

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGILA SPECIALTIES INC. and MYLAN LABORATORIES LIMITED,
Petitioner,

v.

CEPHALON, INC.,
Patent Owner.

Case IPR2015-00503
Patent 8,436,190 B2

Before LINDA M. GAUDETTE, JACQUELINE WRIGHT BONILLA, and
ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Agila Specialties Inc. and Mylan Laboratories Limited (collectively, “Petitioner”) filed a Petition for an *inter partes* review of claims 1–9 of U.S. Patent No. 8,436,190 B2 (“the ’190 patent,” Ex. 1001). Paper 4 (“Pet.”). Cephalon, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1, 4, and 7, we institute an *inter partes* review of these claims. Petitioner, however, has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 2, 3, 5, 6, 8, and 9. Therefore, we deny the Petition regarding the challenges to those claims.

Related Proceedings

According to the parties, Patent Owner previously asserted the ’190 patent against Petitioner in *Cephalon, Inc. v. Agila Specialties Inc.*, Case No. 1:13-cv-02080 (D. Del.). Pet. 14; Paper 6, 2. Patent Owner also asserted the ’190 patent against several other entities in cases filed in district courts. Pet. 14–15; Paper 6, 1–3.

The ’190 Patent

The ’190 patent is directed to stable pharmaceutical compositions of nitrogen mustards, in particular, lyophilized bendamustine, which can be

used to treat various disease states, especially neoplastic diseases and autoimmune diseases. Ex. 1001, 2:66–3:3. According to the '190 patent, “the term ‘lyophilized powder’ or ‘lyophilized preparation’ refers to any solid material obtained by lyophilization, i.e., freeze-drying of an aqueous solution.” *Id.* at 9:1–3.

Bendamustine was first synthesized in East Germany in 1963. *Id.* at 1:50–51. At the time of the '190 patent invention, bendamustine was marketed in Germany under the name Ribomustin® to treat chronic lymphocytic leukemia, Hodgkin’s disease, non-Hodgkin’s lymphoma, multiple myeloma, and breast cancer. *Id.* at 1:53–57.

The '190 patent discloses stable pharmaceutical compositions prepared from bendamustine, in particular, “formulations for the lyophilization of bendamustine HCl.” *Id.* at 12:7–10. According to the '190 patent, the lyophilized powder obtained from such formulations is more easily reconstituted and has a better impurity profile than Ribomustin®. *Id.* at 12:10–16.

Illustrative Claim

Among the challenged claims, claim 1 is the sole independent claim.

It reads:

1. A pharmaceutical composition comprising bendamustine or bendamustine hydrochloride, mannitol, tertiary-butyl alcohol and water.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims	Basis	References
1–9	§ 103	The Rote Liste ¹ and Teagarden ²
1–9	§ 103	The Rote Liste, Teagarden, and Nuijen ³
7–9	§ 103	The Rote Liste, Teagarden, Nuijen, and Gust ⁴
4, 5, 7, and 8	§ 102	The Rote Liste

Patent Owner asserts January 14, 2005 as the priority date of the '190 patent. Prelim. Resp. 13. According to Petitioner, all asserted references are prior art under 35 U.S.C. § 102(b). Pet. 4–7.

In support of its patentability challenge, Petitioner relies on the Declaration of Dr. Raj Suryanarayanan. Ex. 1002.

¹ The Rote Liste 1996 (Ex. 1006, “the Rote Liste”).

² Teagarden and Baker, *Practical Aspects of Lyophilization Using Non-Aqueous Co-Solvent Systems*, 15 EUR. J. PHARM. SCI. 115–33 (2002) (Ex. 1007, “Teagarden”).

³ Nuijen et al., *Pharmaceutical Development of a Parenteral Lyophilized Formulation of the Novel Antitumor Agent Aplidine*, 54 PDA J. PHARM SCI. & TECH. 193–208 (2000) (Ex. 1008, “Nuijen”).

⁴ Gust and Krauser, *Investigations on the Stability of Bendamustin, a Cytostatic Agent of the Nitrogen Mustard Type, I. Synthesis, Isolation, and Characterization of Reference Substances*, 128 CHEMICAL MONTHLY 291–99 (1997) (Ex. 1009, “Gust”).

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner requests that we construe the term “made from.” Pet. 18–19. The term “made from” appears in claim 4, which reads, “[a] lyophilized pharmaceutical composition made from the pharmaceutical composition according to claim 1.” Petitioner argues that claim 4 and claims dependent therefrom are directed to lyophilized products, made from the process of lyophilizing the pharmaceutical composition of claim 1. *Id.* at 18. Thus, Petitioner asserts the term means “made from the process of lyophilizing.” *Id.* Patent Owner disagrees. Prelim. Resp. 19. According to Patent Owner, the plain language of the claim indicates that “made from” refers to the composition of claim 1, and not the process of lyophilizing. *Id.* We agree with Petitioner that claim 4 and claims dependent therefrom are product-by-process claims.

A product-by-process claim is “one in which the product is defined at least in part in terms of the method or process by which it is made.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 n. (1989). Claim

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