

**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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THIS MATTER having been 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 having considered Plaintiffs' Brief and other papers in support thereof, as well as the Verified Complaint; and the Court having further considered any papers filed in opposition thereto by defendant PTC Therapeutics, Inc. ("Defendant"); and the Court having further considered any papers submitted by Plaintiffs in reply thereto; and the Court further having considered the pleadings of record in this matter and oral argument, if any; and for reasons set forth by the Court on the record and in any written opinion; and for other and good cause having been shown;

IT IS on this _____ day of _____, 2008,

ORDERED that Plaintiffs' Motion for a Preliminary Injunction be and the same is

hereby **GRANTED**; and it is further

ORDERED that Defendant be and is hereby enjoined from refusing to permit Jacob Gunvalson access to PTC124; and it is further

ORDERED that Defendant be and is hereby enjoined from refusing to permit Jacob Gunvalson entry into the Phase IIa trial extension being administered at Cincinnati Children's Hospital as a protocol exception; and it is further

ORDERED that, within _____ days of the entry of this Order, Defendant shall provide Jacob, John and Cheri Gunvalson with an informed consent and release form in compliance with 21 C.F.R. Part 50, including but not limited to 21 C.F.R. §§ 50.20, 50.25, 50.27, and 50.55, for Jacob Gunvalson's participation as a protocol exception in the Phase IIa trial extension being administered at Cincinnati Children's Hospital; and it is further

ORDERED that, within _____ days of receipt of the informed consent and release form, Jacob, John and Cheri Gunvalson shall each execute said form and return the executed form to Defendant; and it is further

ORDERED that, within _____ days of the entry of this Order, Defendant shall submit a proper request to the United States Food and Drug Administration ("FDA"), as provided by 21 C.F.R. §§ 312.34 and 312.35, that Jacob Gunvalson be permitted entry into the Phase IIa trial extension being administered at Cincinnati Children's Hospital as a protocol exception, including such information as required by those sections and any other applicable law; and it is further

ORDERED that Jacob, John and Cheri Gunvalson provide all necessary

information requested by Defendant, if any, in connection with the application to the FDA for a protocol exception for Jacob Gunvalson; and it is further

ORDERED that, should the FDA approve the application for Jacob Gunvalson to be treated with PTC124 as a protocol exception, Defendant shall, within _____ days of that approval, take all steps necessary for Jacob Gunvalson to commence treatment as a protocol exception to the Phase IIa trial extension being administered at Cincinnati Children's Hospital; and it is further

ORDERED that, should the FDA approve the application for Jacob Gunvalson to be treated with PTC124 as a protocol exception, Defendant shall cause Jacob Gunvalson to be treated with PTC124 as a protocol exception to the Phase IIa trial extension being administered at Cincinnati Children's Hospital in a manner consistent with all other similarly-situated patients being treated under that study's protocol; 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 IIa trial extension being administered at Cincinnati Children's Hospital.

HONORABLE WILLIAM J. MARTINI
UNITED STATES DISTRICT JUDGE