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Paper No. 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARADIGM CORPORATION,
Petitioner,

v.

INSMED INCORPORATED,
Patent Owner.

Case PGR2017-00021
Patent 9,402,845 B2

Before GRACE KARAFFA OBERMANN, RAMA G. ELLURU, and MICHELLE N. ANKENBRAND, Administrative Patent Judges.

OBERMANN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner filed a Petition for post grant review of claims 1–26 of U.S. Patent No. 9,402,845 B2 (Ex. 1001, "the '845 patent"). Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 8 ("Prelim. Resp."). Based on the information presented, we hold that Petitioner has not demonstrated adequately that the '845 patent is eligible for post grant review.

Accordingly, we deny the Petition.

A. Related Proceedings

Petitioner identifies as a related matter a pending continuation application of the '845 patent. Pet. 7 (citing Application No. 15/376,086). Petitioner states that it "is unaware of any other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding." *Id.*

B. The Priority Application Chain Relating to the '845 Patent

The filing dates of the parent applications pertaining to the '845 patent are critical to our analysis because, if claims 1–26 are entitled to claim priority based on the filing date of a parent application filed before March 16, 2013, the '845 patent is not eligible for post grant review. *See infra* § II.A (statutory analysis pertaining to post grant review eligibility).

The '845 patent issued from an application (No. 14/987,508, "the '508 application") that was filed on January 4, 2016, but claims an earliest possible priority date of December 8, 2005, based on the filing of a provisional application (No. 60/748,468, "the '468 provisional application"). Ex. 1001, Related U.S. Application Data (60). The '845 patent also claims the benefit of filing dates associated with a chain of non-provisional continuation applications stemming from the '468 provisional application. *Id.* at (63).

The first non-provisional application (No. 11/634,343) was filed on December 5, 2006, and issued as U.S. Patent No. 8,226,975. Ex. 1007. The second non-provisional application (No. 13/527,213) was filed on June 19, 2012, and issued as U.S. Patent No. 8,632,804. Ex. 1008. The third non-provisional application (No. 13/666,420) was filed on November 1, 2012, and issued as U.S. Patent No. 8,642,075. Ex. 1009. The fourth non-provisional application (No. 14/080,922, "the '922 application") was filed on November 15, 2013, and is pending. Ex. 1010. The '508 application, from which the '845 patent issued, is a continuation of the '922 application. Ex. 1001.

The parties agree that the earliest-filed priority application (that is, the '468 provisional application) and each non-provisional parent application have essentially the same specification as the '845 patent. Pet. 22, 47; Prelim. Resp. 47. Accordingly, our discussion of the disclosure of the '845 patent applies with equal force to the disclosure of each priority application.

C. The Claimed Subject Matter of the '845 Patent

The '845 patent, entitled "Lipid-Based Compositions of Antiinfectives for Treating Pulmonary Infections and Methods of Use Thereof," relates to a pharmaceutical formulation comprising a mixture of free and liposome-encapsulated antiinfectives. Ex. 1001, Title, Abstract. According to the specification, an objective of the invention is to use lipid-based encapsulation to improve the therapeutic effects of the antiinfectives when administered via the pulmonary route to treat pulmonary infections. *Id*. at 2:34–41.

The specification describes an embodiment in which "the lipid-based composition is a liposome." *Id*. at 3:22–23. Claims 1–26 are directed to a method that employs "a plurality of liposomes" for encapsulating a specific

antiinfective—namely, "quinolone antibiotic agent." *Id*. at 14:55–57 (claim 1, the only independent claim). The claimed method includes administering a mixture of free and liposome-encapsulated "quinolone antibiotic agent" to the lungs of a patient via an inhalation delivery device. *Id*. at 14:51–57. The encapsulated form is "encapsulated in a plurality of liposomes" that "consists of electrically neutral lipids." *Id*. at 14:56–62. The free quinolone provides for immediate bactericidal activity, while the encapsulated quinolone provides a slow release that results in sustained levels of drug in the lungs for prolonged activity between administrations. *Id*. at 2:52–59, 14:66–15:4.

The '845 patent informs that the antiinfective "is selected from the group consisting of antibiotic agents, antiviral agents, and antifungal agents." *Id*. at 3:11–13. Quinolones are among the antibiotic agents expressly identified as antiinfectives suitable for use in the claimed invention. *Id*. at 3:15, 4:9, 9:21. The specification lists specific quinolones, including ciprofloxacin, that are useful in the claimed method. *Id*. at 9:43–48. The specification also describes with particularity lipids suitable for encapsulating the antiinfectives. *Id*. at 3:27–31, 4:16–26, 6:35–8:54. On that point, the specification teaches that suitable "[l]iposomes can be produced by a variety of methods," and identifies at least five U.S. patents that disclose methods for producing liposome-encapsulated antiinfectives. *Id*. at 7:53–8:3.

The '845 patent discloses two working examples, neither of which uses a quinolone as the antiinfective. *Id*. at 13:35–14:35. Both working examples employ amikacin as the antiinfective. *Id*. at 13:42–43, 14:11–15. Amikacin is an aminoglycoside, which, like quinolone, is identified in the specification as an antiinfective suitable for use in the claimed invention. *Id*. at 4:13–15.

D. Illustrative Claim

Claim 1, the only independent claim, is illustrative of the claimed subject matter and is reproduced below:

> 1. A method for treating or providing prophylaxis against a pulmonary infection in a patient in need thereof, comprising:
>
> administering to the lungs of the patient via an inhalation delivery device, a pharmaceutical formulation comprising a mixture of free quinolone antibiotic agent, a quinolone antibiotic agent encapsulated in a plurality of liposomes, and a pharmaceutical excipient, wherein the formulation is a solution or a suspension, the ratio by weight of free quinolone antibiotic agent to the encapsulated quinolone antibiotic agent is between about 1:10 and about 10:1 and the lipid component of the plurality of liposomes consists of electrically neutral lipids,
>
> wherein the pharmaceutical formulation is administered as an aerosolized pharmaceutical formulation, and the aerosolized pharmaceutical formulation comprises free quinolone antibiotic agent in an amount effective to provide immediate bactericidal activity against the pulmonary infection and liposomal encapsulated quinolone antibiotic agent in an amount effective to provide sustained bactericidal activity against the pulmonary infection.

Ex. 1001, 14:51–15:4 (indention added).

E. Evidence Relied Upon

Petitioner raises seven grounds of unpatentability. Pet. 8–9. Our decision, however, turns on the threshold question of whether the '845 patent is eligible for post grant review. Pet. 45–55. Because we ultimately conclude that the patent is not post grant review eligible, we do not reach the merits of any asserted ground of unpatentability. Given that they form no part of our decision, we decline to enumerate the grounds here. *See id*. at 8–9 (Petitioner's recitation of the seven grounds).

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