

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., CELLTRION, INC., and
BIOCON BIOLOGICS INC.,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00884¹
Patent 11,253,572 B2

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

FLAX, *Administrative Patent Judge*.

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

¹ IPR2024-00260 and IPR2024-00298 are joined with IPR2023-00884. *See* Papers 31 and 33.

I. INTRODUCTION

On May 10, 2024, Petitioner, Samsung Bioepis Co., LTD (“Petitioner” or “Samsung”) filed an authorized Motion for (Additional) Discovery (Paper 56 (“Pet. Mot.”)), which is opposed (Paper 57 (“PO Opp.”)) by Patent Owner, Regeneron Pharmaceuticals, Inc. (“Patent Owner” or “Regeneron”). For the reasons discussed below, Petitioner’s Motion is *granted*.

For context, Regeneron is the owner of U.S. Patent 11,253,572 B2 (Ex. 1001, “the ’572 patent”). Paper 5, 1. On April 27, 2023, Samsung filed a Petition for *inter partes* review challenging the patentability of claims 1–30 (all claims) of the ’572 patent. Paper 2, 1 (“Pet.”). Trial was instituted on November 17, 2023. Paper 13. Subsequently, on December 14, 2023, Celltrion, Inc. in IPR2024-00260, and on December 18, 2023, Biocon Biologics Inc. in IPR2024-00298, each respectively filed a petition for *inter partes* review also challenging the patentability of claims 1–30 of the ’572 patent, and filed motions for joinder with IPR2023-00884. Papers 31 and 33. The trials were instituted and the motions were granted. *Id.* These joined petitioners each agreed to take a silent, subordinate role to Samsung in the joined proceeding. Paper 31, 12; Paper 33, 13.

All parties identify *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-00061-TSK (N.D. W.Va.) (the “related district court litigation”) as a related matter. *See* Papers 13, 31, 33. On April 29, 2024, the parties jointly updated the Board on this matter, explaining that the District Court had issued a decision, including a finding that claims 6 and 25 of the ’527 patent (the only claims of the patent remaining in the litigation after the others were stipulated to be invalid under

the Court’s claim construction (*see* Ex. 2031)) were invalid over, *inter alia*, prior art asserted in this proceeding (e.g., Dixon (Ex. 1009), Hecht (Ex. 1016), Regeneron’s 2009 Press Release (Ex. 1005)). Paper 55, n.2.

II. APPLICABLE LEGAL STANDARDS

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* Consolidated 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)–(2). The latter category, additional discovery, is directed to non-routine discovery that should be allowed, in IPRs, in the interests of justice. *Id.* § 42.51(b)(2); *see also* 35 U.S.C. § 316(a)(5).

Regarding the authorization of additional discovery, the Board set forth, in *Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26 at 6–7 (PTAB Mar. 5, 2013) (precedential) (“*Garmin*”), the following factors for consideration:

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.

We address the facts presented and the parties' arguments in view of these factors, below.

III. DISCUSSION

Petitioner seeks discovery of certain documents and "requests that Patent Owner produce transcripts and underlying exhibits of prior testimony from Karen Chu and George Yancopoulos and exhibits cited in the District Court's decision invalidating the '572 patent (collectively, 'Requested Materials' and more specifically listed in Ex. 3003 at 2)." Pet. Mot. 1.

Petitioner identifies the Requested Materials as follows:

1. The deposition transcript of Karen Chu from the Mylan Litigation and all exhibits thereto;
2. The deposition transcript of George Yancopoulos from the Mylan Litigation and all exhibits thereto;
3. The trial exhibits from the Mylan Litigation cited in the trial testimony of Karen Chu and/or George Yancopoulos[,] [which include PTX 0001, PTX 0003, PTX 0080, PTX 0188, PTX 0304, PTX 0311, PTX 0491, PTX 0686, PTX 0932, PTX 1028C, PTX 1170, PTX 3131, PTX 3133, PTX 3150, PTX 3151, PTX 3167, PTX 3168, PTX 3187, PTX 3188, PTX 3216, PTX 3332, PTX 3333, PDX 1-1, PDX 1-2, PDX 3.001, PDX 3.002, PDX 3.004, PDX 3-0311-B, PDX 932-C, DTX 0019, DTX 0212, DTX 0216, DTX 0227, DTX 0228, DTX 0902,

