Trials@uspto.gov
571-272-7822

Paper 10
Entered: March 19, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC and FRESENIUS KABI SWISSBIOSIM GmbH,
Petitioner,

v.

COHERUS BIOSCIENCES, INC.,
Patent Owner.

PGR2019-00064
Patent 10,155,039

Before SUSAN L.C. MITCHELL, CHRISTOPHER G. PAULRAJ, JOHN H. SCHNEIDER, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324 and 37 C.F.R. § 42.208

I. INTRODUCTION

Fresenius Kabi USA, LLC and Fresenius Kabi SwissBioSim GmbH (collectively, "Petitioner") filed a Petition requesting post-grant review of claims 1–12 (the "challenged claims") of U.S. Patent No. 10,155,039 B2 (Ex. 1001, "the '039 patent"). Paper 3 ("Pet."). Coherus BioSciences, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 324.

To institute a post-grant review, we must determine whether the information presented in the petition "would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). After considering the Petition and the Preliminary Response, we determine, for the reasons set forth below, that Petitioner has failed to demonstrate that it is "more likely than not" that any of the challenged claims are unpatentable based on the grounds presented. Therefore, we do not institute a post-grant review of those claims.

A. Related Matters

Petitioner and Patent Owner both indicate that the '039 patent is the subject of the following litigation: *Coherus BioSciences, Inc. v. Amgen Inc.*, Case No. 1:19-cv-00139-RGA (D. Del.). Pet. 2; Paper 6, 2.

B. The '039 Patent

The '039 patent, titled "Stable Aqueous Formulations of Adalimumab," discloses pharmaceutical adalimumab compositions suitable for long-term storage. Ex. 1001, Abstract. The '039 patent issued from an application (Appl. No.

15/799,851) filed October 31, 2017, and claims priority to three provisional applications, all of which were filed before the AIA critical date.

Adalimumab is the active pharmaceutical ingredient in the drug Humira. Ex. 1001, 7:31–32. Adalimumab is described in U.S. Pat. No. 6,090,382, which is incorporated by reference in its entirety in the '039 patent. *Id.* at 1:57–59. Although Humira was commercially available in an aqueous formulation at the time the '039 patent was filed, the '039 patent discloses that the stability of aqueous adalimumab could be improved by removing the citrate and phosphate buffer, mannitol, and sodium chloride. Ex. 1002, 5:5–27.

According to the specification, "adalimumab compositions which comprise only one buffer (as opposed to two or more buffers) are more stable than adalimumab compositions comprising both a citrate buffer and a phosphate buffer." *Id.* at 11:58–61. The specification provides acetate, succinate, histidine, phosphate, tartrate, maleate, and citrate as examples of sole buffers that are more stabilizing than the citrate and phosphate buffer combination. *Id.* at 16:26–27, 21:46–47. The specification further describes that "sodium chloride is destabilizing" and that other stabilizers are "significantly better [options] . . . than mannitol." *Id.* at 5:7–8, 14:23.

The specification also provides testing data used to demonstrate the improved stability of the '039 patent's adalimumab compositions. Some of the tests used Humira as a control for purposes of stability comparison. *See, e.g.*, *id.* at 37:18–23. The data from the Humira-control tests show that single buffer adalimumab formulations are more stable than the commercially available Humira. *Id.* The '039 specification further discloses analyzing the adalimumab compositions using size exclusion chromatography ("SEC") and capillary isoelectric focusing ("cIEF"), among other techniques. *See generally id.* at 25:1–

63:49. Table E-1, reproduced below, displays examples of acetate-buffered formulations that exhibit comparable or superior stability to Humira.

TABLE E-1

Measured pH for Block E formulations at t0 and t1 (one week, 40° C.)

Form No.	pH	citrate	phosphate	sorbitol	Gly	Arg	mannitol	NaCl	PS 80	t0	t1	t2
1	5.2	8	18	0	0	0	65	100	0.1	5.15	5.11	5.21
2	3.5	8	18	0	0	0	65	100	0.1	3.36	3.49	3.50
3	5.2	0	0	0	0	0	65	100	0.1	5.13	5.24	5.24
4	3.5	0	0	0	0	0	65	100	0.1	3.31	3.43	3.45
5	3.5	0	0	65	0	0	0	100	0.1	3.30	3.48	3.42
6	3.5	0	0	0	0	130	0	0	0.1	3.24	3.52	3.42
7	3.5	0	0	0	0	130	0	0	0	3.27	3.59	3.48
8	3.5	0	0	0	240	0	0	0	0	3.27	3.33	3.39
9	5.2	0	0	0	240	0	0	0	0	5.05	5.25	5.20
10	3.5	0	0	0	100	100	0	0	0	3.30	3.45	3.41
11	5.2	0	0	0	100	100	0	0	0	5.20	5.38	5.39
12	3.5	0	0	0	150	50	0	0	0	3.24	3.38	3.37

Id. at 39.

C. Illustrative Claims

Petitioner challenges claims 1–12 of the '039 patent, of which claims 1, 5, and 9 are the only independent claims. Claim 1 is representative of the independent claims and recites:

> 1. A stable aqueous pharmaceutical composition comprising:
>
> a) adalimumab;
>
> b) a buffer;
>
> c) polysorbate 80; and
>
> d) a sugar,
>
> wherein the composition is free of i) mannitol, ii) citrate and phosphate buffers, and iii) sodium chloride and wherein the composition has a pH of about 5 to about 6.

D. Asserted Grounds of Unpatentability

Petitioner advances three grounds of unpatentability in relation to claims 1–12 of the '039 patent and seek cancellation of those claims. Pet. 1. Petitioner argues that the challenged claims are unpatentable for: 1) lack of written description; 2) lack of enablement; and 3) indefiniteness. *Id.*

Ground	Claims	Statutory Basis
1	1–12	35 U.S.C. § 112 (written description)
2	1–12	35 U.S.C. § 112 (enablement)
3	1–12	35 U.S.C. § 112 (indefiniteness)

Petitioner also relies on the declaration of Christian Schöneich, Ph.D. Ex. 1002.

II. ANALYSIS

A. Post-Grant Eligibility

Post-grant reviews are only available for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act, Pub. L. No. 112-20, 125 Stat. 284 (2011) ("AIA"). AIA § 6(f)(2)(A); *see Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 13 at 15 (PTAB Sept. 2, 2016). These patents issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date . . . on or after" March 16, 2013. AIA § 3(n)(1). *See also* 37 C.F.R. § 42.204(a) (requiring that "petitioner . . . certify that the patent for which review is sought is available for post-grant review").

The '039 patent issued on December 18, 2018, from U.S. Application No. 15/799,851, filed on October 31, 2017. Ex. 1001, codes (45), (21), (22). The '851 application, through a continuation application, claims priority to U.S. Provisional Application No. 61/698,138, filed on September 7, 2012, U.S. Provisional Application No. 61/769,581, filed on Feb. 26, 2013, and U.S. Provisional Application No. 61/770,421, filed on Feb. 28, 2013. *Id.* at codes (60), (63).

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