

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 Owner.

---

Case IPR2019-00685  
U.S. Patent 9,211,253

---

**PATENT OWNER'S OBJECTIONS TO EVIDENCE SUBMITTED BY  
PETITIONER IN SUPPORT OF REPLY**

Pursuant to 37 C.F.R. § 42.64, Patent Owners Adapt Pharma Operations Limited and Opiant Pharmaceuticals, Inc. submit the following objections to the exhibits submitted by Petitioner Nalox-1 Pharmaceuticals, LLC in support of its reply filed March 12, 2020.

**Exhibit 1201** is or purports to be a Supplemental Declaration of Maureen Donovan, Ph.D. Patent Owners object to **Exhibit 1201** under FRE 401, 402, and 403 as irrelevant. Patent Owners further object to **Exhibit 1201** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b), including for example in paragraphs 12–18, 20, 22, 24–25, 28, and 30–31 (including their accompanying footnotes).

**Exhibit 1202** is or purports to be a Supplemental Declaration of Günter Hochhaus, Ph.D. Patent Owners object to **Exhibit 1202** under FRE 401, 402, and 403 as irrelevant. Patent Owners further object to **Exhibit 1202** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b), including for example in paragraphs 19–25, 29–31, 34–40, and 42–44 (including their accompanying footnotes). In addition, Patent Owners object under FRE 401, 402, 403, 702 and 703 and 21 C.F.R. § 42.65(a)–(b) for failure to disclose the underlying facts and data on which Dr.

Hochhaus based his “simulations,” “model[s],” and/or “calcula[tions]” or to provide the required affidavit and information in support thereof, including for example in paragraphs 19, 31, 34–35, 49, 51, 53–54 (including their accompanying footnotes). Patent Owners further object under FRE 401, 402, 403, 701, 702, and 703 because Dr. Hochhaus is not qualified to offer opinions about the clinical practice of administering naloxone to treat opioid overdose and does not have personal experience doing so, including for example in paragraphs 21–22, 27–28 (including their accompanying footnotes).

Patent Owners object to **Exhibit 1203** under FRE 401, 402, 403, and 901 as irrelevant (including because it is not prior art) and not authenticated. Patent Owners further object to **Exhibit 1203** as not responsive to the arguments and evidence cited in the Patent Owner’s Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1204** under FRE 401, 402, and 403 as irrelevant. Patent Owners further object to **Exhibit 1204** as not responsive to the arguments and evidence cited in the Patent Owner’s Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1206** under FRE 401, 402, and 403 as irrelevant (including because it is not prior art). Patent Owners further object to **Exhibit 1206** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1207** under FRE 401, 402, and 403 as irrelevant. Patent Owners further object to **Exhibit 1207** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1208** under FRE 106, 401, 402, 403, and 901 as incomplete, irrelevant, and not authenticated. Patent Owners further object to **Exhibit 1208** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1210** under FRE 106, 401, 402, 403, and 901 as incomplete, irrelevant, and not authenticated. Patent Owners further object to **Exhibit 1210** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1211** under FRE 401, 402, 403, 801, 802, 805, and 901 as irrelevant (including because it is not prior art), inadmissible hearsay, and not authenticated. Patent Owners further object to **Exhibit 1211** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1213** under FRE 401, 402, and 403 as irrelevant. Patent Owners further object to **Exhibit 1213** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1214** under FRE 106, 401, 402, 403, and 901 as incomplete, irrelevant, and not authenticated. Patent Owners further object to **Exhibit 1214** as not responsive to the arguments and evidence cited in the Patent Owner's Response and/or an improper attempt to present new evidence that could have been presented earlier in violation of, *e.g.*, 37 C.F.R. § 42.23(b).

Patent Owners object to **Exhibit 1215** under FRE 106, 401, 402, 403, and 901 as incomplete, irrelevant, and not authenticated. Patent Owners further object to **Exhibit 1215** as not responsive to the arguments and evidence cited in the

# 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.