Trials@uspto.gov
Tel: 571-272-7822

Paper 8
Entered: February 6, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KVK-TECH, INC.
FLAT LINE CAPITAL, LLC,
Petitioner,

v.

SILVERGATE PHARMACEUTICALS, INC.,
Patent Owner.

Case PGR2017-00039
Patent 9,463,183

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

OBERMANN, *Administrative Patent Judge*.

DECISION
Instituting Post Grant Review of Claims 1–13
35 U.S.C. § 324; 37 C.F.R. § 42.208

I. INTRODUCTION

Petitioner filed a Petition for post grant review of claims 1–13 of U.S. Patent No. 9,463,183 B1 (Ex. 1001, "the '183 patent"). Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Applying the standard set forth in 35 U.S.C. § 324(a), which requires demonstration that it is more likely than not that at least one challenged claim is unpatentable, we institute post grant review of the challenged claims based on a single ground of unpatentability identified in the Order below.

The following preliminary findings of fact and conclusions of law are made for the sole purpose of determining whether Petitioner meets the threshold for initiating review. Any final decision shall be based on the full trial record, including any response timely filed by Patent Owner. Arguments not raised by Patent Owner in a timely-filed response shall be deemed waived, even if they were presented in the Preliminary Response.

Taking account of the information presented in the Petition and Preliminary Response, we determine that the Petition shows sufficiently the following facts for the purposes of trial institution.

A. Related Proceedings

"Petitioner is unaware of any potentially related matters" and Patent Owner identifies none. Pet. 3; Paper 4.

B. The '183 Patent (Ex. 1001)

The '183 patent is titled "Lisinopril Formulations." Ex. 1001, [54]. The '183 patent specification describes lisinopril as an "antihypertensive" drug useful for treating "high blood pressure," as well as "heart failure and acute myocardial infarction." *Id*. at 1:5–56. The specification further discloses that "[l]isinopril is currently administered in the form of oral

tablets," identifying two commercially-available tablet forms of the drug. *Id*. at 1:52–53. The specification explains that some people, including "children and the elderly," may experience difficulty swallowing lisinopril in tablet form. *Id*. at 4:37. That circumstance may result in "non-compliance with the recommended medical therapy" or even "choking." *Id*. at 4:34–35, 38. A prior art practice of compounding the lisinopril tablets (that is, pulverizing or crushing the tablets into powder and reconstituting the powder in liquid) may lead to undesirable consequences, including inaccurate dosing and rapid instability of the drug. *Id*. at 39–56.

The invention addresses those problems by providing a "lisinopril oral liquid formulation" that is "stable in various storage conditions" and tastes sweet. *Id*. at 6:41, 14:36, 14:67. The claimed invention is directed to an oral liquid formulation of lisinopril (or its pharmaceutically acceptable salts or solvates), a sweetener that is xylitol, a buffer comprising citric acid and sodium citrate, a preservative that is sodium benzoate, and water. *Id*. at 38:27–40 (claim 1). The formulation includes the ingredients in specified weight-to-volume amounts and, further, specifies a pH range for the formulation of about 4 to about 5. *Id*.

The claimed formulation also "is stable at about 25±5° C. for at least 12 months." *Id*. The specification defines the word "stable," which appears in each independent claim of the '183 patent. *Id*. at 15:1–7 (definition of "stable"); 38:28, 38:39, 38:49, 39:60, 39:5, 39:17 (for stability limitations of claims 1, 6, and 12). According to the specification, "[s]table as used herein refer[s] to lisinopril oral liquid formulations having about 95% or greater of the initial lisinopril amount and about 5% w/w or less total impurities or related substances at the end of a given storage period." *Id*. at 15:1–7.

C. Illustrative Claim

Of the challenged claims, only claims 1, 6, and 12 are in independent form. Claim 1 is illustrative and reproduced below:

> 1. A stable oral liquid formulation, comprising:
> (i) about 1 mg/ml lisinopril or a pharmaceutically acceptable salt or solvate thereof;
> (ii) about 150 mg/ml of a sweetener that is xylitol;
> (iii) a buffer comprising about 0.86 mg/ml citric acid and about 1.44 mg/ml sodium citrate;
> (iv) about 0.8 mg/ml of a preservative that is sodium benzoate; and
> (v) water;
> wherein the pH of the formulation is between about 4 and about 5; and
> wherein the formulation is stable at about 25±5° C. for at least 12 months.

Ex. 1001, 38:27–40.

The other claims differ from claim 1 in ways that do not affect our decision on institution. *See id*. at 38:41–39:20 (claims 2–13).

D. Evidence Relied Upon

The Petition identifies the following references as prior art in the grounds of unpatentability:

(1) Ben Beidel, et al., "*Liquid dosage forms intended for pediatric use: Lisinopril & Meclizine*," Department of Pharmaceutical Sciences, School of Pharmacy, Wilkes University, Wilkes-Barre, PA, presented at 2011 AAPS Annual Meeting and Exposition, October 26, 2011, Washington, DC (Ex. 1005, "Beidel");

(2) Ben Beidel, et al., "*Lisinopril as a liquid dosage form intended for pediatric use*," Meeting Abstract, AAPS 2011 (Ex. 1006, "Beidel Two");

(3) Maneesh J. Nerurkar, et al., WO 98/14196, published April 9, 1998 (Ex. 1009, "Nerurkar"); and

(4) Lloyd V. Allen, Jr., "Lisinopril 1-mg/mL, Sodium Citrate, and Citric Acid Oral Liquid," *Int'l J. of Pharma. Compounding*, Vol. 10 No. 5 (September/November 2006) (Ex. 1010, "Pharma Compounding").

The Petition is supported by the Declaration of Arthur Kibbe, Ph. D. Ex. 1002. For the purposes of this decision, we find that Dr. Kibbe is qualified to opine from the perspective of a person of ordinary skill in the art at the time of the invention. *See id*. ¶¶ 2–7 (Dr. Kibbe's background and qualifications), Appendix A (Dr. Kibbe's curriculum vitae).

E. The Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability against claims 1–13 of the '183 patent:

(1) lack of enablement under 35 U.S.C. ¶ 112(a);

(2) lack of written description support under 35 U.S.C. ¶ 112(a); and

(3) obviousness over the combined disclosures of Beidel, Beidel Two, Nerurkar, and Pharma Compounding under 35 U.S.C. § 103. Pet. 4.

II. ANALYSIS

We organize our analysis into three sections. First, we address the level of ordinary skill in the art at the time of the invention. Second, we discuss claim construction. Third, taking account of the information presented, we consider whether the Petition meets the threshold showing for post grant review for each of the three asserted grounds, which are based on enablement, written description, and obviousness.

Based on that analysis, we conclude that the Petition meets the threshold for review only with respect to the third asserted ground, based on obviousness over the prior art. Accordingly, as set forth in the Order below, we institute trial limited to resolving whether the subject matter of the challenged claims would have been obviousness over the asserted prior art.

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