UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2023-00884

U.S. Patent No. 11,253,572

PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF EXHIBITS

Ex.	Description
1001-1064	*Previously presented.*
1065	U.S. Patent App. No. 13/940,370 (July 12, 2013)

Pursuant to the Board's authorization (Ex. 3001), Petitioner submits this reply to Patent Owner's Preliminary Response ("POPR") (Paper 6). Patent Owner's attempt to antedate the 2010 Press Releases and ARVO Abstract fails for three independent reasons. Because Patent Owner's substantive arguments against institution for Grounds II and III and portions of Grounds I and VI-VIII are premised upon Patent Owner's flawed attempts to antedate these references, institution is appropriate as set out further below.

I. Patent Owner's Attempt to Antedate the Art Fails Because the '572 Patent is Subject to AIA 35 U.S.C. §§ 102 and 103

Patent Owner contends (at 12) that a January 2011 provisional application provides written description support for claim 25 and therefore pre-AIA Sections 102 and 103 apply to the '572 patent. On that basis, Patent Owner alleges it can swear behind certain prior art references relied on by Petitioner. But claim 25 has an earliest effective filing date of, at best, July 12, 2013, and thus the '572 patent should be treated as a post-AIA patent and analyzed under post-AIA law. Patent Owner's attempt to antedate these references can be rejected for this reason alone.

"AIA 35 U.S.C. 102 and 103 apply to any patent application that contains or contained at any time a claim to a claimed invention that has an effective filing date that is on or after March 16, 2013." MPEP 2159.02; Leahy–Smith America Invents Act ("AIA"), Pub.L. No. 112–29, § 3(c), 125 Stat. 284 (2011). Patent

Owner has the burden of establishing an earlier effective filing date. *See Rsch. Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010).

Claim 25 depends from claim 15 and requires the treatment of diabetic macular edema through "sequentially administering to the patient a single initial dose of 2 mg of aflibercept, followed by one or more secondary doses of 2 mg of aflibercept [four weeks apart], followed by one or more tertiary doses of 2 mg of aflibercept [eight weeks apart]" wherein "four secondary doses are administered to the patient." Ex. 1001. Thus, claim 25 requires five 2 mg injections of aflibercept spaced four weeks apart, followed by further injections spaced eight weeks apart, all for the treatment of DME. That dosing regimen was not described in any of the priority applications until, at best, July 12, 2013. Specifically, on July 12, 2013, U.S. Patent Application 13/940,370 (the "'370 application") was filed, adding Example 7. *See* Ex. 1065, ¶¶ 69-91. Example 7 provides a list of permutations on dosing regimens, one of which recites five initial loading doses as in claim 25. *Id.*

Patent Owner contends (at 12-13) that paragraph 18 of the earlier January 2011 provisional application provided a "literal description of all elements of claim 25." Paragraph 18 states that "[t]he methods of the invention may comprise administering to a patient ***any*** number of secondary and/or tertiary doses of a VEGF antagonist"—i.e. 2, 8, 20, 40, etc. Ex. 2025, ¶ 18. It singles out only the use of only one secondary dose: "in certain embodiments, only a single secondary

dose is administered to the patient." *Id.* It lists other secondary dose possibilities in an unbounded series: "In other embodiments, two or more (e.g. 2, 3, 4, 5, 6, 7, 8, or more) secondary doses are administered to the patient." *Id*. Accordingly, the series of secondary doses alone could extend from months to years.

Paragraph 18 fails to disclose multiple elements of claim 25. It makes no mention of claim 25's recited interval for initial and secondary doses (4 weeks), the recited dosage amount (2.0 mg), the recited indication (DME), or that the tertiary doses are given at 8 week intervals. Nor is there any indication (in paragraph 18 or elsewhere) of what ***combination*** of those variables should be selected: the possibilities are effectively infinite based on the number of secondary doses or intervals between doses alone, let alone the other recited variables.

At best, paragraph 18 discloses a classic "laundry list" of the number of secondary and tertiary doses—"(e.g. 2, 3, 4, 5, 6, 7, 8, or more)"—nothing more. "[L]aundry list disclosures are insufficient to satisfy the written description requirement when there is no further guidance ('blazemarks') provided about which species or combination of species included as part of the list may be selected to arrive at the claimed invention." *Collegium Pharm., Inc. v. Purdue Pharma L.P.*, PGR2018-00048, Paper 18, 16 (Oct. 4, 2018). There are no blazemarks.

Accordingly, the '572 patent should be treated as a post-AIA patent. Patent Owner's attempt to antedate the prior art can be rejected on that ground alone.

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