

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00481
U.S. Patent No. 8,377,903

**PATENT OWNER'S OBJECTIONS TO EVIDENCE FILED AND SERVED
WITH PETITIONER'S REPLY PURSUANT TO 37 C.F.R. § 42.64**

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply

Pursuant to 37 C.F.R. § 42.64, Patent Owner submits the following objections to evidence filed and served with Petitioner's Reply ("Reply"). Patent Owner's objections apply equally to Petitioner's reliance on these exhibits in any subsequently filed documents. These objections are timely, having been filed within five business days of service of evidence to which the objection is directed (April 5, 2024).

Exhibit 1084 (Second Declaration of Aaron E. Miller, M.D.).

Patent Owner objects to Exhibit 1084 as misleading, incomplete, lacking relevance, and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106 and 401-403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 10, 18, 27-35, 62, 93, and 124-125 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of the '903 patent;
- ¶¶ 7, 9, 12-14, 16, 21-35, 49-50, 53-55, 59, 61-64, 66-67, 69, 72-74, 76, 78, 80-83, 86, 89-91, 97, 99-102, 104-119, 121-130, and 132-133 as misleading,

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply

incomplete, and irrelevant because they lack support for the contentions for which they are cited;

- ¶¶ 8, 10-11, 15, 17-19, 51-52, 56-58, 60, 65, 68, 70-71, 75, 77, 79, 84-85, 87-88, 92-96, 98, 103, 120, and 131 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of Bodor and Stelmasiak;
- ¶¶ 7-15, 17-19, 22-26, 29-31, 50-55, 57-58, 60, 62-97, 102, 104-115, 117, 119-127, and 129-133 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Lublin;
- ¶¶ 8, 15, 17, 58, 60, 63-65, 91, and 94 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Meibohm;
- ¶¶ 8 and 58 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and/or improperly characterize the testimony and opinions of Dr. Bodor; and
- ¶¶ 16, 18, and 91-93 as irrelevant because these paragraphs refer to art not relied upon in the Grounds at issue in this inter partes review. Further, any probative value of these paragraphs is substantially outweighed by the

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply

danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence.

Patent Owner further objects to ¶¶ 7-19, 21-35, and 49-133 as not being based on sufficient facts or data, the product of reliable principles and methods, and/or not reflecting a reliable application of the principles and methods to the facts. *See* Fed. R. Evid. 702-703.

Patent Owner further objects to ¶¶ 9, 21, and 49, because these paragraphs are not directly cited in the Reply and the relevance of these paragraphs is not apparent. *See* Fed. R. Evid. 401-402. Petitioner includes two citations in the Reply to all paragraphs in Exhibit 1084. *See* Reply, 18 (citing “EX1084, ¶¶1-133” for the assertion that “Merck’s remaining arguments also fail”), 23 (citing “EX1084, ¶¶1-133” for the assertion that “Merck’s other arguments” should be rejected). This does not moot Patent Owner’s objection to ¶¶ 9, 21, and 49 because Petitioner’s wholesale citation to every paragraph in Dr. Miller’s second declaration amounts to improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3); *see also Instrumentation Lab. Co. v. HemoSonics LLC*, IPR2017-00855, Paper 55 at 22-23 (P.T.A.B. Feb. 13, 2019) (declining to consider paragraphs of declaration “merely because they are cited in the Petition”).

Patent Owner's Objections to Evidence Filed and Served with Petitioner's Reply

Patent Owner further objects to ¶ 23, n.1, which cites to an exhibit that is not cited in the Reply, as irrelevant. *See* Fed. R. Evid. 402.

Patent Owner further objects to paragraphs that cite to Exhibit 1080 for the same reasons Patent Owner objects to Exhibit 1080 as discussed below.

Exhibit 1080 (Declaration of Rodolfo Pinal, Ph.D.).

Patent Owner objects to Exhibit 1080 as misleading, incomplete, lacking relevance, and because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the fact finder, undue delay, wasting time, and/or needlessly presenting cumulative evidence. *See* Fed. R. Evid. 106 and 401-403. Patent Owner also objects to the extent the content of the declaration is not discussed in the Reply and represents an improper incorporation by reference to impermissibly expand the page limit for the Reply. *See* 37 C.F.R. § 42.6(a)(3). In particular, Patent Owner objects to:

- ¶¶ 14-15, 20, 22, 27-44, 46-49, 51-52, 55, 59, 62-63, 66-68, 70, 74-75, 78-79, 82-83 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited;
- ¶¶ 16-19, 45, 50, 53-54, 56-58, 60-61, 64-65, 69, 71-73, 76-77, and 80-81 as misleading, incomplete, and irrelevant because they lack support for the contentions for which they are cited and improperly characterize the teachings of Bodor and Stelmasiak;

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.