DTX 0913, DTX 0915, DTX 0916, DTX 2053, DTX 2053A, DTX 2730, DTX 2745, DTX 3196, DTX 4070, DTX 4957, DTX 5073, DTX 5082, DTX 5385, DTX 7001, DTX 7212, DTX 7272, DTX 8127, DTX 8180, DTX 8190, DTX 9002, DTX 9003, DTX 9005, DTX 9006];

4. The following trial exhibits from the Mylan Litigation cited in the court’s Memorandum Opinion and Order Following Bench Trial (ECF No. 692 in the Mylan Litigation) related to Regeneron’s clinical development of aflibercept: DTX 0213, DTX 0220, DTX 0222, DTX 0226, DTX 0229, DTX 0230, DTX 0232, DTX 0234.

Ex. 3003, 2; *see also* Ex. 1070, 12 (identifying the “trial exhibits” referenced under above List No. 3).² Petitioner argues that Karen Chu and George Yancopoulos are witnesses having prepared declaration testimony in this proceeding, and also testified in the related district court litigation, on “the same or similar subject matter relating to the patentability of the ’572 patent.” Pet. Mot. 1 (citing Ex. 1071, 87–250, Ex. 1072, 3–44, Ex. 1073, 44–130, Ex. 1074, Ex. 1075). For example, Petitioner argues this “similar subject matter” covers topics such as the history of the claimed drug’s development, clinical trials, objective indicia of non-obviousness, and reduction to practice of the claimed invention. *Id.* at 1–2.

Petitioner first argues that the above-identified Requested Materials constitute *routine* discovery under 37 C.F.R. § 42.51(b)(1)(iii). *Id.* at 3–4. As support for this proposition, Petitioner asserts only that the documents

² Petitioner expressly identified the listed documents set forth in Exhibit 3003, at 2, as its “Requested Materials.” This list differs from a similar list of materials in Exhibit 1070, which further includes list numbers 5 and 6, which refer to collaboration agreements by Bayer and Regeneron and corrected copies of Exhibits 2007 and 2011, respectively. We take this omission by Petitioner to be intentional.

were part of the evidence of record before the District Court, which found the evidence “did not support a finding of patentability.” *Id.* at 3–4. As an initial matter, we find Petitioner has not shown that the sought discovery is routine under our rules. It is not established or even asserted by Petitioner that the documents sought have been cited in any paper or testimony in this proceeding, and Petitioner has not sufficiently identified why any sought information is “inconsistent with a position advanced by” Patent Owner in this proceeding. 37 C.F.R. § 42.51(b)(1); *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) (“Attorney’s argument in a brief cannot take the place of evidence.”).

Petitioner also argues that the above-identified Requested Materials should be produced as compelled additional discovery per 37 C.F.R. §§ 42.51(b)(2) and 42.52, under the guidance of *Garmin*. Petitioner argues that *Garmin* Factors 2, 3, and 4 “undisputedly support the request, that *Garmin* Factor 1 favors Petitioner because the request is not merely speculative, and that *Garmin* Factor 5 favors Petitioner because the request is limited in scope and not overly burdensome. *Id.* at 4–5.

Patent Owner opposes the sought additional discovery. PO Opp. 1. Patent Owner argues that *Garmin* Factors 1–5 all favor denial of Petitioner’s Motion. PO Opp. 3–4.

