

IN THE 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 IPR2018-00421  
Patent 9,693,978

---

**PATENT OWNER'S PRELIMINARY RESPONSE  
UNDER 37 C.F.R. § 42.107(a)**

***Mail Stop "PATENT BOARD"***  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

## TABLE OF CONTENTS

I.	Introduction.....	1
II.	The Board should deny the petition because its grounds for unpatentability rely on a faulty and unreasonably broad claim construction.....	7
A.	The petition relies on an unreasonably broad and faulty construction of “about 5%.”.....	7
B.	The Petition relies on a flawed construction of “fill material.”.....	13
III.	Catalent has not articulated its reasons behind the multiple grounds asserted in the petition. ....	13
IV.	Ground 1: Catalent has not met its burden of establishing a reasonable likelihood that any of the challenged claims is anticipated by Chen or obvious in view of Chen.....	15
A.	The Petition fails to show that Chen anticipates any of the challenged claims.....	15
1.	Chen does not disclose all of the elements of the challenged claims, expressly or inherently. ....	15
2.	Chen does not disclose all the elements of the challenged claims, arranged as claimed.....	22
3.	Chen fails to disclose all the elements of the challenged claims, as evidenced by the Petition’s resort to additional references to purportedly meet the claim limitations. ....	26
4.	Catalent’s anticipation arguments for dependent claims also fail. ....	28
B.	The Petition fails to show that Chen renders obvious any of the challenged claims .....	30
1.	The Petition fails to explain why or how the artisan would have purportedly modified Chen to arrive at the compositions and methods as claimed. ....	31
2.	The Petition fails to explain why the artisan would have had a reasonable expectation of success.....	33
3.	The Petition fails to demonstrate that the claimed invention could have been generated through routine optimization.....	35
4.	The Petition fails to address previously asserted objective indicia of nonobviousness.....	36

V.	Ground 2: Catalent has not met its burden of establishing a reasonable likelihood that any of the challenged claims would have been obvious in view of Kim or in view of Kim and Chen. ....	42
A.	The Petition fails to show that Kim renders obvious any of the challenged claims. ....	42
1.	Kim does not disclose or suggest all the elements of the challenged claims. ....	43
2.	The Petition fails to explain why or how a skilled artisan would have modified Kim to arrive at the compositions as claimed. ....	44
3.	The Petition fails to show why a skilled artisan would have had a reasonable expectation of success. ....	49
4.	The Petition fails to demonstrate that the claimed invention could have been generated through routine optimization. ....	50
5.	Catalent’s obviousness arguments for dependent claims also fail. ....	50
B.	The Petition fails to show that Kim in view of Chen renders obvious any of the challenged claims. ....	51
C.	The Petition fails to address previously asserted objective indicia of nonobviousness. ....	51
VI.	Ground 3: Catalent has not met its burden of establishing a reasonable likelihood that any of the challenged claims are anticipated by Schoenhard or obvious in view of Schoenhard. ....	52
A.	The Petition fails to show that Schoenhard anticipates any of the challenged claims. ....	52
1.	Schoenhard does not disclose all the elements of the challenged claims. ....	53
2.	Schoenhard fails to disclose all the elements of the challenged claims, as evidenced by the Petition’s resort to additional references. ....	58
3.	Catalent’s anticipation arguments for dependent claims also fail. ....	59
B.	The Petition fails to show that Schoenhard renders obvious any of the challenged claims. ....	60

1.	The Petition fails to explain why or how the artisan would have purportedly modified Schoenhard to arrive at the compositions and methods as claimed. ....	60
2.	The Petition fails to explain why the artisan would have had a reasonable expectation of success.....	62
3.	The Petition fails to demonstrate that the claimed invention would have been generated through routine optimization.....	62
4.	The petition fails to address known objective indicia of nonobviousness. ....	63
VII.	Mr. Draper’s declaration provides biased and unsubstantiated testimony—the Board should accord it no weight. ....	64
VIII.	Conclusion .....	67

Patent Owner Patheon Softgels Inc. (“Patheon”) provides this Preliminary Response to the Petition for *inter partes* review (“IPR”) of claims 1-38 of U.S. Patent No. 9,693,978 (“the ’978 Patent”; EX1003) filed by Petitioner Catalent Pharma Solutions, Inc. (“Catalent”).

## I. Introduction

Catalent is attempting to knock out Patheon’s claims protecting novel and commercially successful naproxen formulations. But to even be instituted, a petition for *inter partes* review must meet its burden to establish a reasonable likelihood that it could prevail against at least one challenged claim—a requirement that Catalent’s petition fails to meet because it neither complies with the Board’s filing requirements under 37 C.F.R. § 42.104 nor addresses key elements of anticipation and obviousness necessary to prevail on the merits.

Catalent’s Petition fails to comply with the Board’s filing requirements on several levels. *First*, the Petition does not identify the challenged claims with particularity, but instead presents a vague and conclusory series of attorney arguments. *See* 37 C.F.R. § 42.104(b). *Second*, the grounds in the Petition each include an alternative argument, essentially doubling the number of asserted grounds, and the Petition fails to explain Catalent’s reasoning behind the multiple

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.