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Paper: 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LASSEN THERAPEUTICS 1, INC.,
Petitioner,

v.

SINGAPORE HEALTH SERVICES PTE LTD., and NATIONAL UNIVERSITY OF SIGNAPORE
Patent Owner.

PGR2019-00053
Patent 10,106,603 B2

Before GEORGIANNA W. BRADEN, ROBERT A. POLLOCK, and JAMIE T. WISZ, *Administrative Patent Judges.*

WISZ, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

Lassen Therapeutics 1, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting a post-grant review of claims 1–10 of U.S. Patent No. 10,106,603 B2 (Ex. 1001, "the '603 patent"). Singapore Health Services PTE LTD. and National University of Singapore ("Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp.").

We have authority to determine whether to institute a post-grant review under 35 U.S.C. § 324 and 37 C.F.R. § 42.4(a). We may not institute a post-grant review unless "the information presented in the petition . . . , if such information is not rebutted, 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).

Applying that standard, and upon consideration of the information presented in the Petition and the Preliminary Response, we determine that the information presented fails to demonstrate it is more likely than not that at least 1 of the challenged claims of the '603 patent is unpatentable. Accordingly, we deny institution of post-grant review of claims 1–10 of the '603 patent.

A. Real Parties-in-Interest

Petitioner identifies itself, "Lassen Therapeutics 1, Inc.," as the sole real party-in-interest. Pet. 1. Patent Owner identifies Singapore Health Services PTE LTD., National University of Singapore, Enleofen Bio Pte Ltd., Boehringer Ingelheim International GmbH, Boehringer Ingelheim USA Corporation, and Boehringer Ingelheim Pharmaceuticals, Inc., as the real parties-in-interest. Paper 9, 1.

B. Related Proceedings

Patent Owner indicates that the application from which the '603 patent issued is a Division of U.S. Patent Application No. 15/381,622 (U.S. Patent No. 10,035,852). Paper 9, 1. Patent Owner further indicates that the '603 patent claims priority to United Kingdom Application No. 1522186.4, to which a number of non-U.S. patent matters claim priority, including European Patent 3298040 B1 ("EP '040"). *Id*. at 2–3. Both parties indicate that an Opposition was filed against EP '040. Pet. 2; Paper 9, 3. Patent Owner also indicates that the following pending applications claim the benefit of priority of the filing date of the '603 patent: 16/055,245; 16/055,251; 16/055,261; 16/055,270; 16/055,283; 16/055,295; 16/055,304; 16/055,319; 16/106,041; 16/106,044; 16/106,047; and 16/106,050. Paper 9, 1

C. The '603 Patent

The '603 patent is directed to methods of treating fibrosis, including in humans. Ex. 1001, code (57), 1:14–15, 35:45–50. According to the '603 patent, fibrosis is the formation of excess fibrous connective tissue in a tissue or organ. *Id*. at 33:25–44. Fibrosis can occur in many tissues of the body including the liver, lungs, kidney, heart, blood vessels, eye, skin, pancreas, intestine, brain, and bone marrow. *Id*. at 34:10–13.

According to the '603 patent, the role of the protein Interleukin 11 ("IL-11") in fibrosis was not clear from the published literature; however, the inventors identified IL-11 to have a pro-fibrotic action and the patent provides *in vivo* data demonstrating IL-11 to be pro-fibrotic in heart, kidney, lung, and liver tissue. *Id*. at 1:51–52, 2:34–35, 45:54–46:2; Figures 21B–21C.

The ’603 patent also describes methods of inhibiting or preventing the IL-11 mediated pro-fibrotic signal, e.g., as mediated by binding of IL-11 to an IL-11 receptor. *Id*. at 2:36–38. One disclosed method involves treating fibrosis by administering an Interleukin 11 receptor α (“IL-11Rα”) antibody capable of inhibiting signaling mediated by IL-11. *Id*. at 17:27–34. Such an antibody binds to the α component of a cell’s receptor for IL-11 and inhibits IL-11 from signaling via that receptor. *Id*. The ‘603 patent includes data showing that a neutralizing anti-IL-11Rα antibody had an antifibrotic effect. *Id*. at 46:51–67; Fig. 24.

The ’603 patent lists examples of known anti-IL-11R antibodies including “monoclonal antibody clone 025 (Sino Biological), clone EPR5446 (Abcam), clone 473143 (R & D Systems), clones 8E2 and 8E4 described in US 2014/0219919 A1 and the monoclonal antibodies described in Blanc et al (J. Immunol Methods. 2000 Jul. 31; 241(1–2); 43–59).” *Id*. at 18:41–46. The ’603 patent teaches how to make new anti-IL-11Rα antibodies by conventional immunization techniques and also describes the use of phage display. *Id*. at 50:40–51:18; 54:55–57:46.

D. Illustrative Claim

Petitioner challenges claims 1–10 of the ’603 patent. Claim 1, which is the only independent claim of the ’603 patent, is illustrative of the challenged claims, and is reproduced below:

> 1. A method of treating fibrosis in a human subject, the method comprising administering to the human subject in need of treatment a therapeutically effective amount of an Interleukin 11 receptor α (IL-11Rα) antibody which is capable of inhibiting

> Interleukin 11 (IL-11) mediated signaling, wherein the fibrosis is fibrosis of the heart, liver, kidney or eye.

Ex. 1001, 93:15–21.[1] Challenged claims 2–10 depend directly from claim 1.

E. The Asserted Grounds of Unpatentability

Petitioner contends claims 1–10 of the '603 patent are unpatentable in view of the following grounds. Pet. 3–4.

Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–10	112(a)	Written Description
2	1–10	112(a)	Enablement
3	1–4, 6, 8–10	102	Edwards[2]
4	1–10	103	Edwards
5	1–10	103	Edwards, Wynn[3], Chegini[4]

Petitioner submits the Declarations of Peter Bowers, Ph.D. (Ex. 1003) and Stephen Ledbetter, Ph.D. (Ex. 1004) in support of institution of post-grant review.

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[1] The recited claim language incorporates the modifications from the Certificate of Correction issued on February 5, 2019. Ex. 1002, 1.

[2] Edwards et al., US 2014/0219919 A1, published Aug. 7, 2014 (Ex. 1008, "Edwards").

[3] Thomas A. Wynn, Fibrotic Disease and the T_{H1}/T_{H2} Paradigm, 4 Nat. Rev. Immunol., 583–594 (2004) (Ex. 1010, "Wynn").

[4] Chegini et al., US 2008/0300147 A1, published Dec. 4, 2008 (Ex. 1065, "Chegini").

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