

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2019-00688
U.S. Patent No. 9,468,747

PATENT OWNERS' SURREPLY

TABLE OF CONTENTS

I. Nalox-1 Has Not Met Its Burden As To BZK.....2
A. The POSA Would Recognize That BZK Could Cause Naloxone Degradation.3
B. Wyse Discourages Using BZK With Naloxone.....5
C. Nalox-1 Offers No Plausible Reason *To* Use BZK, And Other Art Also Discourages It.....6
D. The POSA Had No Reason To Conduct Further Testing To Investigate The “Root Cause” Of Wyse’s Degradation.....8
II. The “Preservative” Limitations Are Non-Obvious.11
III. It Would Not Be Obvious To Select And Combine The Claim Elements.11
IV. The Claimed 4 Milligram Dose Is Non-Obvious.12
A. Dr. Hochhaus Is Unqualified To Address Clinical Motivations.....13
B. Wyse Does Not Teach A 4 Milligram Dose.14
C. Wyse Teaches Away From “High and Fast” Doses.15
D. Nalox-1’s Pharmacokinetics Arguments Are Flawed.....17
E. Nalox-1’s New Motivations Do Not Support Obviousness.....19
V. Objective Indicia Confirm Non-Obviousness.22
A. Failure of Others, Skepticism, Copying22
B. Unexpected Properties.....24
C. Praise, Commercial Success, Long-Felt Need27
VI. Conclusion28

TABLE OF AUTHORITIES

CASES

Allergan, Inc. v. Sandoz Inc.,
796 F.3d 1293 (Fed. Cir. 2015)15

Bayer Schering Pharma AG v. Barr Labs., Inc.,
575 F.3d 1341 (Fed. Cir. 2009)10

Bone Care Int’l, LLC v. Roxane Labs, Inc.,
2012 WL 2126896 (D. Del. June 11, 2012)10

Daubert v. Merrell Dow Pharms., Inc.,
509 U.S. 579 (1993).....14

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.,
567 F.3d 1314 (Fed. Cir. 2009)16

Henny Penny Corp. v. Frymaster LLC,
938 F.3d 1324 (Fed. Cir. 2019)19

In re Armodafinil Patent Litig.,
939 F. Supp. 2d 456 (D. Del. 2013).....9

In re Fulton,
391 F.3d 1195 (Fed. Cir. 2004)5

In re Gurley,
27 F.3d 551 (Fed. Cir. 1994)6

Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.,
821 F.3d 1359 (Fed. Cir. 2016)3, 19

Juniper Networks, Inc. v. Chrimar Sys., Inc.,
2017 WL 6549892 (P.T.A.B. Dec. 20, 2017).....23

KSR Int’l Co. v. Teleflex Inc.,
550 U.S. 398 (2007).....10, 12

Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH,
139 F.3d 877 (Fed. Cir. 1998)23

Skky, Inc. v. MindGeek, s.a.r.l.,
859 F.3d 1014 (Fed. Cir. 2017)14

WBIP, LLC v. Kohler Co.,
829 F.3d 1317 (Fed. Cir. 2016)28

Nalox-1's Reply introduces brand-new theories that it claims, without a hint of irony, support obviousness, even though it took Nalox-1 over a year to arrive at them. Nalox-1's new theories fare no better than its old ones. The Board should reject them all.

Particularly astonishing is how frequently Nalox-1 sets about trying to discredit its own references. An obviousness case should have the POSA follow the teachings of its references. Here, at every turn, Nalox-1 would have the POSA read Wyse and HPE and do precisely what they instruct *not* to do—try to achieve high and fast naloxone levels, use BZK, and combine it with EDTA.

In reply, Nalox-1 attempts to discredit Wyse's BZK teachings based on a new and incorrect theory that BZK "could not cause the naloxone degradation reported in Wyse." Reply 2. Wyse did not conclude that, and Nalox-1's evidence does not support it. Nalox-1's expert contends only that BZK cannot "directly" react with naloxone to form a particular naloxone degradant—a far cry from Nalox-1's blanket assertion of impossibility. And the POSA would know that BZK could *indirectly* cause degradation.

Nalox-1 also claims for the first time that the POSA would ignore Wyse and undertake extensive testing to find some alternate "root cause" of the degradation—one Nalox-1 is glaringly unable to identify. Nalox-1's suggestion that the POSA would try to pull BZK from the reject pile is hindsight at its worst.

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