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Paper 10
Date: September 1, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONTIER THERAPEUTICS, LLC,
Petitioner,

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH,
Patent Owner.

Case IPR2016-00649
Patent 8,664,231 B2

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Frontier Therapeutics, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–22 of U.S. Patent No. 8,664,231 B2 (Ex. 1001, "the '231 patent"). Paper 1 ("Pet."). medac Gesellschaft für klinische Spezialpräparate mbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–22. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner and Patent Owner identify a district court action involving the '231 patent, titled *medac Pharma, Inc. v. Antares Pharma, Inc.*, No. 1:14-cv-01498-JBS-KMW (D.N.J.). Pet. 5; Paper 8, 2. The parties also identify a prior proceeding at the Board, IPR2014-01091, as well as a Decision on Institution in that case, addressing challenges of the same patent and claims at issue here. Pet. 5–6; Prelim. Resp. 2; *Antares Pharma, Inc. v. medac Gesellschaft für klinische Spezialpräparate mbH*, Case No. IPR2014-01091 (PTAB Jan. 6, 2015) (Paper 7) ("IPR2014-01091" or "prior IPR"). Both the district court litigation and the prior IPR settled in April 2015. Paper 8, 2.

The parties also identify U.S. Patent Application 14/635,542, filed March 2, 2015, which is currently pending. Pet. 5–6, Paper 8, 2.

B. The '231 Patent (Ex. 1001)

The '231 patent relates to a method for treating inflammatory autoimmune diseases, such as rheumatoid arthritis, juvenile rheumatoid arthritis, or psoriasis, comprising administering subcutaneously a concentrated methotrexate solution comprising more than 30 mg/ml of methotrexate. Ex. 1001, Abstract. Methotrexate is a cytostatic agent that is well known for treating breast cancer, leukemia in children, and psoriasis. *Id*. at 1:24–30. "Over the years, methotrexate has become the gold standard in the treatment of rheumatoid arthritis." *Id*. at 2:34–36. As a basic therapeutic for rheumatoid arthritis, methotrexate is administered once a week, orally or parenterally. *Id*. at 2:37–41.

The '231 patent is directed to a ready-made syringe and carpule containing the methotrexate solution, as well as a pen-injector comprising the ready-made syringe and/or carpule. *Id*. at 1:10–13. Preparing methotrexate, including drawing it up in a syringe from a bottle, is subject to strict restrictions, such as requiring the preparation to occur within a suitable venting system. *Id*. at 2:7–17.

Previously, ready-made syringes were developed to avoid the step of preparing a methotrexate solution for injection. *Id*. at 2:18–19. The '231 patent states, "[f]or the first time, the applicant in the present invention was able to have such ready-made syringes for subcutaneous application approved throughout Europe." *Id*. at 2:19–22. Those ready-made syringes may be administered by the physician, medical staff, or by the patient as a

self-application, without requiring any preparation of the injection. *Id*. at 2:22–25.

The ’231 patent discloses that “subcutaneous administration in particular has its difficulties . . . due to the problem of having to inject the required relatively large amount of active substance solution (e.g. up to 3 ml in the case of a certain dosage) under the skin every week.” *Id*. at 2:44–52. Thus, according to the ’231 patent, a need exists to provide a concentrated methotrexate solution for subcutaneous administration that allows a smaller volume of the solution to be injected. *Id*. at 2:53–60.

The ’231 patent defines “inflammatory autoimmune disease” to encompass all inflammatory autoimmune diseases that can reasonably be treated with methotrexate, such as rheumatoid arthritis and psoriasis. *Id*. at 3:57–67. It further states that “medicaments of the present invention are administered parenterally,” and in particular, “by intravenous, intramuscular or subcutaneous injection.” *Id*. at 4:4–6.

C. Illustrative Claim

Claim 1 of the ’231 patent, the only independent claim, is illustrative and is reproduced below:

> 1. A method for the treatment of inflammatory autoimmune diseases in a patient in need thereof, comprising subcutaneously administering to said patient a medicament comprising methotrexate in a pharmaceutically acceptable solvent at a concentration of more than 30 mg/ml.

Id. at 8:43–47. Dependent claims 2–22 recite additional limitations regarding methotrexate concentrations, solvent, inflammatory autoimmune diseases, and the medicament being contained in an injection device for a

single application, such as a pen injector, or in a storage container, such as a carpule.

D. Proposed Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–22 of the '231 patent on the following grounds:

Reference(s)	**Statutory Basis**	**Claims Challenged**
Grint (Ex. 1003)[1]	§ 102(b)	1, 2, 4–6, 11–13, 17, and 22
Grint and Insulin Admin. (Ex. 1015)[2]	§ 103(a)	7–10, 14–16, and 19–21
Grint and Alsufyani (Ex. 1006)[3]	§ 103(a)	18

[1] Grint et al., U.S. Pat. No. 6,544,504 B1, issued Apr. 8, 2003 ("Grint") (Ex. 1003).

[2] American Diabetes Assn., *Insulin Admin.*, 26 DIABETES CARE Supp. 1, S121–S124 (2003) ("Insulin Admin.") (Ex. 1015).

[3] Alsufyani et al., *The Role of Subcutaneous Adm. of Methotrexate in Children with Juvenile Idiopathic Arthritis Who Have Failed Oral Methotrexate*, 31:1 J. RHEUMATOLOGY 179–82 (2004) ("Alsufyani") (Ex. 1006).

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