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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR2016-00829
Patent 9,095,559 B2

Before TONI R. SCHEINER, DEBORAH KATZ, and GRACE KARAFFA OBERMANN, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Petitioners") filed a request for an *inter partes* review ("IPR") of claims 1–15 of U.S. Patent No. 9,095,559 B2 (Ex. 1001 ("the '559 patent")) (Paper 3 ("Pet.")), which was accorded a filing date of April 1, 2016 (Paper 4). Horizon

Therapeutics, Inc. ("Patent Owner") timely filed a Preliminary Response (Paper 9 ("Prelim. Resp.")).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless Petitioners show that there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Petitioners make that showing with respect to the grounds for unpatentability of claims 1–15. Therefore, we institute review as to claims 1–15.

Our findings of fact and conclusions of law are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. If a final decision is issued in this case, it will be based on the full record developed during trial.

A. Related proceedings

Petitioners and Patent Owner report that Patent Owner served Petitioners with a complaint in the District Court for the District of New Jersey (Case No. 1:15-cv-07624) alleging that Petitioners infringed the '559 patent, as well other related patents. Pet. 7; Prelim. Resp. 2.

Petitioners also report that patent 8,404,215, which issued from the parent application of the '559 patent, was the subject of IPR2015-01127, filed by Par Pharmaceutical, Inc., and IPR2016-00284, which was instituted and joined with the IPR2015-01127 proceeding.

Petitioners report further that PR2015-01117 and IPR2016-00283 were instituted and joined, both involving Horizon's U.S. Patent 8,642,012,[1] although that patent is not related by lineage to the '559 patent.

B. The '559 Patent (Ex. 1001)

The '559 patent issued from an application filed February 22, 2013. Ex. 1001. It cites two provisional applications filed November 29, 2011 and September 30, 2011, for priority. Ex. 1001, at [60].

C. Applied Prior Art

Petitioner relies on the following prior art references:

Abbreviation	Citation	Exhibit Number
Blau	PHYSICIAN'S GUIDE TO THE LABORATORY DIAGNOSIS OF METABOLIC DISEASES, 261–76 (Nenad Blau et al. eds., 2d ed. 1996).	1006
Simell	Olli Simell et al., *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 PEDIATRIC RESEARCH 1117–21 (1986).	1005
'859 Publication	U.S. Patent Publication 2010/0008859 A1, filed January 7, 2009, published January 14, 2010.	1007
Brusilow '84	Saul W. Brusilow et al., *Treatment of Episodic Hyperammonia in Children with Inborn Errors of Urea Synthesis*, 310 THE NEW ENGLAND JOURNAL OF MEDICINE 1630–34 (1984).	1004

[1] The application that became U.S. Patent 8,642,012 was published as U.S. Patent Publication 2010/0008859, which was cited as prior art in Petitioner's challenges.

D. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of '559 patent claims 1–15 under 35 U.S.C. § 103 over the following groups of references:

Ground	References	Claims
1	Blau, Simell, and the '859 Publication	1, 2, 4, 5, 7–10, 12, and 13
2	Blau, Simell, the '859 publication, and Brusilow '84	3, 6, 11, 14, and 15

II. Analysis

Under 35 U.S.C. § 103, subject matter is unpatentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007), the Supreme Court explained that, where there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, if the person of ordinary skill could have arrived at the claimed subject matter using common sense to combine different teachings of the prior art, then that subject matter is likely obvious, not innovative.

A. Ground 1

The claims of the '559 patent are directed to methods of using a drug, glyceryl tri-[4-phenylbutryate], to treat subjects with urea cycle disorders. Petitioner's witness, Keith Vaux, M.D., Ph.D.[2], testifies that subjects

[2] Petitioner relies on the testimony of Keith Vaux, M.D. Ex. 1002. Dr. Vaux testifies that he is Professor and Clinical Chief of the Division of

suffering from urea cycle disorders ("UCDs") are unable to remove excess nitrogen waste, which is normally excreted in the urine. *Id.* ¶ 30. When the body functions normally, dietary amino acids are converted first to ammonia and then to urea in the urea cycle and, finally, excreted in the urine. *Id.* ¶ 31. In those with UCDs, the enzymes controlling the urea cycle are deficient, leading to high levels of ammonia in the blood and toxicity. *Id.* ¶ 32.

Claim 1 of the '559 patent is representative of the claims challenged in Petitioners' Ground 1 and recites:

> A method for adjusting the dosage of glyceryl tri-[4-phenylbutyrate] in a subject being treated for a urea cycle disorder who has previously been administered an initial dosage of glyceryl tri-[4-phenylbutyrate] and who has a fasting plasma ammonia level less than the upper limit of normal for plasma ammonia level, the method comprising:
>
> (a) measuring a fasting plasma ammonia level for the subject;
>
> (b) comparing the fasting plasma ammonia level to the upper limit of normal for plasma ammonia level; and
>
> (c) administering an adjusted dosage of glyceryl tri-[4-phenylbutyrate], wherein the adjusted dosage is greater than the initial dosage if the fasting plasma ammonia level is greater than half the upper limit of normal for plasma ammonia level.

Ex. 1001, 24:20–35. Independent claim 2, the only other independent claim challenged in Ground 1, is similar to claim 1, differing mostly in the

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Medical Genetics in the Department of Medicine at UC San Diego. Ex.1002 ¶ 1. Dr. Vaux testifies that he regularly prescribes nitrogen scavenging drugs and treats patients who are maintained on therapy with nitrogen scavenging drugs. *Id.* ¶ 2. Dr. Vaux testifies that he has published articles in peer reviewed journals on metabolic disorders and speaks at national and international conferences on genetics and metabolic and genomic medicine. *Id.* ¶ 4. At this stage of the proceeding, we find Dr. Vaux to be qualified to provide opinions on the subject matter at issue.

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