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Paper 100
Entered: June 30, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

IPR2021-00816
Patent 9,220,631 B2

Before ERICA A. FRANKLIN, ROBERT L. KINDER, and JAMIE T. WISZ, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE

PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

On October 26, 2021, we instituted trial as to claims 1–26 of U.S. Patent No. 9,220,631 B2 (Ex. 1001, "the '631 patent"). Paper 13. After institution, Patent Owner filed a Contingent Motion to Amend on January 18, 2022. Paper 37 ("Motion" or "Mot."). Should we find in a final written decision that the challenged claims are unpatentable, Patent Owner proposes substitute claims 27–52, each of which corresponds to a respective one of challenged claims 1–26. Mot. 6–11. Petitioner filed its Opposition to the Motion. Paper 74 ("Opposition" or "Opp.").

In the Motion, Patent Owner requested that we provide preliminary guidance concerning the Motion in accordance with the Board's pilot program concerning motion to amend practice and procedures. Mot. 1; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) ("Notice"). We have considered Patent Owner's Motion and Petitioner's Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner (or the record) establishes a reasonable likelihood that the substitute claims are unpatentable. Notice, 84 Fed. Reg. at 9,497 ("The preliminary guidance . . . provides preliminary, non-binding guidance from the Board to the parties about the [motion to amend]." Further, "the preliminary guidance will provide an initial

discussion about whether there is a reasonable likelihood that the MTA meets statutory and regulatory requirements for an MTA," and "also will provide an initial discussion about whether petitioner (or the record then before the Office, including any opposition to the MTA and accompanying evidence) establishes a reasonable likelihood that the substitute claims are unpatentable.").

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties' other substantive papers on the underlying merits of Petitioner's challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

Does Patent Owner propose a reasonable number of substitute claims? (35 U.S.C. § 316(d)(1)(B))

Yes, Patent Owner proposes no more than 1 substitute claim for each challenged claim. *See* Mot. 6–11. Petitioner does not argue otherwise.

2. Respond to Ground of Unpatentability

Does the Motion respond to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.121(a)(2)(i))
Yes. Patent Owner responds to the grounds of unpatentability. *See* Mot. 12–25. Petitioner does not argue otherwise.

3. Scope of Amended Claims

Does the amendment seek to enlarge the scope of the claims? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))
No. Each of the proposed substitute claims includes narrowing limitations or additional limitations. *See* Mot. 3–4. Petitioner does not argue otherwise.

4. New Matter

Does the amendment seek to add new subject matter? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))
No. On this record, and having considered Petitioner's contrary arguments (Opp. 1–10), we find Patent Owner provides written description support for the added limitations according to their plain meaning. Patent Owner asserts that the proposed substitute claims are supported by the specification of the original application, No. 13/750,352 ("the '352 Application" (Ex. 2227)) and the priority application EP 12189649 ("EP

'649," (Ex. 2014)).[1] Mot. 6. Patent Owner asserts that the added limitation of "from about 1 μg to about 25 μg silicone oil" in proposed substitute claims 27 and 48 is supported in the original application at page 6, lines 13–20, and claims 7 and 8.[2] Mot. 7, 10. Patent Owner cites the same disclosure for supporting proposed substitute claim 29, reciting a range "of from about 3 μg to about 25 μg silicone oil." *Id.* The cited portion of the '352 Application discloses that

> in one embodiment a syringe according to the invention comprises less than about 800 μg, (i.e. about less than about 500 μg, less than about 300 μg, less than about 200 μg, less than about 150 μg, less than about 75 μg, less than about 50 μg, less than about 25 μg, less than about 15 μg, less than about l0 μg) silicone oil in the barrel. If the syringe comprises a low level of silicone oil, this may be more than about 1 μg, more than about 3 μg, more than about 5 μg, more than about 7 μg or more than about 10 μg silicone oil in the barrel.

Ex. 2227, 6:13–20. Original claim 7 recites the maximum amounts of silicone oil for internally coating a syringe barrel (less than about 500 μg, 100 μg, 50 μg, 25 μg, and 10 μg). *Id.* at 18. Original claim 8 recites the minimum amounts of silicone oil for internally coating a syringe barrel (more than about 1 μg, 3 μg, 5 μg, 7 μg, and 10 μg). *Id.*

As to the new limitation that the VEGF solution "has a shelf life of at least twelve months after terminal sterilization" in proposed substitute claim 27, Patent Owner cites the original application at page 12, lines 15–17. Mot. 7. The cited portion of the specification recites: "[t]hus, in one embodiment, a syringe according to the invention (whilst in its blister pack) may have a shelf life of up to 6 months, 9 months, 12 months, 15 months, 18 months, 24 months or longer," following a description of a sterilization process. Ex. 2227, 12:13–17.

Patent Owner argues that Dr. Sigg testifies that he developed syringe barrels comprising amounts of silicone oil range from [redacted]. Mot.

[1] Both applications appear to disclose the same subject matter. *See generally*, Ex. 2227; Ex. 2014. The parties do not argue otherwise. For expediency, we cite to Ex. 2227.

[2] Patent Owner cites the Bates numbers of the exhibit.

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