A. GARMIN FACTOR 1—MORE THAN A POSSIBILITY AND MERE ALLEGATION; BEYOND SPECULATION

Garmin Factor 1 seeks to prevent mere speculative grabs for evidence of unknown usefulness. *Garmin*, at 7. Under this factor, the movant should have a “threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered,” meaning something favorable in substantive value to the movant’s contentions. *Id.*

Petitioner argues that the information sought here in the specific documents requested includes information on the validity of the claims of the '572 patent, generally, but more specifically on matters covered by the testimony of Ms. Chu and Dr. Yancopoulos in this proceeding and in the related district court litigation, such as the development of the patented invention. Pet. Mot. 4–5. Implicit in Petitioner's argument is that the credibility of these witnesses might also be illuminated by the sought information.

Patent Owner argues that the testimony of these witnesses in this proceeding does not relate to the District Court's bases for unpatentability, but provides factual testimony on actual reduction to practice and whether certain exhibits here are prior art (i.e., Regeneron's Dec. 2010 Press Release (Ex. 1006), Regeneron's Nov. 2010 Press Release (Ex. 1007), and an ARVO 2010 Abstract (Ex. 1010)). PO Opp. 3. Patent Owner calls Petitioner's request a "fishing expedition." *Id.* at 1.

Regardless of whether Patent Owner's position is correct that the District Court did not base its finding of invalidity of the '572 patent's claims on the subject matter to which Ms. Chu and Dr. Yancopoulos testify in this proceeding, a brief review of their testimony in the related district court litigation shows that these witnesses did address relevant topics like inventorship, clinical trials, and development of the drug covered by the challenged claims in partnership with third parties. *See, e.g.*, Ex. 1071, 112–113, 124, 133, 142, 151, 160; Ex. 1072, 1230–231, 1238, 1242–243, 1256, 1259. Thus, we find that the sought discovery has some relation to subjects at issue in this proceeding.

We agree with Petitioner that its requests for discovery outlined above are not merely speculative, but are tailored, based on Petitioner's knowledge and reasoning gleaned from the exhibits of record in this proceeding, to obtain the limited production of relevant evidence in the form of specific identified documents that were cited in the related district court litigation as relating to subject matter and witness credibility at issue in this proceeding. Therefore, we conclude Petitioner is in possession of a threshold amount of evidence or reasoning tending to show beyond mere speculation that something useful will be uncovered in the requested specific documents. *Garmin*, at 7.

B. GARMIN FACTOR 2—LITIGATION POSITIONS

Petitioner argues that the sought discovery “requests are targeted at Patent Owner’s witness testimony and underlying exhibits and not seeking to unearth any litigation positions.” Pet. Mot. 4. Patent Owner disagrees and argues that “the exhibits requested by Samsung include Regeneron’s interrogatory responses, Rule 26(a) disclosures, Rule 30(b)(6) deposition topics, and a case narrowing stipulation.” PO Opp. 4.

Petitioner’s sought discovery is tailored and relates to the testimony of witnesses and bases for witnesses’ positions in this proceeding. Moreover, the related litigation at issue has concluded, but for any appeal. It is not apparent that any of the requested discovery would inappropriately reveal any litigation position of Patent Owner.

We find this factor weighs in favor granting the Motion.

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

Petitioner argues that “[b]ecause the Requested Materials are not publicly available, Petitioner has no other methods available to ascertain this information.” Pet. Mot. 4.

Patent Owner argues that this is incorrect and that “many” of the Requested Materials are publicly available. PO Opp. 4. Patent Owner lists, as examples of publicly available documents, the ’572 patent, U.S. Patent 10,888,601, certain scientific publications, and other papers from the public docket of the related district court litigation. *Id.*

Although it appears that some of the Requested Materials may be publicly available, most appear not to be (at least, it is not alleged otherwise); however, we find that all of them are, essentially, at Patent Owner’s fingertips and can be readily produced, having just been the subject of or at issue in the recently concluded related district court litigation. Thus, we find this factor weighs in favor of granting the Motion.

