Trials@uspto.gov
Tel: 571-272-7822

Paper 69
Entered: September 28, 2015

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.*

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

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

I. INTRODUCTION

Noven Pharmaceuticals, Inc. ("Noven") filed a petition to institute an *inter partes* review of claims 1, 2, 4, 5, 7 and 8 of U.S. Patent No. 6,316,023 B1 (Ex. 1001, "the '023 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, 2, 4, 5, 7 and 8 was instituted.

After the Institution Decision, Mylan Pharmaceuticals Inc. ("Mylan") timely filed a separate petition to institute an *inter partes* review of claims 1, 2, 4, 5, 7 and 8 of the '023 patent based on identical grounds as presented in Noven's Petition. Case IPR2015-00265, 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 Waiver of Patent Owner's Preliminary Response. *Id.*, Papers 10, 13. In an Institution Decision, an *inter partes* review of claims 1, 2, 4, 5, 7 and 8 was instituted in IPR2015-00265, the Motion for Joinder was granted, and the proceeding in IPR2015-00265 was terminated. *Id.*, 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.").[3]

---

[2] Pursuant to an order, Paper 27, granting an unopposed motion by Petitioner, Paper 21, Petitioner filed a Corrected Petition, Paper 38, to correct certain clerical and typographical errors in the list of exhibits included in the Petition.

[3] Pursuant to an order, Paper 28, granting an unopposed motion by Patent Owner, Paper 26, Patent Owner filed a Corrected Patent Owner Response, Paper 37, to correct clerical errors.

Petitioner filed a Reply. Papers 31 and 32 ("Pet. Reply").[4] Patent Owner filed motions for observations on the cross-examinations of two deposed declarant witnesses. Papers 43, 44, 45.[5] Petitioner filed oppositions to the motions. Papers 52, 53 and 54.[6] Additionally, Petitioner filed a motion to exclude a number of Patent Owner's exhibits. Paper 48. Patent Owner filed an opposition to the motion. Paper 49. Petitioner responded 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.").[7]

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, 2, 4, 5, 7 and 8 are unpatentable.

A. Related Proceedings

According to Petitioner and Patent Owner, the '023 patent was involved in various district court actions, including two actions involving the

[4] Paper 31 was filed under seal and Paper 32 is a redacted public version.
[5] Patent Owner filed a Confidential Motion for Observations on Cross-Examination of Dr. Agis Kydonieus under seal, Paper 43, and a redacted, "Non-Confidential" public version, Paper 44. Paper 45 is Patent Owner's Motion for Observation on Cross-Examination of Dr. Christian Schöneich.
[6] 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.
[7] 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.

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 the District of Delaware issued a decision finding that Noven failed to prove by clear and convincing evidence that claims 7 and 16 of a related patent, U.S. Patent No. 6,335,031 ("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). The decision did not address the '023 patent beyond stating that it was "no longer at issue." *Id.* at *1.

In another case involving Novartis, but not Noven or Mylan, the same District Court held that claims 2 and 7 of the '023 patent and claims 3, 7, 13, 16 and 18 of the '031 patent are not invalid as obvious. *Novartis Pharm. 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 '023 and '031 patents. *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*"). 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.

A final decision in an *inter partes* review of claims of the '031 patent has been entered concurrently with this decision. IPR2014-00550, Paper 69.

B. The '023 Patent (Ex. 1001)

The '023 patent is directed to a pharmaceutical composition comprising (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl carbamate ("compound A"; "rivastigmine"; "S-enantiomer of RA_7") 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 1:15–17. 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 1:18–22. The inventors of the '023 patent explained that the composition of the prior art "is susceptible to degradation, particularly in the presence of oxygen." *Id*. at 1:23–25. The '023 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.
>
> The pharmaceutical compositions of the present invention show a reduction in degradation by-products in stress stability tests.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.