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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS (ADROCA) LLC,
Petitioner,

v.

ACORDA THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-01850 (Patent 8,440,703 B2)
Case IPR2015-01853 (Patent 8,007,826 B2)
Case IPR2015-01857 (Patent 8,663,685 B2)
Case IPR2015-01858 (Patent 8,354,437 B2)[1]

Before JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative Patent Judge*,
LORA M. GREEN and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

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

[1] Because resolution of issues common to all four *inter partes* reviews resolves the outstanding disputes between the parties with respect to all challenged claims of the four patents at issue, we exercise our discretion to issue a single Final Written Decision to be entered in each case.

I. INTRODUCTION

This is a Final Written Decision in four *inter partes* reviews IPR2015-01850, IPR2015-01853, IPR2015-01857, and IPR2015-01858. IPR2015-01850 involves review of claims 1–52 of U.S. Patent No. 8,440,703 B2 (Ex. 1001, "the '703 patent). As this case is representative of the dispositive issues in all four *inter partes* reviews, we will refer to the papers in IPR2015-01850 unless otherwise indicated.

Coalition for Affordable Drugs (ADROCA), LLC ("Petitioner"), filed a Petition (Paper 2, "Pet.") on September 2, 2015, requesting an *inter partes* review of claims 1–52 of the '703 patent. Patent Owner, Acorda Therapeutics, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp.") on December 14, 2015. On March 11, 2015, we instituted trial on the following grounds:

Reference(s)	Basis	Claims Challenged
S-1[2]	§ 103	1–7, 10, 11, 26–33, 44–46, 52
S-1 and Hayes[3]	§ 103	8, 9, 12–21, 34–41, 47–49

[2] Acorda Therapeutics, Inc., Registration Statement under the Securities Act of 1933 (Form S-1) (Sept. 26, 2003) ("S-1") (Ex. 1003).
[3] Keith C. Hayes et al., *Pharmacokinetic Studies of Single and Multiple Oral Doses of Fampridine-SR (Sustained-Release 4-Aminopyridine) in Patients With Chronic Spinal Cord Injury*, 26 CLIN. NEUROPHARMACOLCOY 185–92 (2003) ("Hayes") (Ex. 1005).

Reference(s)	Basis	Claims Challenged
S-1 and Juarez[4]	§ 103	22–25, 42, 43, 50, 51

Paper 14 ("Dec. Instit."), 21. As discussed in more detail below, every instituted ground in all four *inter partes* reviews relies on S-1, either alone or in combination with other references.

Subsequently, Patent Owner filed a Response (Paper 34, "PO Resp."), and Petitioner filed a Reply (Paper 43, "Reply").[5]

Petitioner filed a Motion to Exclude (Paper 56) certain of Patent Owner's exhibits and testimony by Dr. Gregory K. Bell. Paper 56, 1, 15. Patent Owner filed an Opposition to the Motion to Exclude (Paper 60), and Petitioner filed a Reply (Paper 64).[6]

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[4] Haydee Juárez et al., *Influence of Admixed Carboxymethylcellulose on Release of 4-Aminopyridine from Hydroxypropyl Methylcellulose Matrix Tablets*, 216 INT'L J. PHARM., 115–25 (2001) ("Juarez") (Ex. 1006).

[5] Both Patent Owner and Petitioner filed the Response and Reply, respectively, as confidential with accompanying motions to seal. *See* Papers 28, 29, 44, 45. Because we do not need to refer to any confidential information in our Final Written Decision, we will reference the public versions of the Response and Reply.

[6] Petitioner and Patent Owner filed Objections to Evidence, *see* Papers 35, 47, and Patent Owner filed Observations regarding the Cross-Examination of Dr. Fairweather, Dr. Pleasure, and Ms. Distler, to which Petitioner filed a response, *see* Papers 58, 63, respectively (public versions). We have reviewed these papers and will give the evidence the appropriate weight in light of these observations and objections. We do not need to refer to any confidential information in our Final Written Decision.

A final hearing was conducted on January 19, 2016. Paper 68 ("Tr."). We have jurisdiction under 35 U.S.C. § 6. Petitioner bears the burden of proving unpatentability of the challenged claims, and that burden never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish facts supporting its challenge by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–52 ("the challenged claims") are unpatentable on the instituted grounds.

A. Related Proceedings

The parties identify a number of judicial matters involving the patents in the four *inter partes* proceedings at issue in this Final Written Decision, including, among others, *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 1:14-cv-00935 (D. Del); *Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, No. 1:14-cv-00139 (N.D. W. Va.); *Acorda Therapeutics, Inc. v. Accord Healthcare Inc.*, No. 1:14-cv-00932 (D. Del.); and *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, Case 15-124 (Fed. Cir.). Pet. 2–3; Paper 5, 3–5. The parties also identify Case No. IPR2015-00817, previously denying *inter partes* review of U.S. Patent No. 8,007,826 patent, as well as Case No.

IPR2015-00720, previously denying *inter partes* review of U.S. Patent No. 8,663,685. Pet. 3; Paper 5, 2–3.

B. The '703 Patent (Ex. 1001)

The '703 is directed to a sustained release oral dosage of an aminopyridine pharmaceutical composition that can be used to treat individuals affected with neurological disorders. Ex. 1001, 1:14–16. The most preferred aminopyridine is 4-aminopyridine ("4-AP" or "fampridine"). *Id*. at 1:35–41, 2:29–32. According to the '703 patent, its pharmaceutical composition can be used to treat spinal cord injury, multiple sclerosis ("MS"), Alzheimer's disease, and amyotrophic lateral sclerosis ("ALS"). *Id*. at 2:23–27. The composition is said to maximize therapeutic effects while minimizing side effects. *Id*. at 1:17–18.

In one embodiment of the '703 patent, the composition is administered to patients with MS to increase their walking speed. *Id*. at 3:65–4:3. The composition is administered twice daily in an amount of less than about 15 milligrams of aminopyridine, preferably about 10 to 15 milligrams of aminopyridine. *Id*. at 4:1–5. In other embodiments, the composition is said to improve lower extremity muscle tone and lower extremity muscle strength in patients with MS. *Id*. at 4:6–19. The '703 states that in responsive patients (approximately 37%), "treatment with fampridine at doses of 10–20 mg produced a substantial and persistent improvement in walking." *Id*. at 29:23–26.

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