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Paper No. 9
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CATALENT PHARMA SOLUTIONS, INC.
Petitioner,

v.

PATHEON SOFTGELS INC.,
Patent Owner.

Case No. IPR2018-00421
Patent 9,693,978 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

A. Background

Catalent Pharma Solutions, Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–38 of U.S. Patent No. 9,693,978 B2 (Ex. 1003, "the '978 patent"). Paper 2 ("Pet."). Patheon Softgels Inc. ("Patent Owner") filed a Preliminary Response contending that the Petition should be denied as to all the challenged claims. Paper 8 ("Prelim. Resp.").

We have authority under 37 C.F.R. § 42.4(a) and 35 U.S.C. § 314(a) to institute an *inter partes* review, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the arguments and the evidence presented, for the reasons described below, we determine that Petitioner has failed to demonstrate that there is a reasonable likelihood that it would prevail with respect to claims 1–38 challenged by the Petition. Accordingly, we decline to institute an *inter partes* review of claims 1–38 of the '978 patent.

B. Additional Proceedings

Petitioner represents that the '978 patent is at issue in *Patheon Softgels Inc. v. Apotex Inc. et al.*, No 3:17-cv-13819 (D.N.J.) and *Patheon Softgels Inc. v. Apotex Inc. et al.*, No. 1:18-cv-00003 (D. Del.). Petitioner also represents that a petition for *inter partes* review has been filed challenging related patent U.S. Patent No. 9,693,979 B2, which is now IPR2018-00422.

C. The '978 Patent (Ex. 1003)

The '978 patent, titled "SOLVENT SYSTEM FOR ENHANCING THE SOLUBILITY OF PHARMACEUTICAL AGENTS," purports to disclose oral pharmaceutical compositions comprising liquid dosage forms of sodium naproxen in soft gel capsules. Ex. 1003, (54), Abstract.

Softgel capsules using concentrated solutions are known in the art and often use polyethylene glycol as part of the solvent system. *Id.* at col. 1, ll. 58–65. Use of polyethylene glycol with certain pharmaceutical agents such as naproxen sodium, can lead to the formation of polyethylene glycol esters, which reduce the availability of the pharmaceutical agent. *Id.* at col. 2, ll. 25–30.

The specification of the '978 patent describes pharmaceutical compositions comprising the salt of one or more active agents such as naproxen and a de-ionizing agent. *Id.* at col. 2, ll. 41–44. The de-ionizing agent causes partial de-ionization of the salt of the active ingredient, which enhances bioavailability of the active agent and reduces the formation of polyethylene glycol esters. *Id.* at col. 2, ll. 45–49.

D. Illustrative Claim

Of the challenged claims, claims 1, 10, 18, 20, and 21 are independent. Claims 2–9 and 22–25 depend from claim 1; claims 11–17, 26, and 27 depend from claim 10; claims 19 and 28–30 depend from claim 18; claims 31–34 depend from claim 20; and claims 35–38 depend from claim 21. Claim 1 below is illustrative of the claimed subject matter and reads as follows:

> 1. A pharmaceutical composition comprising soft gelatin capsule comprising a fill material comprising:
> (a) a naproxen salt;

(b) about 5% lactic acid by weight of the fill material; and
(c) polyethylene glycol.

Ex. 1003, col. 9, ll. 63–67. The other independent clams, claims 10, 18, 20, and 21, are similar to claim 1 and include limitations regarding the amount of naproxen salt and polyethylene glycol that should be present and limitations calling for the presence of additional solubilizers. Ex. 1003, col. 10, ll. 30–32, 57–64, col. 11, ll. 1–17.

E. The Alleged Grounds of Unpatentability

Petitioner contends that the challenged claims of the '978 patent are unpatentable on the following grounds.[1]

References	Basis	Claims Challenged
Chen[2]	§ 102; § 103(a)	1–38
Kim[3]	§ 103(a)	1–38
Kim and Chen	§ 103(a)	1–38
Schoenhard[4]	§ 102; § 103(a)	1–38

[1] Petitioner supports its challenge with the Declaration of Peter Draper. Ex. 1001.
[2] Chen et al., US 6,383,471 B1; issued May 7, 2002 ("Chen") (Ex. 1009).
[3] Kim et al., US 2004/0157928 A1; published Aug. 12, 2004 ("Kim") (Ex. 1010).
[4] Schoenhard, US 2004/0224020 A1; published Nov. 11, 2004 ("Schoenhard") (Ex. 1011).

II. CLAIM CONSTRUCTION

A. Legal Standard

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given 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, the claim terms are generally given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning 'is the meaning that the term would have to a person of ordinary skill in the art in question.'" (Quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005))). Only terms that are in controversy need to be construed and only then to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Science & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

1. About 5%

Each of the claims includes the limitation that the composition comprise "about 5% lactic acid by weight of the fill material." *See, e.g.*, Ex. 1003, col. 9, l. 66.

Petitioner contends that the term "about 5% . . . by weight" should be interpreted as embracing the range of from 2 to 8%. Pet. 12–13. Petitioner argues that this range is supported by Examples 8–12 in the specification, which specify 0.24 to 0.35 mole equivalents of lactic acid per mole equivalent of sodium naproxen. Pet. 12–13. Petitioner contends that this mole equivalent range equals a range of from 2 to 8% by weight of the fill material. *Id.*

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