

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COMPLEX INNOVATIONS, LLC,  
Petitioner,

v.

ASTRAZENECA AB,  
Patent Owner.

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Case IPR2017-00631  
Patent 7,759,328 B2

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Before ERICA A. FRANKLIN, SUSAN L.C. MITCHELL, and  
ZHENYU YANG, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

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

## I. INTRODUCTION

Complex Innovations, LLC (“Petitioner”) filed a Petition (Paper 2; “Pet.”) to institute an *inter partes* review of claims 1–15 of US 7,759,328 B2 (Ex. 1001; “the ’328 patent”). Astrazeneca AB (“Patent Owner”) filed a Patent Owner Preliminary Response. Paper 9 (“Prelim. Resp.”). Upon request, we authorized Petitioner to file a Reply to Patent Owner’s Preliminary Response, and we authorized Patent Owner to file a Sur-Reply. Paper 10. Each of those authorized filings was limited to a discussion of the canister fill weights asserted by Petitioner’s declarant. Paper 11 (“Reply”) and Paper 12 (“Sur-Reply”).

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 consideration of the Petition and Preliminary Response, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. 35 U.S.C. § 314(a). Accordingly, we deny the Petition and decline to institute an *inter partes* review.

### A. *Related Proceedings*

The parties inform us that there are no pending proceedings concerning the ’328 patent. Pet. 13; Paper 3, 2.

*B. The '328 patent*

The '328 patent discloses pharmaceutical compositions comprising formoterol, budesonide, 1,1,1,2,3,3,3-heptafluoropropane (“HFA227”), polyvinylpyrrolidone (“PVP”), and polyethylene glycol (“PEG”), along with methods of using those formulations in the treatment of respiratory diseases. Ex. 1001, 1:14–17, 39–44. Formulations comprising formoterol and budesonide were known in the art at the time of the invention. *Id.* at 1:25–26. For example, such a combination has been marketed as Symbicort<sup>®</sup> in a dry powder inhaler. *Id.* at 1:26–28. The Specification states, however, that “[i]t has now been found that certain HFA formulations comprising formoterol and budesonide together with polyvinylpyrrolidone (PVP) and polyethylene glycol (PEG) exhibit excellent physical suspension stability.” *Id.* at 1:32–35.

*C. Illustrative Claims*

Claims 1 and 4 are illustrative of the challenges claims and are reproduced below:

1. A pharmaceutical composition comprising formoterol fumarate dehydrate, budesonide, 1,1,1,2,3,3,3-heptafluoropropane (HFA227), PVP K25 (polyvinyl pyrrolidone with a nominal K-value of 25), and PEG-1000 (polyethylene glycol with an average molecular weight of 1,000), wherein the formoterol fumarate dehydrate is present at a concentration of 0.09 mg/ml, the budesonide is present at a concentration in the range of 1 mg/ml to 8 mg/ml, the PVP K25 is present at a concentration of 0.01%w/w, and the PEG-1000 is present at a concentration of 0.3% w/w.

4. A method of treating symptoms of a respiratory disorder comprising administering to a patient the pharmaceutical composition according to claim 1, wherein the respiratory disorder is asthma, rhinitis, or chronic obstructive pulmonary disease (COPD).

*D. The Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 1–15 of the '328 patent on the following grounds:

Reference[s]	Basis	Claims challenged
Mistry <sup>1</sup>	§ 102	1, 4–15
Rogueda <sup>2</sup>	§ 102	1, 4–15
Mistry, Rogueda, and Carling <sup>3</sup>	§ 103(a)	1, 4–15
Mistry, Rogueda, Meade, <sup>4</sup> and Lewis <sup>5</sup>	§ 103(a)	2, 3

Petitioner also relies on the Declaration of Martin Beasley, Ph.D. (Ex. 1012).

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<sup>1</sup> Patent No. US 6,123,924 issued to Suresh N. Mistry et al., Sep. 26, 2000. Ex. 1003 (“Mistry”).

<sup>2</sup> Patent Application Publication No. WO 02/03958 A1 by Philippe Rogueda, published Jan. 17, 2002. Ex. 1004 (“Rogueda”).

<sup>3</sup> Patent No. US 5,674,860 issued to Christer Cari Gustav Carling et al., Oct. 7, 1997. Ex. 1005 (“Carling”).

<sup>4</sup> Patent Application Publication No. US 2003/0018019 A1 by Christopher J.M. Meade et al., published Jan. 23, 2003. Ex. 1007 (“Meade”).

<sup>5</sup> Patent No. US 8,142,763 issued to David Lewis et al., Mar. 27, 2012. Ex. 1008 (“Lewis”).

## II. ANALYSIS

### A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give 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 re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner asserts that “the plain and ordinary meaning should apply to all claims.” Pet. 26. Patent Owner agrees that “no claim terms require express construction.” Prelim. Resp. 1.

In view of our analysis, we determine that no claim terms require express construction for the purpose of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (Only terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

### B. Anticipation by Mistry

Petitioner asserts that Mistry anticipates claims 1 and 4–15. Pet. 28–36. Patent Owner disagrees. Prelim. Resp. 2–17.

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