

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.,
Patent Owner

IPR2019-00694
U.S. Patent No. 9,629,965

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,629,965
AS OBVIOUS OVER WYSE**

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A. “pre-primed”24

B. “patient”25

C. “delivery time”25

D. “90% confidence interval for dose delivered per actuation is ± about 2.0%” and “95% confidence interval for dose delivered per actuation is ± about 2.5%”25

E. “yields, when intranasally administered to a patient, a mean naloxone plasma concentration” and “yields a mean naloxone plasma concentration... in said patient”26

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11. Claim 2545

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1. Claim 2347

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TABLE OF EXHIBITS

| Exhibit Number | Description |
|-----------------------|---|
| Nalox1001 | U.S. Patent No. 9,629,965 (the '965 patent) |
| Nalox1002 | Expert Declaration of Maureen Donovan |
| Nalox1003 | Expert Declaration of Günther Hochhaus |
| Nalox1004 | Excerpt of File History of U.S. Patent No. 9,561,177, Aug. 22, 2016 Office Action, Non-Final Rejection (Aug. 22, 2016 Non-Final Rejection) |
| Nalox1005 | Excerpt of File History of U.S. Patent No. 9,561,177, Oct. 21, 2016 Amendment and Response to Office Action (Oct. 21, 2016 Response to Office Action) |
| Nalox1006 | Excerpt of File History of U.S. Patent No. 9,561,177, Dec. 21, 2016 Office Action, Notice of Allowance and Fees Due (Notice of Allowance) |
| Nalox1007 | U.S. Patent No. 9,192,570 (Wyse) |
| Nalox1008 | Chinese Patent No. 1,575,795 (Wang) |
| Nalox1009 | PCT International App. Pub. No. WO00/62757 (Davies) |
| Nalox1010 | Djupesland, P., <i>Nasal Drug Delivery Device: Characteristics and Performance in a Clinical Perspective - A Review</i> , 3 Drug Deliv. & Transl. Res. 42–62 (2013) (Djupesland) |
| Nalox1011 | Grassin-Delyle, S. et al., <i>Intranasal Drug Delivery: An Efficient and Non-invasive Route for Systemic Administration, Focus on Opioids</i> , 134 Pharm. & Ther. 366–79 (2012) (Grassin-Delyle) |
| Nalox1012 | Handbook of Pharmaceutical Excipients, 56–60, 64–66, 78–81, 220–22, 242–44, 270–72, 441–45, 517–22, 596–98 (Rowe, R. et al. eds., 6th ed. 2009) (HPE) |
| Nalox1013 | Kushwaha, S. et al., <i>Advances in Nasal Trans-Mucosal Drug Delivery</i> , (1)7 J. Applied Pharm. Sci. 21–28 (2011) (Kushwaha) |
| Nalox1014 | U.S. Patent No. 5,866,154 (Bahal) |
| Nalox1015 | U.S. Patent No. 8,198,291 (the '291 patent) |

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