Paper 1 Filed: February 19, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC, Petitioner,

v.

OPIANT PHARMACEUTICALS, INC.
Patent Owner

IPR2019-00687 U.S. Patent No. 9,211,253

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,211,253
AS OBVIOUS OVER DAVIES



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| A. Nal | A POSA Would Have Been Motivated to Develop Improved Intranasa oxone Formulations to Combat the Opioid Epidemic | |
| B. Intr | A POSA Would Have Had the Know-How to Readily Develop an Improved an analy Naloxone Formulation | |
| 1 n | . The volume of the nasal cavity naturally limits the volume of a naloxon asal spray to about 100 μL per spray1 | |
| 2 a | . A POSA would have been motivated to use a 4-6 mg naloxone dose to chieve desirable naloxone exposure levels | |



| 3. A POSA would have had adequate know-how and ability to select commonplace excipients to make a stable, well-tolerated intranasal naloxon formulation |
|--|
| 4. A POSA would have been motivated to load an intranasal naloxon formulation into an easy-to-use single-dose, pre-primed nasal sprayer2 |
| VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(b)(3)2 |
| A. "pre-primed"2 |
| B. "patient" |
| C. "delivery time" |
| 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%"2 |
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| 2. Claim 2 |
| 3. Claim 3 |
| 4. Claim 44 |
| 5. Claim 16 |
| 6. Claims 17 and 184 |
| 7. Claim 194 |
| 8. Claims 20–23 |
| 9. Claim 244 |
| B. Ground 2: Claims 28 and 29 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Wys (Nalox1007) |



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| C. Ground 3: Claims 5–7 and 10–14 are obvious over Davies (Nalox1009) in view of HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), and Djupesland (Nalox1010) | | | |
|---|--|--|--|
| 1. Claim 5 | | | |
| 2. Claim 6 | | | |
| 3. Claim 749 | | | |
| 4. Claims 10 and 11 | | | |
| 5. Claims 12–1450 | | | |
| D. Ground 4: Claims 8 and 9 are obvious over Davies (Nalox1009), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), Djupesland (Nalox1010), and the '291 Patent (Nalox1015) | | | |
| E. Ground 5: Claims 25–27 are obvious over Davies (Nalox1009), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013), Djupesland (Nalox1010), and Wyse (Nalox1007) | | | |
| F. Ground 6: Claim 15 is obvious over Davies (Nalox1009) in view of Djupesland (Nalox1010), HPE (Nalox1012), Bahal (Nalox1014), Kushwaha (Nalox1013) and Wyse (Nalox1007) or Wermeling 2013 (Nalox1016) or Wang (Nalox1008) and Pharmacologist POSA Knowledge | | | |
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TABLE OF EXHIBITS

| Exhibit No. | Description |
|-------------|---|
| Nalox1001 | U.S. Patent No. 9,211,253 (the '253 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., Advances in Nasal Trans-Mucosal Drug Delivery, (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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