

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC, AMNEAL  
PHARMACEUTICALS OF NEW YORK, LLC, and MYLAN  
PHARMACEUTICALS INC.,  
Petitioners,

v.

ALMIRALL, LLC,  
Patent Owner.

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IPR2019-00207<sup>1</sup>  
Patent 9,517,219 B2

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Before SUSAN L. C. MITCHELL and RYAN H. FLAX, *Administrative  
Patent Judges.*

FLAX, *Administrative Patent Judge.*

ORDER  
*Granting Patent Owner's Motion for Additional Discovery*  
*37 C.F.R. § 42.51(b)(2)*

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<sup>1</sup> Cases IPR2019-00207 and IPR2019-01095 have been joined in this proceeding.

I. INTRODUCTION

On October 18, 2019, Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively “Petitioner”) filed an authorized Motion for Additional Discovery. Paper 26 (“Pet. Mot.”). On October 25, 2019, Patent Owner filed an authorized Opposition to this Motion (corrected). Paper 27 (“PO Opp.”). For the reasons discussed below, Petitioner’s Motion is *granted*.

As described in our Trial Practice Guide, in trials before the Board, “[d]iscovery is a tool to develop a fair record and to aid the Board in assessing the credibility of witnesses” and “discovery before the Board is focused on what the parties reasonably need to respond to the grounds raised by an opponent.” *See* Office Patent Trial Practice Guide, 84 Fed. Reg. 64,280, § I.F (Nov. 21, 2019) (“Trial Practice Guide”). By rule, such discovery is divided into routine and additional discovery, the former category requiring production of a party’s cited exhibits, cross-examination of witnesses, and if not previously served, evidence relevant to information inconsistent with a position advanced by the producing party during the proceeding. 37 C.F.R. § 42.51(b)(1). The latter category, additional discovery, is directed to non-routine discovery that should be allowed in the interests of justice. *Id.* § 42.51(b)(2); *see also* 35 U.S.C. § 316(a)(5).

We conclude the additional discovery sought by Petitioner should be authorized in the interests of justice, as discussed below. Regarding the authorization of additional discovery, the Board set forth factors for consideration in *Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 at 6–7 (PTAB Mar. 5, 2013) (precedential), which are:

Factor 1: Whether there is more than a possibility and mere allegation that something useful will be found and whether the party requesting discovery is already in possession of evidence tending to show beyond speculation that something useful will be discovered;

Factor 2: Whether the party requesting discovery is seeking its opponent's litigation positions and underlying basis for those positions;

Factor 3: Whether the party requesting discovery has the ability to generate equivalent information by other means;

Factor 4: Whether the party requesting discovery has presented easily understandable instructions and questions; and

Factor 5: Whether the request for discovery is overly burdensome to answer or sensible and reasonably tailored according to a genuine need.

## II. DISCUSSION

Petitioner seeks additional discovery in the form of the deposition of Dr. Kevin S. Warner and the production of Dr. Warner's deposition transcripts from a related district court litigation, *Almirall LLC v. Taro Pharms. Indus. Ltd.*, 17-663 (D. Del.) (the "related district court litigation"), involving U.S. Patent No. 9,571,219 ("the '219 patent") challenged here. *See* Pet. Mot. 1; *see also* Paper 3, 64 (Petitioner's Mandatory Notices); Paper 5, 2 (Patent Owner's Mandatory Notices). Petitioner argues that Patent Owner has asserted that the claims of the '219 patent are non-obvious based on evidence of unexpected results and has submitted a Declaration of Dr. David Osborne (Ex. 2057) in support of this argument, but that Dr. Osborne's sole basis for this opinion on unexpected results is Dr. Warner's declaration dated February 2, 2015 (Ex. 1017, 289–293 ("Warner Declaration")), which was submitted during the prosecution of

the '219 patent (having previously been submitted during the prosecution of its parent application 14/082,955).

Patent Owner opposes the sought additional discovery. PO Opp. 1. Patent Owner argues that the Warner Declaration is publically available and itself provides sufficient information to assess the results reported therein, and Dr. Warner's further deposition would not provide useful information. *Id.* Further, Patent Owner argues that the transcripts from the related district court litigation are not relevant because that litigation concerned a different product (accused of infringement). *Id.*

A. *GARMIN FACTOR I—MORE THAN A POSSIBILITY AND MERE ALLEGATION; BEYOND SPECULATION*

Petitioner argues that Dr. Warner is the source of “information necessary for a scientific analysis,” which is “‘necessary to evaluate’ data relied on by [P]atent [O]wner” in its case for non-obviousness based on secondary indicia thereof. Pet. Mot. 4. Petitioner contends “Dr. Warner was the sole observer of the information contained in his declaration,” which is “the sole basis for Almirall's allegations of [and Dr. Osborne's opinions on] purported unexpected results.” *Id.* Petitioner argues Dr. Warner has information on and can explain the data that underlies his declaration, in particular, regarding “undesired polymer aggregates” and how his discussed compositions were prepared. *Id.* at 5. Petitioner argues that this makes Dr. Warner's knowledge relevant. *Id.* Petitioner argues that Dr. Warner testified in the related district court litigation regarding the validity of the '219 patent's claims, which makes the transcripts thereof also relevant here. *Id.* at 6.

Patent Owner argues Petitioner's request for a deposition is speculative because the data sought is already provided by the Warner

Declaration (visual observations, data on particle size). PO Opp. 4–5. Patent Owner argues Petitioner’s request for transcript(s) is speculative because Petitioner does not know whether such testimony is useful (Patent Owner noted Dr. Warner was not designated in the related district court litigation to testify on validity, secondary considerations, objective indicia, unexpected results, or any similar concept). *Id.* at 3, 5.

We agree with Petitioner that its requests for discovery outlined above are not merely speculative, but are tailored, based on Petitioner’s knowledge, to obtain the limited production of relevant evidence on objective indicia of non-obviousness. Hence, we conclude Petitioner is in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered in the requested specific documents and testimony concerning Dr. Warner’s position on and evidence regarding unexpected results. *Garmin*, IPR2012-00001, Paper 26 at 7.

*B. GARMIN FACTOR 2—LITIGATION POSITIONS*

Petitioner argues that the sought discovery “has nothing to do with [Patent Owner’s] litigation position[s].” Pet. Mot. 6. Patent Owner makes no argument opposing Petitioner’s position on this factor.

Petitioner’s sought discovery is tailored to and relates to Patent Owner’s specific defenses regarding patentability that are relevant here. It is not apparent why the production of existing transcripts or cross examination on unexpected results would inappropriately reveal any litigation position of Patent Owner that is not relevant.

*C. GARMIN FACTOR 3—ABILITY TO GENERATE EQUIVALENT INFORMATION BY OTHER MEANS*

Petitioner argues that “[t]here is no other way for [it] to obtain this discovery as Dr. Osborne has no personal knowledge and [Patent Owner’s]

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