Filed on behalf of: Par Pharmaceutical, Inc. et al.

Entered: October 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., ARGENTUM PHARMACEUTICAL LLC, AND WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,
Petitioners

v.

NOVARTIS AG
Patent Owner

Case IPR2016-01479[1]
U.S. Patent No. 9,006,224

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PETITIONERS' RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS

[1] Argentum Pharmaceutical LLC was joined as a party to this proceeding via a Motion for Joinder in IPR2017-01063; West-Ward Pharmaceuticals International Limited was joined as a party via a Motion for Joinder in IPR2017-01078.

Table of Contents

I. The Board should deny Novartis's motion because each observation presents impermissible additional argument

The Board should deny Novartis's motion for observations of Dr. Ratain's deposition (Paper 34, "Mot.") in its entirety because Novartis impermissibly argues its case rather than concisely pointing out relevant testimony and its relevance as required by the Trial Practice Guide. 77 Fed. Reg. 48756, 48767-68 (Aug. 14, 2012). That is, Novartis's argumentative observations impermissibly characterize the subject testimony rather than quoting it or accurately summarizing it, address multiple passages in a single observation, characterize other exhibits, and re-argue old arguments and introduce new ones. *Actelion Pharm. v. Icos*, IPR2015-00561, Paper 33 at 2-3 (Mar. 18, 2016) (examples of offending observations are in *Actelion* Ex. 1049 at 14-15); *LG Elecs. v. ATI Techs.*, IPR2015-00325, Paper 52 at 3-4 (Jan. 25, 2016); *Medtronic v. Nuvasive*, IPR2013-00506, Paper 37 at 3-4 (Oct. 15, 2014) (dismissing motion that included argument).

Petitioners therefore bring Novartis's improper motion to the Board's attention in its response and ask the Board to dismiss or deny it in its entirety without leave to correct. *Green Cross v. Shire Human Genetic Therapies*, IPR2016-00258, Paper 78 (Dec. 21, 2016) (ordering petitioner to do the same); *Zhonghan* at 32-33 (no leave to correct); *LG Elecs.* at 3-4 (also no leave).

II. Responses to observations

Novartis's impermissible arguments and characterizations include all of its section headings and each observation as detailed in the following paragraphs with Petitioners' responses.

A. Mot. 1 "PNETS and Carcinoids . . . ."

Novartis cites Ex. 2111, 25:9-11, 28:18-25, and 30:8-15 and Reply 6: Novartis argues that the cited testimony and argument are relevant to whether therapies were administered to both PNETs and carcinoids and that "clinical trials typically evaluated them separately." (Mot. 1.) Ex. 2111, 30:16-31:21 is relevant to Novartis's argument regarding the responses to treatment of PNETs and carcinoids. (Mot. 1; POR 7-10.)

Novartis paraphrases Ex. 2111 at 254:16-255:10 and 256:19-257:8: Ex. 2111 at 251:5-254:12 is relevant to Dr. Ratain's reliance and citation to Ex. 1096, where he states that he "do[es]n't know what a POSA would understand in 2005 on this topic. I've not considered that." He further states "I only cited this reference in the context of paragraph 34 of my supplemental declaration to support my opinion that a POSA would have expected any cell tumor that had been previously treated with nitrosourea, including advanced PNETs, to fail to respond to another nitrosourea as a prior art explicitly identified." Finally, Dr. Ratain states "I cited page 81 of this document" and "I did not cite page 77 of this document."

B. Mot. 1-5: "Evidence [of] Resistance To Second-Line Therapy In Advanced PNETs . . ."

Novartis cites 49:7-52:18 (Mot. 1-2) to argue that molecularly targeted therapies were not effective after prior cytotoxic chemotherapy. Novartis further argues that Ex. 2015 and Ex. 2050 show that "temsirolimus failed to effectively treat tumors treated with prior cytotoxic chemotherapy." (Mot. 2.) Ex. 2015 at 1047 does not identify any difference in results between tumors previously treated with chemotherapy and chemotherapy-naïve tumors, stating "[t]he results of our clinical trial demonstrated that CCI-779 given at the dose and schedule. . . did not have sufficient antitumor activity in melanoma to warrant further evaluation as a single agent," which is relevant to Novartis's reliance on this reference as allegedly supporting temsirolimus's different activity in PNET after failure of cytotoxic chemotherapy versus PNETs that are chemotherapy-naïve. *See also* Ex. 2050 at 359 ("This phase II study sought to evaluate the efficacy of CCI-779 . . . in patients with recurrent GBM irrespective of the use of EIAEDs. Unfortunately, despite good tolerance of the agent, CCI-779 did not demonstrate sufficient antitumor activity to warrant further study as a single agent."). Further, Ex. 1078 at Table 3 and Ex. 2111 at 275:24-276:25 indicate that prior cytotoxic chemotherapy does not result in any difference in response.

Novartis cites 52:19-55:17, 57:7-14, 59:2-13, 62:25-63:9, 63:20-64:4 as identifying certain exhibits discussing treatment of tumors that are not PNETs and

DOCKET ALARM

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.