IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

HYPERION THERAPEUTICS, INC., Plaintiff, v. PAR PHARMACEUTICAL, INC., Defendant.	Case No. 2:14-CV-384-JRG-RSP

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to the Court's Docket Control Order (D.I. 36) and Local Patent Rule 4-3, Plaintiff Hyperion Therapeutics, Inc. ("Hyperion") and Defendant Par Pharmaceutical, Inc. ("Par") hereby submit their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 8,404,215 ("the '215 patent") and 8,642,012 ("the '012 patent").

I. Construction of Claim Terms on which the Parties Agree (L. Pat. R. 4-3(a))

In accordance with Local Patent Rule 4-3(a), the parties agree that the terms below should be construed as follows:

U.S. Patent No. 8,404,215

Term Identified for Construction	Joint Proposed Construction
"35 μmol/L" (claim 10)	plain and ordinary meaning
"adjusting" (claims 1, 4, 5, 6, 8, 9, 10, 11)	plain and ordinary meaning
"administering" (claims 1-6, 8-11)	plain and ordinary meaning
"based on" (claim 11)	plain and ordinary meaning

"blood ammonia level" (claims 1-6, 8-11)	"ammonia level in blood"
"combination of two or more" (claim 6)	plain and ordinary meaning
"comparing" (claims 1-6, 8-11)	plain and ordinary meaning
"effective dosage" (claim 11)	"dosage administered in step (c) of claims 1–3, which is calculated to decrease the blood ammonia level"
"excretion" (claim 11)	plain and ordinary meaning
"fasting blood ammonia level" (claims 1-6, 8-11)	"ammonia in blood level measured after fasting"
"greater than" (claims 1-6, 8-11)	plain and ordinary meaning
"hepatic encephalopathy" (claim 4)	"a spectrum of neurologic signs and symptoms believed to result from hyperammonemia, which frequently occur in subjects with cirrhosis or certain other types of liver disease"
"mean conversion" (claim 11)	plain and ordinary meaning
"measuring" (claims 1-6, 8-11)	plain and ordinary meaning
"nitrogen retention disorder" (claims 2-6, 8-11)	"a condition associated with elevated blood nitrogen / ammonia levels"
"nitrogen scavenging drug" (claims 1-6, 8-11)	"drug that decreases blood nitrogen and/or ammonia levels"
"previously been administered" (claims 1-6, 8-11)	plain and ordinary meaning
"PAA prodrug" (claims 5, 6, 11)	plain and ordinary meaning
"prior to step (b)" (claim 9)	plain and ordinary meaning
"prodrug" (claims 5, 6, 11)	plain and ordinary meaning
"produces" (claim 8)	plain and ordinary meaning
"subject" (claims 1-6, 8-11)	plain and ordinary meaning
"urinary" (claim 11)	plain and ordinary meaning

U.S. Patent No. 8,642,012

Term Identified for Construction	Joint Proposed Construction
"about 60%" (claims 8, 11, 12)	"approximately 60%"
"administering" (claims 8, 11, 12)	plain and ordinary meaning
"based on" (claims 8, 11, 12)	plain and ordinary meaning
"concentration" (claim 9)	plain and ordinary meaning
"determining" (claims 8, 11, 12)	plain and ordinary meaning
"effective dosage" (claims 8, 11, 12)	"dosage calculated to decrease the blood ammonia level"
"following administration" (claims 8, 11, 12)	plain and ordinary meaning
"mean conversion of PAA prodrug to urinary PAGN" (claims 8, 11, 12)	plain and ordinary meaning
"patient" (claims 8, 11, 12)	plain and ordinary meaning
"pharmaceutically acceptable salt" (claims 8, 11, 12)	plain and ordinary meaning
"phenylacetic acid (PAA) prodrug" (claims 8, 11, 12)	plain and ordinary meaning
"phenylbutyric acid" (claims 8, 11, 12)	plain and ordinary meaning
"prodrug" (claims 8, 11, 12)	plain and ordinary meaning
"produces" (claim 12)	plain and ordinary meaning
"urinary PAGN excretion" (claims 8, 11, 12)	plain and ordinary meaning

II. Proposed Constructions of Disputed Claim Terms (L. Pat. R. 4-3(b))

In accordance with Local Patent Rule 4-3(b), the parties propose the following constructions for the disputed claim terms identified below:

U.S. Patent No. 8,404,215

Term Identified for Construction	Hyperion's Proposed Construction	Par's Proposed Construction
"adjusted dosage" (claims 1, 3-6, 8-11)	"second dosage"	"a different dose than the initial dose"
"determining an upper limit of normal" (claim 9)	"determining the highest level in the range of normal values"	indefinite
"half the upper limit of normal" (claims 1-6, 8-11)	"half the highest level in the range of normal values"	indefinite
"initial dosage" (claims 1, 3-6, 8-11)	"first dosage"	"starting dosage"
"normal average daily ammonia level" (claim 8)	plain and ordinary meaning To the extent additional construction is necessary: "an average daily blood ammonia level within the range of normal values"	indefinite
"treating" (claims 3-6, 8-11)	plain and ordinary meaning	"decreasing the blood nitrogen and/or ammonia level"
"upper limit of normal" (claims 1-6, 8-11)	"the highest level in the range of normal values"	indefinite
"urea cycle disorder" (claim 4)	"an inherited deficiency of an enzyme or transporter necessary for the synthesis of urea from ammonia, including enzymes involved in the urea cycle"	"deficiency in the synthesis of urea from ammonia"
"urinary PAGN of 60-75%" (claim 11)	plain and ordinary meaning	"urinary PAGN about 60-75% This construction is informed by the prosecution history of the '012 patent.

U.S. Patent No. 8,642,012

Term Identified for Construction	Hyperion's Proposed Construction	Par's Proposed Construction
"first dosage" (claims 8, 11, 12)	plain and ordinary meaning	indefinite
"normal plasma ammonia level" (claim 12)	plain and ordinary meaning	indefinite
"urea cycle disorder" (claims 8, 11, 12)	"an inherited deficiency of an enzyme or transporter necessary for the synthesis of urea from ammonia, including enzymes involved in the urea cycle."	"deficiency in the synthesis of urea from ammonia"

As required by Local Patent Rule 4-3(b), Exhibit A provides Hyperion's proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Hyperion intends to rely to support its proposed constructions or to oppose Par's proposed constructions. In addition to the documentary evidence listed in Exhibit A, Hyperion intends to rely on a written declaration by its expert witness, Dr. Gregory Enns, as described in section IV, below.

As required by Local Patent Rule 4-3(b), Exhibit B provides Par's proposed constructions for each of these terms and identifies the intrinsic and extrinsic evidence on which Par intends to rely to support its proposed constructions or to oppose Hyperion's proposed constructions. In addition to the documentary evidenced listed in Exhibit B, Par may rely on a written declaration by its expert witness, Dr. V. Reid Sutton, as described in section IV, below.

III. Anticipated Time Needed for the Claim Construction Hearing (L. Pat. R. 4-3(c))

The parties estimate that the claim construction hearing will require approximately 3 hours, divided equally between Par (1.5 hours) and Hyperion (1.5 hours).

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