Trials@uspto.gov
571-272-7822

Paper 79
Entered: January 4, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORP.,
Patent Owner.

Case IPR2017-01592[1]
Patent 8,410,131 B2

Before SHERIDAN K. SNEDDEN, ROBERT A. POLLOCK, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

ORDER
Authorizing Additional Briefing
37 C.F.R. § 42.5; 37 C.F.R. 42.20(d)

[1] IPR2018-00507 has been joined to this proceeding. Paper 29, 6–7.

Breckenridge Pharmaceutical, Inc. ("Breckenridge") filed a Petition for an *inter partes* review of claims 1–3 and 5–9 of U.S. Patent No. 8,410,131 B2. Paper 1. On January 3, 2018, we instituted trial with respect to all challenged claims. Paper 12, 35. We subsequently joined Petitioner West-Ward Pharmaceuticals International, Inc. ("West-Ward") from proceeding IPR2018-00507 to the present proceeding. Paper 29, 6–7. Breckenridge and Patent Owner later filed a Joint Motion to Terminate IPR as to Breckenridge (Paper 52), which we granted (Paper 57, 4). Counsel for West-Ward and for Patent Owner presented oral argument on September 19, 2018 (*see* Paper 77), and on December 31, 2018, we adjusted the pendency of this proceeding by six months, such that a Final Written Decision in this matter is due no later than July 3, 2019 (Paper 78). In the particular circumstances of this case, we exercise our discretion under 37 C.F.R. § 42.20(d) to authorize post-hearing briefing as described below.

With respect to claim construction, Petitioner argues that the solid excretory system tumors of the challenged claims need not arise from the tissues of the recited subject and, thus, include xenografts and metastases thereof, in experimental animal models. *See, e.g.*, Pet. 16; Pet. Reply 7 ("[A]ll that is required by the claims is that the tumor be present in the subject when the method starts (i.e. when everolimus begins to be administered)."); *see also* PO Resp. 7 (agreeing that the claim term "'subject' should be construed as 'an animal'").

With respect to Ground 4, Petitioner presents a three-part argument wherein (1) Hildalgo and Alexandre teach that a rapamycin derivative, temsirolimus, inhibits growth of solid excretory tumors, specifically renal cell carcinomas, and that its antitumor activity, like that of rapamycin, is due to mTOR inhibition; (2) Schuler and Crowe teach that, as mTOR inhibitors, rapamycin and everolimus

share the same mechanism of action but that everolimus has an improved oral absorption profile as compared to rapamycin; and (3) Neumayer and Navarro further teach that that everolimus is more convenient to administer than rapamycin and therapeutically effective oral doses of everolimus are well tolerated. *See generally*, Pet. 45–54.

In addressing step 1 of Petitioner's argument, Patent Owner contends that the combination of Hidalgo and Alexandre "would not have provided a reasonable expectation that temsirolimus . . . would be therapeutically effective against solid kidney system tumors, like advanced RCC." PO Resp. 56–63. Although the parties' arguments in this regard are largely focused on the Phase I clinical trial data reported in Hidalgo and Alexandre, the record indicates that temsirolimus was known to have antitumor activity in preclinical studies, including against advanced renal cell carcinomas. *See e.g.*, Ex. 1016 (Dancey); Ex. 1039 (Dukart).

In view of the above, we invite the parties to submit additional briefing directed to (1) whether the claims encompass inhibiting growth of solid excretory system tumors in experimental animal models (i.e., xenografts); (2) the weight we should accord the experimental animal data of record in determining whether one of ordinary skill in the art reading Hidalgo and Alexandre would understand that temsirolimus inhibits growth of solid excretory tumors including RCC; and (3) the extent, if any, that a claim construction that encompasses inhibiting growth of solid excretory system tumors in experimental animal models affects the parties' arguments regarding reasonable expectation of success. Timing and length requirements of the authorized briefing are set forth in the Order below. The parties are not authorized to file additional evidence in support of their respective briefs beyond that already of record in this proceeding.

It is

ORDERED that both Petitioner and Patent Owner are authorized to submit initial and responsive briefing on the topics set forth above;

FURTHER ORDERED that initial briefs shall not exceed seven pages and shall be due no later than two weeks from the date of this Order;

FURTHER ORDERED that responsive briefs shall not exceed five pages and shall be due no later than four weeks from the date of this Order.

For PETITIONER:

Keith Zullow
Marta Delsignore
Michael Cottler
GOODWIN PROCTER LLP
kzullow@goodwinprocter.com
mdelsignore@goodwinprocter.com
mcottler@goodwinlaw.com

For PATENT OWNER:

Nicholas Kallas
VENABLE LLP
nkallas@venable.com

Laura Fishwick
Susanne Flanders
FITZPATRICK, CELLA, HARPER & SCINTO
lfishwick@fchs.com
sflanders@fchs.com