UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Coalition For Affordable Drugs XI LLC, Petitioner

V.

Insys Pharma, Inc., Patent Owner

U.S. Patent 8,486,972

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,486,972 AND MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

Mailed August 24, 2015



TABLE OF CONTENTS

<u>NO</u>	TICE OF RELATED MATTERS	3
<u>NO</u>	TICE OF SERVICE INFORMATION	3
<u>GR</u>	OUNDS FOR STANDING	3
STA	ATEMENT OF PRECISE RELIEF REQUESTED	3
STA	ATEMENT OF REASONS FOR RELIEF REQUESTED.	6
II.	THE CLAIMS UNDER CONSIDERATION	8
III.	THE '972 PATENT AND PROSECUTION HISTORY OF THE '972 PATENT	9
IV.	CLAIM CONSTRUCTION	23
A.	"MEAN TIME TO MAXIMUM PLASMA CONCENTRATION (T _{MAX}) OF FENTANYL OF FROM ABOUT 5 TO ABOUT 120 MINUTES"	23
B.	"DISCRETE LIQUID DROPLETS"	25
V.	LEVEL OF SKILL IN THE ART	26
VI.	CLAIMS 1-3 ARE OBVIOUS	26
<u>A.</u>	GROUND 1 CLAIMS 1 AND 3 ARE UNPATENTABLE AS OBVIOUS OVER ROSS GB, IN VIEW OF ROSS US2006, AND THE '862 PATENT	27
1.	INDEPENDENT CLAIM 1	27
A.	UNIT DOSE	28
В.	NON-PROPELLANT	28
<i>C</i> .	SUBLINGUAL FENTANYL FORMULATION COMPRISING DISCRETE LIQUID DROPLETS	28
D.	AN EFFECTIVE AMOUNT OF FENTANYL	29
E .	A PHARMACEUTICALLY ACCEPTABLE LIQUID CARRIER	29
F.	WHEREIN THE SUBLINGUAL FENTANYL FORMULATION COMPRISES: FROM ABOUT 0.1% TO ABOUT 0.8% BY WEIGHT OF FENTANYL OR A PHARMACEUTICALLY ACCEPTABLE SALT THEREOF	30
G.	THE SUBLINGUAL FENTANYL FORMULATION COMPRISES FROM ABOUT 20% TO ABOUT 60% BY WEIGHT OF ETHANOL	31



Н.	THE SUBLINGUAL FENTANYL FORMULATION COMPRISES FROM ABOUT 4% TO ABOUT 6% BY WEIGHT OF PROPYLENE GLYCOL	31
I.	SUBLINGUAL ADMINISTRATION TO A HUMAN	34
J.	SAID SUBLINGUAL FENTANYL FORMULATION PROVIDES A MEAN TIME TO MAXIMUM PLASMA CONCENTRATION (TMAX) OF FENTANYL OF FROM ABOUT 5 TO ABOUT 120 MINUTES	34
3.	DEPENDENT CLAIM 3	37
<i>A</i> .	AFTER SUBLINGUAL ADMINISTRATION TO A HUMAN, THE SUBLINGUAL FENTANYL FORMULATION PROVIDES A MEAN TIME TO MAXIMUM PLASMA CONCENTRATION (T _{MAX}) OF FENTANYL OF FROM ABOUT 10 TO ABOUT 60 MINUTES.	38
<u>B.</u>	GROUND 2 CLAIM 2 IS UNPATENTABLE AS OBVIOUS OVER ROSS GB, IN VIEW OF ROSS US2006, THE '862 PATENT, AND THE '496 PUBLICATION	40
1.	DEPENDENT CLAIM 2	40
2.	THE PRIOR ART AND ITS COMPARISON TO CLAIM 2	40
<i>A</i> .	SAID DISCRETE LIQUID DROPLETS HAVE A SIZE DISTRIBUTION OF FROM ABOUT 10 μM TO ABOUT 200 μM.	41
<u>C.</u>	THE PATENT OWNER'S ARGUMENT FOR SECONDARY CONSIDERATIONS SET FORTH IN THE PROSECUTION FILE HISTORY ARE MISLEADING AND WRONG	43
1.	PATENT OWNER'S ARGUMENT FOR SECONDARY CONSIDERATIONS IS NOT COMMENSURATE WITH THE SCOPE OF THE CLAIMS	44
2.	A FAST ONSET OF FIVE MINUTES WAS NOT UNEXPECTED BECAUSE A COMMERCIAL FENTANYL NASAL SPRAY ACHIEVED A FIVE MINUTES ONSET EFFECT	47
3.	A FAST ONSET OF FIVE MINUTES WAS NOT UNEXPECTED BECAUSE OTHER PRIOR ART REFERENCES REPORTED EFFICACIOUS PAIN RELIEF AT FIVE MINUTES OR LESS	50
4.	A PRIOR ART FENTANYL NASAL SPRAY ACHIEVED A BLOOD CONCENTRATION FIVE MINUTES POST ADMINISTRATION THAT WAS HIGHER THAN THE CONCENTRATION OF THE CLAIMED INVENTION WITH THE SAME DOSAGE	52
1711	CONCLUSION	33 55
VII	CADINGLADATORI	רר



TABLE OF AUTHORITIES

0.1.0.2.0	
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007)	26, 27
In re Cuozzo Speed Techs., LLC, No. 2014-1301, 2015 U.S. App.	LEXIS 1699,
Slip. Op. at 21 (Fed. Cir. Feb. 4, 2015)	23
Alcon Research, Ltd. v. Apotex Inc., 687 F.3d 1362, 1369 (Fed.	Cir. 2012),
cert denied, 133 S. Ct. 1736 (2013))	27

RULES

CASES

37 C.F.R § 42.8(b)(1)	1
37 C.F.R. § 42.100(b)	23



Coalition For Affordable Drugs XI LLC ("CFAD" or "Petitioner") requests *inter partes* review of claims 1 - 3 of U.S. Patent No. 8,486,972 ("the '972 Patent") (Exhibit 1001) assigned to Insys Pharma, Inc. ("Insys").

NOTICE OF LEAD AND BACKUP COUNSEL

Lead Counsel:	Backup Counsel:
Dr. Gregory J. Gonsalves	Christopher Casieri
Reg. No. 43,639	McNeely, Hare & War LLP
2216 Beacon Lane	12 Roszel Road, Suite C104
Falls Church, VA 22043	Princeton, NJ 08540
(571) 419-7252	Phone: 609 731 3668
gonsalves@gonsalveslawfirm.com	chris@miplaw.com

NOTICE OF EACH REAL-PARTY-IN-INTEREST

Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner certifies that Coalition For Affordable Drugs XI LLC ("CFAD"), Hayman Credes Master Fund, L.P. ("Credes"), Hayman Orange Fund SPC – Portfolio A ("HOF"), Hayman Capital Master Fund, L.P. ("HCMF"), Hayman Capital Management, L.P. ("HCM"), Hayman Offshore Management, Inc. ("HOM"), Hayman Investments, L.L.C. ("HI"), nXn Partners, LLC ("nXnP"), IP Navigation Group, LLC ("IPNav"), J Kyle Bass, and Erich Spangenberg are the real parties in interest (collectively, "RPI"). The RPI hereby certify the following information: CFAD is a wholly owned



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.

