

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

**PATENT OWNER'S OPPOSITION TO PETITIONER'S
MOTION FOR DISCOVERY PURSUANT TO 37 C.F.R. § 42.51(b)**

¹ IPR2024-00260 and IPR2024-00298 are joined with this proceeding.

Regeneron challenged the prior art status of three references relied upon by Samsung Bioepis in its Patent Owner Preliminary Response on August 25, 2023. Regeneron further developed these arguments in its Response, filed February 23, 2024, with declarations from named inventor and Regeneron's CSO George Yancopoulos and Regeneron's Global Program Head for Ophthalmology, Karen Chu. Dr. Yancopoulos and Ms. Chu sat for deposition on April 11-12, 2024, and answered all questions posed by Samsung's counsel.

Now, apparently unhappy with the evidentiary record, Samsung requests over 100 deposition and trial exhibits from parallel litigation between Mylan and Regeneron, without articulating any specific reason the exhibits are relevant to the subject matter of the declarations. Samsung argues that its Motion should be granted because the District Court and PTAB proceedings both implicate the patentability of the '572 patent. But Dr. Yancopoulos and Ms. Chu's declarations do not address the district court's bases for unpatentability. They provide factual testimony regarding whether Exhibits 1006, 1007, and 1010 are prior art. The District Court did not address that issue and found the claims obvious over different references. Moreover, several exhibits post-date the priority date of the '572 patent, so their relevance to declarations about antedation remains unclear.

The Board should not condone Samsung's fishing expedition. Before filing its Motion, Samsung never suggested that its request was routine discovery. It is

not, nor do the *Garmin* factors support Samsung's request for additional discovery. For the reasons set forth below, its Motion should be denied.

I. PETITIONER'S REQUEST IS NOT ROUTINE DISCOVERY

Samsung never contended that its request for over 100 trial and deposition exhibits was routine discovery, until the Board requested that the parties consider that possibility on May 7. (Ex.3003; Ex.1070, 11-12.) Samsung now argues, however, that its request is routine discovery under 37 C.F.R. § 42.51(b)(1)(iii) because the District Court found two claims of the '572 patent invalid. (*See* Mot. 3-4.) While that is true, Regeneron disagrees with the District Court's determination. And more importantly, there is no inconsistency in Regeneron's position. In both proceedings, Regeneron has vigorously defended the patentability of the claims in the '572 patent. Moreover, even after Samsung obtained the public District Court transcripts of Dr. Yancopoulos and Ms. Chu's trial and deposition testimony, Samsung does not provide any basis for its assertion that the requested exhibits would reveal inconsistencies with Regeneron's positions here. Routine discovery is "not broadly directed to any subject area in general within which the requesting party hopes to discover such inconsistent information." *Synaptive Med. Inc. v. Karl Storz Endoscopy-America, Inc.*, IPR2018-00462, Paper 14, at *3 (P.T.A.B. Oct. 11, 2017) (denying routine discovery). Therefore, Samsung's request is not for routine discovery.

II. ADDITIONAL DISCOVERY IS NOT WARRANTED UNDER THE GARMIN FACTORS

Factor 1. Samsung has not shown “more than a possibility or mere allegation” of something useful in its requested materials. *Garmin*, IPR2012-00001, Paper 26 at 6. Samsung has repeatedly failed to explain what would be relevant, much less useful, in its requested materials. (*See* Mot.; Ex.1070.) Samsung’s gesture toward the District Court finding claims 6 and 25 unpatentable is irrelevant. (Mot., 3-4.) Dr. Yancopoulos and Ms. Chu’s IPR declarations are limited in scope; they address actual reduction to practice of certain ’572 claims (not claim 25) and whether Exhibits 1006, 1007, and 1010 are Dr. Yancopoulos’s own work. (Ex.2063; Ex.2064.) The Mylan trial addressed neither reduction to practice nor these three references. (Ex.2032, 21-30; Ex.2093, 236-311.)

In view of these facts, the Board’s decision in *Amneal Pharms. LLC v. Alemirall, LLC*, IPR2019-00207, Paper 39 (P.T.A.B. Dec. 31, 2019) does not support Samsung’s request. There, the movant requested a “limited production” of only deposition testimony (not exhibits). *Id.* at 5. Because the nonmovant’s expert relied on a patent office declaration showing unexpected results, additional discovery was the only way for the movant to obtain cross examination testimony of the declarant, the only person with personal knowledge of that subject matter. *Id.* at 6. In stark contrast, Samsung has failed to tailor its request for information relating to the subject matter of the two Regeneron employee declarations.

Factor 2. Samsung's request for additional discovery is improper because Samsung *is* requesting litigation positions (which are also largely irrelevant to Dr. Yancopoulos and Ms. Chu's testimony), despite its argument otherwise. (Mot., 4.) Specifically, 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. (*See* Ex.1073, 1654:10-13; Ex.1075, 17:15-23, 40:2-11, 43:5-19.)

Factor 3. Samsung is wrong that its requested materials are "not publicly available." (Mot., 4.) Not only are many of them public, but the public documents that Samsung requests further illustrate Samsung's untargeted approach. For example, PTX 1 and PTX 3 are the '572 patent and '601 patent. (Ex.1071, 100:16-101:21.) PTX 311 and DTX 8180 are scientific publications that Samsung already *filed in this proceeding* as Exs.1038, 1039. (*See* Ex.1071, 150:2-17, 182:1-8, 255:2-8.) The public docket includes several more exhibits that Samsung contends are important additional discovery, but that Samsung did not bother to pull before filing its Motion. For example, DTX 913, 915, 5385, and 8190 are documents filed as ECF Nos. 505-29, -24, -44, and -42, respectively. (*See* Ex.1071, 190:25-191:5, 220:12-18; Ex.1073, 1606:2-24, 1629:7-15.) Samsung also had ample opportunity to ask Ms. Chu and Dr. Yancopoulos about any relevant requested information during their respective depositions. Having chosen not to do so, it

should not now be permitted to pursue litigation-style discovery requests, particularly given its lack of diligence and justification.

Factor 5. Samsung argues that this factor favors additional discovery because its request is allegedly “limited in scope and not overly burdensome.” But as discussed above, Samsung’s request is overbroad. Additionally, some of the requested materials are sensitive, requiring careful review for Regeneron’s confidential information as well as entry of a new protective order for “outside counsel’s eyes only” materials. (*See* Ex.1070, 7-8.) Even if the Board is willing to enter such a protective order, the production of Regeneron materials implicating proprietary, highly confidential, and competitively sensitive information in another forum, to two new parties (Samsung and Celltrion) and more outside counsel, increases the risk of inadvertent disclosure, without sufficient justification. Furthermore, Samsung’s request for more than 100 exhibits is not “responsibly tailored according to a genuine need.” *Garmin*, IPR2012-00001, Paper 26 at 7. The list includes documents far post-dating the last events discussed in Dr. Yancopoulos’s and Ms. Chu’s declarations (*e.g.*, Ex.1074, 55:2-5), and documents clearly unrelated to the facts of whether Dr. Yancopoulos reduced certain challenged claims to practice (*e.g.*, Ex.1073, 1624:2-6 (addressing diabetic retinopathy indication)).

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached “PATENT OWNER’S OPPOSITION TO PETITIONER’S MOTION FOR DISCOVERY PURSUANT TO 37 C.F.R. § 42.51(b)” was served on the below date on the Petitioner via e-mail (by consent) to the following counsel of record:

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