

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

ETON PHARMACEUTICALS, INC.,

Petitioner

v.

EXELA PHARMA SCIENCES, LLC,

Patent Owner

---

**U.S. PATENT NO. 10,478,453**

**DECLARATION OF BARRETT RABINOW**

## TABLE OF CONTENTS

I. INTRODUCTION.....	1
II. SUMMARY OF OPINIONS .....	1
III. BACKGROUND/QUALIFICATIONS .....	2
IV. DOCUMENTS AND MATERIALS CONSIDERED .....	4
V. LEGAL PRINCIPLES .....	5
VI. PERSON OF ORDINARY SKILL IN THE ART .....	8
VII. THE SCOPE & CONTENT OF THE PRIOR ART .....	9
A. L-Cysteine and Aluminum Toxicity.....	9
B. The Sandoz Label .....	12
C. Regulatory and Market Demand For Reducing Aluminum .....	16
D. L-Cysteine’s Known Oxygen Sensitivity.....	22
E. Other Impurities Including Heavy Metals.....	33
F. Optimizing The Sandoz L-Cysteine Product .....	34
VIII. THE ’453 PATENT .....	50
A. Summary.....	50
B. Prosecution History .....	56
IX. CLAIM CONSTRUCTION .....	63
X. CLAIMS 1-22 ARE UNPATENTABLE UNDER § 103.....	64
A. Claim 1 .....	65
B. Claim 2 .....	73

C. Claim 3 .....	74
D. Claim 4 .....	75
E. Claim 5 .....	75
F. Claim 6 .....	76
G. Claim 7 .....	77
H. Claim 8 .....	78
I. Claim 9 .....	82
J. Claim 10 .....	83
K. Claim 11 .....	83
L. Claim 12 .....	85
M. Claim 13 .....	85
N. Claim 14 .....	86
O. Claim 15 .....	87
P. Claim 16 .....	91
Q. Claim 17 .....	95
R. Claim 18 .....	99
S. Claim 19 .....	100
T. Claim 20 .....	101
U. Claim 21 .....	102
V. Claim 22 .....	107
XI. SECONDARY CONSIDERATIONS.....	111

XII. CONCLUSION.....112

## **I. INTRODUCTION**

1. My name is Barrett Rabinow. My findings, as set forth herein, are based on my education and background in the fields discussed below.

2. I have been retained by, and submit this Declaration on behalf of, Eton Pharmaceuticals, Inc. (“Eton” or “Petitioner”), which I understand is challenging the validity of claims 1-22 of U.S. Patent No. 10,478,453 (“’453 patent”) in a petition for post grant review (“PGR”). I have been asked to offer opinions generally regarding the prior art, the understandings of the person of ordinary skill in the art, and whether claims 1-22 would have been obvious to the person of ordinary skill in the art. I reserve the right to supplement this Declaration in response to additional evidence that may come to light or that I am asked to consider.

3. I am being compensated for my time in connection with this PGR at my standard consulting rate of \$350 per hour. My compensation is not affected by the substance of my opinions or the outcome of this matter.

## **II. SUMMARY OF OPINIONS**

4. The ’453 patent issued with twenty-two claims. Claims 1-14 and 21, respectively, are directed to an L-Cysteine composition and a method for making such a composition. Claims 15-20 and 22, respectively, are directed to a total parenteral nutrition composition comprising an L-Cysteine composition admixed with an amino acid composition and method for preparing the same. Claims 1-22

# 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.