

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner.

Case IPR2020-00770
Patent 9,604,901

**PATENT OWNER'S OBJECTIONS TO PETITIONER'S EVIDENCE
SUBMITTED WITH PETITION**

Patent Owner United Therapeutics Corporation (“Patent Owner”) hereby objects to the admissibility of certain evidence cited in support of the Petition for *Inter Partes* Review filed on March 30, 2020 (“Petition”). Patent Owner’s objections are based on the Federal Rules of Evidence (“FRE”), relevant case law, federal statute, and the Patent Trial and Appeal Board (“PTAB”) Rules. Patent Owner’s objections are set forth with particularity below.

EXHIBIT 1002

Exhibit 1002 is described as “Declaration of Jeffrey D. Winkler, Ph.D.” Patent Owner objects to Exhibit 1002, under FRE 701, because the opinion testimony contained in this exhibit reaches legal conclusions for which the declarant has not established that he is capable of providing. For example, paragraphs 4, 5, 12, 16, 18-21, 23, 34, 36, 37, 46, 50, 52, 57, 62, 65, 66, 71, 72, 73, 82, 92, 96, 97, 99, 103, 115, 117, 131, 136, 138, 148, 151, 152, 153, 178, 184, 185, 187, 207, 208, 226, 235, and 240 each recite an unsupported legal conclusion and, thus, should not be considered by the PTAB in this proceeding. Patent Owner objects to Exhibit 1002 under FRE 702, on the basis that the testimony (over half of which is substantively identical to the Petition) is not based on sufficient facts or data, with respect to reliance on experimental data disclosed in references, and on other informal and unpublished documents that are hearsay under FRE 802, have not been

authenticated under FRE 901, are not self-authenticating under FRE 902, and are not duplicates as defined by FRE 1001(e). For example, paragraphs 16, 27, 38, 47, 71, 72, 74, 93, 95, 96, 102, 115, 117, 118, 122, 132, 134, 148, 151, 168, 170, 179, 180, 182, 183, 188, 191, 204, 207, 208, 221, 227, and 235 lack any cited basis.

Patent Owner objects to Exhibit 1002 to the extent it includes subject matter that is not permitted pursuant to FRE 602 or 701, including without limitation, to the extent that the declaration presents as "facts" information that is outside the personal knowledge of the declarant, and/or to the extent that the document offers improper lay opinion testimony. Exhibit 1002 is also objected to as irrelevant under FRE 401 and 402 because it does not make any facts at issue in the *inter partes* review more or less probable than it would have been without the evidence.

Patent Owner objects to Exhibit 1002 as unfairly prejudicial, confusing the issues, and a waste of time under FRE 403. Patent Owner objects to the portions of Exhibit 1002 that cite an exhibit objected to herein for the reasons stated herein.

Patent Owner objects to Exhibit 1002 under FRE 802 as hearsay without exception. Patent Owner objects to Exhibit 1002 under FRE 901-902 as lacking authentication and not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be.

Patent Owner objects under FRE 105 that use of Exhibit 1002 should be restricted to the purpose for which it was admitted.

EXHIBIT 1005

Exhibit 1005 is described as “*SteadyMed Ltd. v. United Therapeutics Corp.*, IPR2016-00006, Paper 82 (PTAB March 31, 2017).” Patent Owner objects to Exhibit 1005 under FRE 402 and 403. Exhibit 1005 concerns a proceeding with a different petitioner and a different patent, and it is therefore irrelevant. Even if Exhibit 1005 has some marginal relevance, the relevance is substantially outweighed by the unfair prejudice and likelihood of confusing the issues based on use of a document from another proceeding involving different claims and different prior art. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein (*e.g.*, Petition at 5-6, 19, 30, and 53), but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

EXHIBIT 1007

Exhibit 1007 is described as “U.S. Patent No. 6,765,117 to Moriarty, et al.” Patent Owner objects to Exhibit 1007, which is purported to be a United States patent, under FRE 802, including to the extent Petitioner has asserted that its products are inherently the same as a product claimed in the '901 patent and to the extent Petitioner has asserted that Exhibit 1007's statements regarding or relating

to the level of skill in the art are true and accurate. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807.

Patent Owner objects under FRE 105 that use of Exhibit 1007 should be restricted to the purpose for which it was admitted.

EXHIBIT 1008

Exhibit 1008 is described as "PCT Application No. WO 2005/007081." Patent Owner objects to Exhibit 1008, which is purported to be an International application published under the Patent Cooperation Treaty, under FRE 802, including to the extent Petitioner has asserted that its products are inherently the same as a product claimed in the '901 patent and to the extent Petitioner has asserted that Exhibit 1008's statements regarding or relating to whether certain practices or procedures were well-known, routine, or conventional, the level of skill in the art, and/or the underlying chemical and physical principles discussed therein are true and accurate. The Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807. Exhibit 1008 is also objected to as irrelevant under FRE 401 and 402 because it does not make any facts at issue in

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.