

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 IPR2014-00550¹
Patent 6,335,031 B1

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

FRANKLIN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

¹ Case IPR2015-00268 has been joined with this proceeding.

I. INTRODUCTION

Noven Pharmaceuticals, Inc. (“Noven”) filed a petition to institute an *inter partes* review of claims 1–3, 7, 15, 16 and 18 of U.S. Patent No. 6,335,031 B1 (Ex. 1001, “the ’031 patent”). Paper 1 (“Petition” or “Pet.”).² Novartis AG and LTS Lohmann Therapie-Systeme AG (collectively, “Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). In an Institution Decision (Paper 10), an *inter partes* review of claims 1–3, 7, 15, 16 and 18 was instituted.

After the Institution Decision, Mylan Pharmaceuticals Inc. (“Mylan”) timely filed a separate petition to institute an *inter partes* review of claims 1–3, 7, 15, 16 and 18 of the ’031 patent based on identical grounds as presented in Noven’s Petition. Case IPR2015-00268, Paper 1. At the same time, Mylan filed a Motion for Joinder with the instituted case. *Id.*, Paper 3. Patent Owner filed an Opposition to the Motion for Joinder and a Patent Owner’s Preliminary Response. Papers 10, 13. In an Institution Decision, an *inter partes* review of claims 1–3, 7, 15, 16 and 18 was instituted in IPR2015-00268, the Motion for Joinder was granted, and the proceeding in IPR2015-00268 was terminated. Paper 17. Therefore, in the instant *inter partes* review, Noven and Mylan are, collectively, the “Petitioner.”

In the instant *inter partes* review, Patent Owner filed a Response to the Petition. Paper 25 (“Patent Owner Response” or “PO Resp.”). Petitioner filed a Reply. Papers 31 and 32 (“Pet. Reply”).³ Patent Owner filed motions for observations on the cross-examinations of two deposed declarant

² Pursuant to an order, Paper 27, granting an unopposed motion by Petitioner, Paper 21, Petitioner filed a Corrected Petition, Paper 37, to correct certain clerical and typographical errors in the list of exhibits.

³ Paper 31 was filed under seal and Paper 32 is a redacted public version.

witnesses. Papers 42, 43, 44.⁴ Petitioner filed responses to the motions. Papers 52, 53 and 54.⁵ Additionally, Petitioner filed a motion to exclude a number of Patent Owner's exhibits. Paper 47. Patent Owner filed an opposition to the motion. Paper 49. Petitioner responds to the opposition in a Reply in Support of the Motion to Exclude. Paper 57. On June 2, 2015, the parties presented arguments at an oral hearing. Paper 67, ("Tr.").⁶

The Board has jurisdiction under 35 U.S.C. § 6(c). In this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we determine Petitioner has shown by a preponderance of the evidence that challenged claims 1–3, 7, 15, 16 and 18 are unpatentable.

A. Related Proceedings

According to Petitioner and Patent Owner, the '031 patent was involved in various district court actions, including two actions involving the parties to this proceeding, titled: *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, 1:13-cv-00527 (D. Del.); and *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, 1:14-cv-00111 (D. Del.). Pet. 1–2; Paper 6 at 2. Those cases were consolidated, and on August 31, 2015, the United States District Court for

⁴ Patent Owner filed a Confidential Motion for Observations on Cross-Examination of Dr. Agis Kydonieus under seal, Paper 42, and a redacted, "Non-Confidential" public version, Paper 43. Paper 44 is Patent Owner's Motion for Observation on Cross-Examination of Dr. Christian Schöneich.

⁵ Petitioner filed a Response to Patent Owner's Confidential Motion for Observations on Cross-Examination of Dr. Kydonieus under seal, Paper 54, and a redacted, "Non-Confidential" public version, Paper 53. Paper 52 is Petitioner's Response to Patent Owner's Motion for Observation on Cross-Examination of Dr. Schöneich.

⁶ Patent Owner filed Objections to Petitioner's Demonstrative Exhibits. Paper 63. In this Final Written Decision, we have not considered any arguments presented in the demonstrative exhibits that were not presented previously and/or are not supported by the record.

the District of Delaware issued a decision finding that Noven failed to prove by clear and convincing evidence that claims 7 and 16 of the '031 patent are invalid as obvious or invalid under the obviousness-type double patenting doctrine. *Novartis Pharm. Corp. v. Noven Pharm., Inc.*, —F. Supp. 3d—, Civ. Nos. 13-527-RGA, 14-111-RGA, 2015 WL 5121157 (D. Del. Aug. 31, 2015) (“*Noven*”). Although in *Noven*, the District Court considered the same prior art presented in this *inter partes* review, the District Court’s opinion is not binding in this proceeding. We have independently analyzed the prior art in view of the record evidence as a whole, including the knowledge of a person of ordinary skill in the art. Our findings and conclusions differ from the District Court in that we have accorded persuasive weight to the testimony of Petitioner’s declarants. Moreover, the petitioner in an *inter partes* review proves unpatentability by a preponderance of the evidence (*see* 35 U.S.C. § 316(e)) rather than by clear and convincing evidence, as required in district court litigation.

In another case involving Novartis, but not Noven or Mylan, the same District Court held that claims 3, 7, 13, 16 and 18 of the '031 patent are not invalid as obvious. *Novartis Pharms. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733 (D. Del. 2014). The Court of Appeals for the Federal Circuit affirmed that District Court decision upholding the validity of the '031 patent. *Novartis Pharm. 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*”). 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, as discussed previously, 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. 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.

A final decision in an *inter partes* review of claims of a related patent, U.S. Patent No. 6,316,023 B1, has been entered concurrently with this decision. IPR2014-00549, Paper 69.

B. The '031 Patent (Ex. 1001)

The '031 patent is directed to a pharmaceutical composition comprising (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl carbamate (“compound A”; “rivastigmine”; “S-enantiomer of RA₇”) in the form of a free base or acid addition salt, along with an antioxidant, and a diluent or carrier. Ex. 1001, 1:7–47. “Compound A is useful in inhibiting acetylcholinesterase in the central nervous system, e.g. for the treatment of Alzheimer's disease.” *Id.* at 1:14–16. A transdermal composition comprising compound A in the form of a free base or acid addition salt, two polymers, and a plasticizer is disclosed in the prior art. *Id.* at 1:17–21. The inventors of the '031 patent explained that the composition of the prior art “is susceptible to degradation, particularly in the presence of oxygen.” *Id.* at 1:22–24. The '031 patent states:

The present applicant has found that stable pharmaceutical compositions comprising compound A can now be obtained, which show insignificant degradation of compound A over a prolonged time period, e.g. 2 years, as indicated by standard tests, e.g. stress tests.

In one aspect, the invention provides a pharmaceutical composition comprising Compound A in free base or acid addition salt form and an anti-oxidant.

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