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Paper 77
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS, INC.,
and MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

NOVARTIS AG and LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owner.

Case IPR2014-00549[1]
Patent 6,316,023 B1

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

[1] Case IPR2015-00265 has been joined with this proceeding.

I. INTRODUCTION

Novartis AG and LTS Lohmann Therapie-Systeme AG (collectively, "Patent Owner") request reconsideration of the Final Decision entered on September 28, 2015, Paper 69 ("Final Decision" or "Final Dec."). Paper 71 ("Rehearing Request" or "Req. Reh'g").

In the Final Decision, we addressed the following grounds of unpatentability for challenged claims 1, 2, 4, 5, 7 and 8 of U.S. Patent No. 6,316,023 B1 (Ex. 1001, "the '023 patent"):

References	Basis	'023 Patent Claims
Enz,[2] the Handbook,[3] Rosin,[4] Elmalem,[5] and Ebert[6]	§ 103(a)	1, 7
Enz, the Handbook, Rosin, and Ebert	§ 103(a)	2
Enz and the Handbook, and Ebert	§ 103(a)	4, 5
Enz, the Handbook, and Ebert or Kissel[7]	§ 103(a)	8
Enz and Sasaki[8]	§ 103(a)	1, 2, 4, 5 and 7
Enz, Sasaki, and Ebert or Kissel	§ 103(a)	8

[2] Ex. 1002, UK Patent Application GB 2,203,040 A, published Oct. 12, 1988 ("Enz").
[3] Ex. 1003, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (A. Wade & P.J. Weller eds., 2d ed. 1994) ("the Handbook").
[4] Ex. 1008, US 4,948,807, issued Aug. 14, 1990 ("Rosin").
[5] Ex. 1009, *Antagonism of Morphine-Induced Respiratory Depression by Novel Anticholinesterase Agents*, 30 NEUROPHARMACOLOGY 1059–64 (1991) ("Elmalem").
[6] Ex. 1006, WO 95/24172, published Sept. 14, 1995 ("Ebert").
[7] Ex. 1007, EP Patent Application 0155229A2, published Sept. 18, 1985 ("Kissel").
[8] Ex. 1005, JP Patent Application 59-184121, published Oct. 19, 1984 ("Sasaki").

Petitioner relied on two declarations of Dr. Agis Kydonieus, Ex. 1010; Ex. 1031, and two declarations of Dr. Christian Schöneich, Ex. 1011; Ex. 1032. Patent Owner relied on the declaration of Dr. Alexander M. Klibanov, Ex. 2012.

In the Final Decision, we held that Noven Pharmaceuticals, Inc. and Mylan Pharmaceuticals Inc. (collectively, Petitioner) had shown by a preponderance of the evidence that claims 1, 2, 4, 5, 7 and 8 of U.S. Patent No. 6, 316, 023 B1 (Ex. 1001, "the '023 patent") are unpatentable for obviousness under 35 U.S.C. § 103(a). Final Dec. 41.

II. ANALYSIS

"When rehearing a decision on petition, a panel will review the decision for an abuse of discretion." 37 C.F.R. § 42.71(c). "The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." 37 C.F.R. § 42.71(d). For the reasons discussed below, Petitioner's Rehearing Request is *denied*.

A. Federal Circuit Decision in Watson

Patent Owner asserts that we overlooked the Federal Circuit's decision in *Novartis Pharms. Corp. v. Watson Labs, Inc., — F. App'x —, Nos. 2014-1799 et al., 2015 WL 2403308 at *5–8 (Fed. Cir. May 21, 2015) ("Watson")* in two respects. Req. Reh'g 2–7, 9–13. First, according to Patent Owner, "the Board erred in overlooking the Federal Circuit's holding in *Watson* that Elmalem would not have taught a person of ordinary skill in the art that rivastigmine is oxidatively unstable or required an antioxidant."

Id. at 7.[9] Second, Patent Owner asserts that the Board overlooked the Federal Circuit's holding in *Watson* that "'susceptibility' to oxidative degradation would not have motivated a person of ordinary skill in the art to add an antioxidant to the transdermal formulation in Enz." *Id*. at 10.

We have carefully reviewed Patent Owner's arguments presented in the Request for Rehearing, but do not find them persuasive. In particular, the Decision squarely addresses the Federal Circuit's decision in *Watson* and explains why that decision does not control in this proceeding. Final Dec. 4. Specifically, we stated:

> The Federal Circuit's *Watson* decision does not control here because Noven has presented additional prior art and declaratory evidence that was not before the Court in *Watson*. Moreover, in an *inter partes* review, a petitioner's burden of proving unpatentability is by a preponderance of the evidence rather than by clear and convincing evidence, as required in district court litigation. Thus, while we have considered the Federal Circuit's decision, we have independently analyzed patentability of the challenged claims based on the evidence and standards that are applicable to this proceeding.

Id.

Significantly, the Federal Circuit noted that "[t]he district court admitted that there 'does not appear to be an objectively 'correct' reading [of Elmalem]," rather both arguments regarding whether Elmalem teaches or suggests adding an antioxidant to rivastigmine "seem logical and are

[9] Patent Owner asserts also that we "overlooked that district court expert credibility determinations should be accorded great deference 'because the court saw the witnesses and heard the testimony.'" Req. Reh'g 6 (quoting *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 929 (Fed. Cir. 2012)). However, the deference a district court receives for expert credibility determinations is accorded by the Federal Circuit reviewing an appeal from the district court, not by the Board in an *inter partes* trial proceeding.

supported by highly qualified experts in the field." *Watson* at 992 (quoting *Novartis Pharm. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733, 757 (D. Del. 2014). Further, the Federal Circuit explained that the district court credited Novartis' expert testimony as being more credible than Watson's expert. *Id.* at 993. Based upon that credibility assessment, the district court found that Elmalem's use of an antioxidant was to reduce variability among samples tested, and not a teaching or suggestion that rivastigmine is susceptible to oxidative degradation so as to motivate one of skill in the art to combine an antioxidant with it. *Id.* (citing *Novartis Pharm. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733 at 756–57).

While acknowledging that "the plain language of the Elmalem article appears to present a close[] question," on appeal, the Federal Circuit gave "great deference" to the credibility determination of the district court. *Id.* at 996. Based upon that deference, the Federal Circuit affirmed the district court's holding that Watson failed to prove by clear and convincing evidence that the asserted claims of the '023 patent would have been obvious. *Id.* at 997.

In this proceeding, the Petitioners Noven and Mylan presented different evidence than what Watson presented in district court regarding what Elmalem would have taught a person of ordinary skill in the art. Specifically, the Petitioners relied upon the declaration testimony of Dr. Kydonieus and Dr. Schöneich. Patent Owner has not shown that the same declaratory evidence was presented in the district court case reviewed by the Federal Circuit. In the Decision, we explain our finding that Elmalem's disclosure suggests adding an antioxidant to rivastigmine to prevent oxidation was based upon our consideration of the evidence and arguments

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