D. GARMIN FACTOR 4: EASILY UNDERSTANDABLE REQUESTS

Petitioner argues its request for discovery is easily understood because it “provided a tailored list of specific materials and exhibits from” the related district court litigation. Pet. Mot. 4. Patent Owner does not contest this.

We agree with Petitioner that its discovery requests are understandable. They are specific as to the documents desired. *See* Ex. 3002. We find this factor weighs in favor of granting the Motion.

E. GARMIN FACTOR 5—OVERLY BURDENSOME, OR SENSIBLE AND REASONABLY TAILORED

Petitioner argues its sought discovery is limited in scope and not overly burdensome. Pet. Mot. 5. Petitioner states that it

seeks only the deposition testimony, and related exhibits, of two witnesses in the Mylan Litigation as well as the exhibits cited in relevant portions of the district court decision. These materials are readily available to Patent Owner from the ongoing Mylan Litigation. Further, there is no additional burden based on the timing of Petitioner's request. Petitioner's reply is not due until June 10, leaving several weeks for Patent Owner to complete what should be a straightforward production of a small set of specifically enumerated items.

Id.

Patent Owner argues that the request is overbroad and seeks sensitive material that should be subject to the protective order, which it argues will have to be amended to cover the production of material for "outside counsel's eyes only." PO Opp. 5. Patent Owner argues that Petitioner seeks "more than 100 exhibits," and its request is not tailored to any genuine need.

Id.

We find this factor weighs in favor of granting the Motion. As noted above, the Requested Materials are expected to be immediately available to Patent Owner and in form for production. We find there is little if any burden on Patent Owner in producing the documents requested, which should be produced no later than May 31, 2024. We would entertain a request for an appropriate amendment to the protective order to maintain confidentiality of sensitive material.

IV. CONCLUSION

We find that the *Garmin* factors favor granting Petitioner's requested discovery, as set forth above, and Petitioner has made a sufficient showing to justify its requested additional discovery. We authorize Petitioner's tailored requests for document production and set the deadline for producing the Requested Materials (as defined above) at May 31, 2024.

We remind the parties that if any confidential information is produced as discovery, a modified protective order may be requested, if necessary. *See* 37 C.F.R. §§ 42.14 and 42.54.

For the foregoing reasons, it is
ORDERED that Petitioner's Motion for Additional Discovery is *granted*;

FUTHER ORDERED that the discovery sought and identified above as the "Requested Materials" (*see* Ex. 3003) shall be produced to Petitioner by Patent Owner; and

FURTHER ORDERED that the above-ordered discovery shall be completed by May 31, 2024.

For PETITIONER SAMSUNG BIOEPIS CO., LTD.:

Raymond N. Nimrod
Matthew A. Traupman
Landon Andrew Smith
QUINN EMANUEL URQUHART & SULLIVAN LLP
raynimrod@quinnemanuel.com
matthewtraupman@quinnemanuel.com
landonsmith@quinnemanuel.com
qe-samsungbioepis@quinnemanuel.com.

For PETITIONER CELLTRION, INC.:

Lora Green
Yahn Lin Chu
GEMINI LAW LLP
lgreen@geminilaw.com
fchu@geminilaw.com

For PETITIONER BIOCON BIOLOGICS INC.:

Paul Molino
Jeffrey Marx
Neil McLaughlin
Steven Birkos
Deanne Mazzochi
Thomas Ehrich
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
paul@rmmslegal.com
jmarx@rmmslegal.com
nmclaughlin@rmmslegal.com
sbirkos@rmmslegal.com
dmazzochi@rmmslegal.com
tehrich@rmmslegal.com

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For PATENT OWNER:

Adam R. Brausa
Rebecca Weires
Kira Davis
Daralyn Durie
MORRISON & FOERSTER LLP
ABrausa@mofo.com
RWeires@mofo.com
kiradavis@mofo.com
ddurie@mofo.com