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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROSELLINI SCIENTIFIC, LLC,
Petitioner,

v.

GRÜNENTHAL GMBH,
Patent Owner.

Case IPR2016-00471
Patent 7,994,364 B2

Before TONI R. SCHEINER, ZHENYU YANG, and TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Rosellini Scientific, LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–4 and 24–27 of U.S. Patent No. 7,994,364 B2 (Ex. 1001, "the '364 patent"). Paper 1 ("Pet."). Grünenthal GmbH ("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 not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–4 and 24–27 of the '364 patent. Accordingly, we decline to institute an *inter partes* review of those claims.

A. Related Proceedings

The parties identify several district court proceedings as relating to the '364 patent. Pet. 2; Paper 7, 1–2.

Patent Owner also identifies pending U.S. Patent Application No. 14/930,337, which claims benefit of priority to the application that issued as the '364 patent. Paper 7, 1.

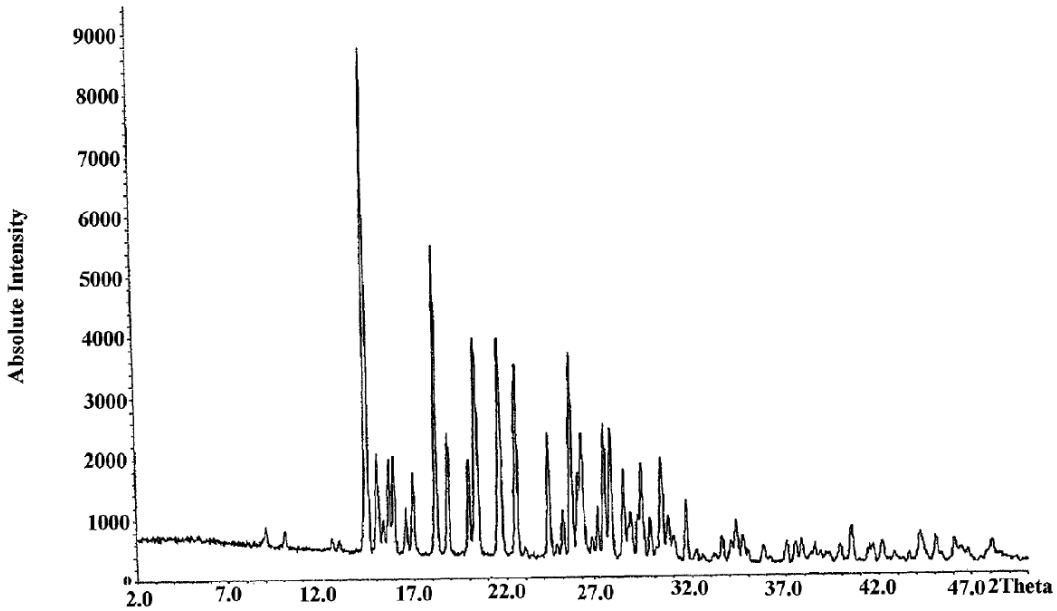
B. The '364 Patent

The '364 patent relates to solid crystalline forms of (−)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride ("tapentadol HCl") compounds, methods of producing the compounds, and related treatments. Ex. 1001, 1:21–24. The Specification states that tapentadol HCl can be produced in two different crystalline forms. *Id.* at

1:55–58. The present invention provides a new form (Form A) of the compound. *Id.* at 1:58–60. Form B was already known and obtained by the procedure described in Example 25 of U.S. Patent Nos. 6,248,737 and 6,344,558, as well as EP 693 475 B1. *Id.* at 1:61–63. According to the Specification, the new Form A "is very stable at ambient conditions and therefore useful for producing a pharmaceutical composition." *Id.* at 1:63–67.

The crystalline Form A can be identified by X-ray powder diffraction ("XRPD"). The XRPD pattern of Form A is shown in Figure 1, which is reproduced below:

Fig. 1: XRPD pattern of Form A



C. Illustrative Claim

Petitioner challenges claims 1–4 and 24–27 of the '364 patent, of which claims 1, 25, and 27 are independent claims. Claim 1 is representative and is reproduced below:

> 1. A crystalline Form A of (−)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride exhibiting at least X-ray lines (2-theta values) in a powder diffraction pattern when measured using CuK_{α} radiation at 15.1±0.2, 16.0±0.2, 18.9±0.2, 20.4±0.2, 22.5±0.2, 27.3±0.2, 29.3±0.2 and 30.4±0.2

Independent claim 25 recites a "solid pharmaceutical composition" comprising the crystalline Form A recited in claim 1, and independent claim 27 recites a "method of treating or inhibiting pain or urinary incontinence" comprising administering a pharmaceutically effective amount of the crystalline Form A recited in claim 1.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–4 and 24–27 of the '364 patent on the following grounds:

Reference	Basis	Claim(s) challenged
EP '475[1]	§ 102(b)	1–4 and 24–27
Bartholomäus[2]	§ 102(b)	1–4 and 24–27

[1] EP 0 693 475 A1, issued Jan. 24, 1996 (Ex. 1007). In this Decision, we cite to Exhibit 1006, the certified English translation of EP '475.
[2] Bartholomäus et al., WO 03/035053 A1, published May 1, 2003 (Ex. 1010). In this Decision, we cite to Exhibit 1009, the certified English translation of Bartholomaus.

Petitioner also relies on the testimony of William E. Mayo, Ph.D. (Ex. 1012) and Ron Bihovsky, Ph.D. (Ex. 1014).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had a "Ph.D. in fields relevant to small molecule drug development, such as biochemistry, medicinal chemistry, organic chemistry, or the equivalent." Pet. 17 (citing Ex. 1012 ¶ 26; Ex. 1014 ¶ 10). Patent Owner asserts a person of ordinary skill in the art would have had a bachelor's degree in chemistry, chemical engineering, or related disciplines, and "either (i) at least three years of experience related to organic synthesis, API manufacturing and formulation, or detection and/or evaluation of solid state forms in the pharmaceutical industry; or (ii) an advanced degree in chemistry, chemical engineering, or related disciplines." Prelim. Resp. 14. Patent Owner further asserts that an ordinary artisan would have had "working knowledge of the preparation, characterization, and analysis of solid state forms, including a working knowledge of crystallography." *Id.*

At this stage of the proceeding, we note that any difference in the levels of ordinary skill in the art asserted by the parties would not impact our Decision. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (holding the absence of specific findings on "level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown'") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

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