IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

ADAMIS PHARMACEUTICALS CORPORATION Petitioner

v.

BELCHER PHARMACEUTICALS, LLC
Patent Owner

CASE: IPR2019-01021 U.S. PATENT NO. 9,283,197

PETITION FOR INTER PARTES REVIEW

Mail Stop PATENT BOARD

Patent Trial and Appeal Board United States Patent and Trademark Office PO Box 1450 Alexandria, Virginia 22313–1450



Petition for Inter Partes Review of U.S. Patent No. 9,283,197

Table of Contents

		Page
I.	INTRODUCTION	1
II.	OVERVIEW OF THE TECHNOLOGY	2
A.	. Epinephrine Compound	2
В.	Epinephrine Injection Formulations	3
C.	. Racemization and Oxidation Processes	5
D.	. Adrenalone and Other Impurities	7
III.	U.S. PATENT NO. 9,283,197	8
A	. '197 Patent Overview	8
В.	Prosecution History of the '197 Patent	9
IV.	GROUNDS FOR STANDING (37 C.F.R. §42.104(a))	11
V.	PAYMENT OF FEES (37 C.F.R. §§42.15 AND 42.103)	11
VI.	MANDATORY NOTICES (37 C.F.R. §42.8)	11
A	. Real Parties-In-Interest	11
В.	. Related Matters	11
C.	. Lead and Backup Counsel and Service	12
D.	. The Petition Relies on Previously Unapplied Prior Art	12
VII.	PERSON OF ORDINARY SKILL IN THE ART	14
VIII	CLAIM CONSTRUCTION	15
IX.	STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. §§42.22(a) AND 42.104(b))	



1

A.	Ground 1: Claim 6 is Unpatentable Under 35 U.S.C. §102 as
	Anticipated by Stepensky18
1.	Overview of the Prior Art of Ground 118
8	. Stepensky18
2.	Claim 6
a	. Preamble 21
ŀ	said liquid pharmaceutical formulation having a pH between 2.8 and 3.321
C	said injectable liquid pharmaceutical formulation compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine, and further including a tonicity agent
Ċ	said liquid pharmaceutical formulation including no more than about 6% d-epinephrine and no more than about 0.5% adrenalone at release
e	said liquid pharmaceutical formulation including no more than about 12% d-epinephrine and no more than about 0.5% adrenalone over a shelf-life of at least 12 months24
	Ground 2: The Challenged Claims are Unpatentable Under 35 U.S.C. §103 Over <i>Stepensky</i> in view of <i>USP</i> 25
1.	Overview of the Prior Art of Ground 225
8	. Stepensky25
k	. <i>USP</i> 25
C	. The Combination of Stepensky and USP26
2.	Claim 6
	Programble



b.	said liquid pharmaceutical formulation having a pH between 2.8
	and 3.328
c.	said injectable liquid pharmaceutical formulation compounded in
	an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine, and further
	including a tonicity agent29
d.	said liquid pharmaceutical formulation including no more than
	about 6% d-epinephrine and no more than about 0.5% adrenalone
	at release30
e.	said liquid pharmaceutical formulation including no more than
	about 12% d-epinephrine and no more than about 0.5% adrenalone
	over a shelf-life of at least 12 months30
3.	Claim 7 31
a.	The said injectable liquid pharmaceutical formulation of claim 6
	further having a concentration of 1 mg per mL l-epinephrine31
C. G	round 3: The Challenged Claims are Unpatentable Under 35 U.S.C.
	103 Over Stepensky in View of Gupta32
1.	Overview of the Prior Art of Ground 3
a.	<i>Gupta</i> 32
	•
b.	The Combination of Stepensky and Gupta35
2.	Claim 6 36
a.	Preamble 36
b.	said liquid pharmaceutical formulation having a pH between 2.8
	and 3.337
c.	said injectable liquid pharmaceutical formulation compounded in
•	an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine, and further
	including a tonicity agent 37



d	said liquid pharmaceutical formulation including no more than
	about 6% d-epinephrine and no more than about 0.5% adrenalone at release38
e	. said liquid pharmaceutical formulation including no more than
	about 12% d-epinephrine and no more than about 0.5% adrenalone
	over a shelf-life of at least 12 months39
3.	Claim 7
a	. The said injectable liquid pharmaceutical formulation of claim 6
	further having a concentration of 1 mg per mL l-epinephrine40
D. (Ground 4: the Challenged Claims are Unpatentable Under 35 U.S.C.
	§103 Over <i>Bruss</i> in View of <i>USP</i> and <i>Fyllingen</i>
1.	Overview of the Prior Art of Ground 441
a	. Bruss
b	. <i>USP</i>
c	. Fyllingen
d	The Combination of <i>Bruss</i> in view of <i>USP</i> and <i>Fyllingen</i>
2.	Claim 6 44
a	. Preamble44
b	said liquid pharmaceutical formulation having a pH between 2.8
	and 3.345
c	. said injectable liquid pharmaceutical formulation compounded in
	an aqueous solution as 1.0 to 1.06 mg/mL l -epinephrine, and further
	including a tonicity agent46
d	said liquid pharmaceutical formulation including no more than
	about 6% d-epinephrine and no more than about 0.5% adrenalone
	at release



DOCKET

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.

