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Paper No. 31
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRÜNENTHAL GMBH,
Petitioner,

v.

ANTECIP BIOVENTURES II LLC,
Patent Owner.

Case PGR2018-00001
Patent 9,539,268 B2

Before TONI R. SCHEINER, GRACE KARAFFA OBERMANN, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge.*

ORDER

Denying Petitioner's Motion to Compel Routine Discovery
And Denying Petitioner's Motion for Additional Discovery
37 C.F.R. §§ 42.51, 42.65, 42.224

This is a post grant review of claims 3–30 of U.S. Patent 9,539,268 B2 ("the '268 patent"). Paper 17, 38. We authorized Petitioner to file a combined Motion to Compel Routine Discovery and Motion for Additional Discovery. Paper 27, 3 (Order authorizing motion); *see* Paper 28 (Petitioner's combined motion ("Mot.")); Paper 30 (Patent Owner's opposition to the combined motion ("Opp.")). For reasons that follow, we *deny* that combined motion.

The Discovery Dispute

On the same day that Patent Owner filed its Response (Paper 22, "Resp.") to the Petition, Patent Owner filed also Exhibit 2026, a document titled "AXS-02 (disodium zoledronate tetrahydrate) Phase 1 Results Summary."[1] The Response does not cite Exhibit 2026. *See* Resp. The supporting declaration of Dr. William Wargin, however, refers to that exhibit and contains extensive information alleged to pertain to that Phase I study. Ex. 2017 ¶¶ 54–78.

Petitioner asserts that documents pertaining to a Phase III study (hereinafter "the Phase III documents")[2] are inconsistent with a position taken by Patent Owner in the Response. Mot. 1–2 (citing Resp. 35); *see* Ex. 1091 (press release); Ex. 1092 (FDA guidance). Accordingly, Petitioner

[1] Although each page of Exhibit 2026 is marked "Confidential," Patent Owner filed that document without any restriction on public access.
[2] As an initial matter, Patent Owner argues that the Phase III documents are not adequately defined in a "single set of clearly articulated requests." Opp. 1. We determine that Petitioner identifies the Phase III documents with sufficient particularity for purposes of the combined motion, given the limited information available to Petitioner regarding the documents. Mot. 1 (seeking "documents sufficient to show the complete results of the CREATE-1 phase III clinical trial"); *see* Ex. 1091 (press release).

seeks to compel the production of the Phase III documents as routine discovery. *See* Mot. 1–3; 37 C.F.R. § 42.51(b)(1)(iii). Patent Owner avers that the Phase III documents are not subject to routine discovery and refuses to produce them. Opp. 2, 5.

Petitioner, in the alternative, requests production of the Phase III documents as additional discovery. Mot. 3–5. Petitioner further seeks additional discovery pertaining to individuals allegedly consulted by Dr. Wargin in connection with the Phase I study (hereinafter "the Phase I individuals").[3] *Id*. at 5–7. Patent Owner disagrees that additional discovery, pertaining to the Phase III documents or the Phase I individuals, is warranted given the facts and circumstances of this case. Opp. 5–7.

We first address Petitioner's Motion to Compel Routine Discovery of the Phase III documents. We then turn to Petitioner's Motion for Additional Discovery pertaining to the Phase III documents and the Phase I individuals.

Denying Petitioner's Motion to Compel Routine Discovery

Petitioner argues that the Phase III documents should be produced as routine discovery because they reflect information "inconsistent with a position advanced by" Patent Owner. Mot. 3 (quoting Rule 42.51(b)(1)(iii)). In that regard, Petitioner directs us to Patent Owner's allegation, reflected in the Response, that the salt forms of zoledronic acid "can have a higher bioavailability than the diacid form, and that dosage forms having this

[3] The Board granted Petitioner's request to move for additional discovery pertaining to the Phase I individuals during a telephonic conference call conducted on September 12, 2018; however, we inadvertently failed to mention that component of Petitioner's discovery request in our Order memorializing the call. Paper 27. Accordingly, we reject Patent Owner's contention that this component of Petitioner's discovery request "should be denied as not authorized by the Board's order." Opp. 6 (citing Paper 27).

bioavailability range are effective in treating disease." *Id*. at 1–2 (quoting Resp. 35). Petitioner further observes that Patent Owner's own witness, Dr. Wargin, asserts in his declaration that the claimed invention "teaches that 'an *effective* bioavailability range for oral zoledronic acid is about 1.1% to about 4%.'" *Id*. at 2 (emphasis in original) (quoting Ex. 2017 ¶ 19).

Petitioner acknowledges that the Phase III documents relate to the "treatment of a specific condition called complex regional pain syndrome, or CRPS." Opp. 2 (citing Ex. 1091). In Petitioner's view, the Phase III documents establish that the claimed invention is ineffective "for treating CRPS." Mot. 2. Significantly, however, none of the challenged claims of the '268 patent includes "treatment of CRPS as a limitation" and neither Patent Owner nor Dr. Wargin asserts that the claimed invention is effective for treating CRPS. Opp. 2. Claims 3–22 relate to "[a] method of treating *arthritis*" whereas claims 23–30 "cover '[a] pharmaceutical dosage form for oral administration'" not limited to any particular condition or disease. *Id*. (emphasis in original) (quotation omitted); *see* Ex. 1001, claims 3–30.

The press release advanced by Petitioner in support of its motion to compel routine discovery of the Phase III documents confirms the utility of the claimed dosage form for modulating bone resorption in osteoarthritis, a condition discussed in the specification of the '268 patent. Opp. 3 (citing Ex. 1091 and Ex. 1001, 2:52–67). Neither Patent Owner nor Dr. Wargin purports "to make the rather grandiose claim of efficacy for treating all conditions or maladies." Opp. 4 (emphasis omitted). We agree with Patent Owner that Dr. Wargin's testimony, taken in context, does not include "a claim of efficacy for treating every condition known to man," including CRPS. *Id*.; Ex. 2017 ¶¶ 54–78.

Given that the Phase III documents purportedly establish that the claimed dosage form is ineffective only "for treating CRPS" (Mot. 2), on this record, we discern no inconsistency between a position taken by Patent Owner (or Dr. Wargin) and the information allegedly reflected in the Phase III documents. Petitioner does not show that the Phase III documents are subject to routine discovery as inconsistent with a position taken by Patent Owner in this proceeding. Accordingly, we *deny* Petitioner's Motion to Compel Routine Discovery of the Phase III documents.

Denying Petitioner's Motion for Additional Discovery

Petitioner asserts, and we agree, that "additional discovery of 'evidence directly related to factual assertions advanced by either party' may be granted" during a post grant review "upon a 'showing of good cause.'" Mot. 3–4 (citing 37 C.F.R. ¶ 42.224). Applying the good cause standard, however, we are not persuaded that Petitioner demonstrates, at this time, that good cause exists for securing additional discovery of information pertaining to the Phase III documents or the Phase I individuals. *See Bloomberg Inc. v. Markets-Alert Pty Ltd.*, CBM2013-00005, Paper 32 at 2-3 (P.T.A.B. May 29, 2013) (precedential); *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 at 4 (P.T.A.B. Mar. 5, 2013) (precedential) (discussing factors that bear on the "good cause" standard).

Regarding the Phase III documents, Petitioner does not advance "a specific factual reason" that supports production of them, aside from "the debunked notion that" those documents are "inconsistent with a position advanced by Patent Owner." Opp. 5 (quotation and emphasis omitted); *see* Mot. 4 (arguing that the Phase III documents "plainly exist and contradict [Patent Owner's] assertions"). Two other pending reviews before the Board,

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