for the reasons set forth by the Court on the record and in any written opinion; and it is further

ORDERED that, within five (5) business days of entry of this Order, Defendant shall provide a copy of the protocol being utilized in its Phase 2a extended clinical study for PTC124 at Cincinnati Children's Hospital to Plaintiffs' counsel to be forwarded to Dr. John Parkin, the pediatrician and primary care provider for Plaintiff Jacob Gunvalson. PTC Therapeutics may require Dr. Parkin to execute reasonable confidentiality agreements with respect to this paragraph and any other confidential information disclosed by PTC Therapeutics pursuant to this Order; and it is further

ORDERED that PTC Therapeutics shall take all measures within its control to promptly provide Dr. Parkin any further information he deems necessary for his submission of a request for treatment use of PTC124 through a single-patient IND study on Jacob Gunvalson to the FDA; and it is further

ORDERED that, should the FDA and an Institutional Review Board ("IRB") approve of the request for treatment use submitted by Dr. Parkin, within ten (10) business days of the notification of PTC Therapeutics' counsel by Plaintiffs' counsel of such approval, PTC Therapeutics shall provide PTC124 to Dr. Parkin in the same dosage

levels and amounts as approved by the FDA and IRB. PTC shall also provide any other information or materials Dr. Parkin reasonably deems necessary for the administration of PTC124 to Jacob Gunvalson through a single patient IND. PTC Therapeutics may require the submission to it of the following prior to release of PTC124 to Dr. Parkin and shall notify plaintiffs' counsel in writing of the same within 10 business days of the entry of this Order:

- A. An informed consent and release form executed by Plaintiffs, which form shall comply with 21 C.F.R. Part 50;
- B. Documentation of approval by an IRB consistent with 21 C.F.R. Part 56;
- C. An agreement that the Plaintiffs shall pay a reasonable cost for PTC124;
- D. A copy of the documentation exchanged between Dr. Parkin and the FDA, and between Dr. Parkin and the IRB, on an ongoing basis and any responses thereto; and/or
- E. A reasonable confidentiality agreement executed by plaintiffs; and it is further

ORDERED that, if either the FDA or IRB denies Dr. Parkin's request for treatment use of PTC124 through a single-patient IND study on Jacob Gunvalson, within twenty business (20) days of notification of Defendant of such denial by Plaintiffs' counsel, then PTC Therapeutics shall submit a treatment protocol to the FDA as provided by 21 C.F.R. §312.35(a) for a protocol exception to the Phase 2a extension being

administered at Cincinnati Children's Hospital; and it is further

ORDERED that John and Cheri Gunvalson pay all reasonable costs for PTC124 and its administration in connection with Jacob's treatment with PTC124 as a protocol exception to the Phase 2a trial extension being administered at Cincinnati Children's Hospital; and it is further

ORDERED that defendant PTC Therapeutics' motion for a stay of this Order pending appeal shall be and hereby is **DENIED** for the reasons set forth on the record, and in any written opinion.

HONORABLE WILLIAM J. MARTINI
UNITED STATES DISTRICT JUDGE