

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 IPR2019-00694
U.S. Patent 9,629,965

**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

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