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Paper 13
Date: October 26, 2021

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 KRISTI L. R. SAWERT, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

On April 16, 2021, Regeneron Pharmaceuticals, Inc. ("Petitioner" or "Regeneron")[1] filed a Petition to institute *inter partes* review of claims 1–26 (all claims) of U.S. Patent No. 9,220,631 B2 (Ex. 1001, "the '631 patent"). Paper 1 ("Petition" or "Pet."). Novartis Pharma, AG, et al., ("Patent Owner" or "Novartis")[2] filed a Preliminary Response to the Petition. Paper 8 ("Preliminary Response" or "Prelim. Resp."). Pursuant to our authorization, Petitioner filed a Reply (Paper 11, "Reply") and Patent Owner filed a Sur-Reply (Paper 12, "Sur-Reply").

An *inter partes* review may not be instituted unless the information presented in the petition and the preliminary response shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a) (2018). For the reasons set forth below, upon considering the Petition, Preliminary Response, Reply, Sur-Reply, and evidence of record, we are persuaded that Petitioner has demonstrated, under 35 U.S.C. § 314(a), a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we institute an *inter partes* review of the challenged claims.

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[1] Petitioner identifies Regeneron Pharmaceuticals, Inc. as the real party in interest. Pet. 1.

[2] Patent Owner identifies the named parties (Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation) as the real parties in interest. Paper 4, 2.

II. BACKGROUND

A. Related Cases and Proceedings

The '631 patent is involved in two district court cases. Pet. 1–2. On June 19, 2020, Patent Owner filed a complaint[3] in the United States District Court for the Northern District of New York (NDNY) alleging that Petitioner infringes at least claim 1 of the '631 patent. Pet. 2 ("parallel district court litigation"). On July 17, 2020, Regeneron filed a complaint[4] in the Southern District of New York (SDNY) against Novartis and Vetter Pharma International GmbH seeking judgment that (i) Novartis's and Vetter's conduct violates Section 1 of the Sherman Act, (ii) Novartis's conduct violates Section 2 of the Sherman Act, and (iii) the '631 patent be declared unenforceable. Pet. 2–3 ("antitrust litigation").

On June 19, 2020, Novartis filed a complaint at the International Trade Commission ("ITC") alleging that Regeneron infringed claims 1–6 and 11–26 of the '631 patent. Pet. 1–2 ("ITC Investigation"). On April 8, 2021, Novartis filed a motion to terminate the ITC Investigation on the basis of withdrawal of the complaint. Pet. 2; Ex. 1006. On April 8, 2021, the Administrative Law Judge issued an initial determination terminating the ITC Investigation. Ex. 1010.

On July 16, 2020, Petitioner filed petitions in IPR2020-01317 (IPR'1317) and IPR2020-01318 (IPR'1318) challenging claims 1–26 of the

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[3] Novartis Pharma AG et al. v. Regeneron Pharms., Inc., No. 20-cv-690 (N.D.N.Y.) (filed Jun. 19, 2020).
[4] Regeneron Pharms., Inc. v. Novartis Pharma AG et al., No. 20-cv-5502 (S.D.N.Y.) (filed July 17, 2020).

'631 patent. Pet. 2. On December 2, 2020, Petitioner filed a motion to terminate IPR'1318 and the Board issued an order terminating the proceeding on December 7, 2020. On January 15, 2021, the Board exercised its discretion under 35 U.S.C. § 314(a) and denied institution of IPR'1317 based on the ITC Investigation that was co-pending at that time.

B. The '631 Patent

The '631 patent is titled "SYRINGE." Ex. 1001, code (54). The '631 patent "relates to a syringe, particularly to a small volume syringe such as a syringe suitable for ophthalmic injections." *Id.* at code (57). The U.S. application resulting in the '631 patent was filed on January 25, 2013 (*id.* at code (22)), and identifies multiple purported foreign priority applications, the earliest of which was filed in July 2012 (*id.* at code (30)).

The Specification notes that for small volume syringes intended for eye injections, sterilization can present issues that are not necessarily associated with larger syringes. *Id.* at 1:22–30. Further, certain therapeutics are particularly sensitive to sterilization techniques, thus it is important for the syringe to remain robustly sealed but also easy to use in that the force required to depress the plunger to administer the medicament must not be too high. *Id.* at 1:31–40.

Figure 2 of the '631 patent, reproduced below, illustrates a cross section through the syringe. *Id.* at 10:60–67.

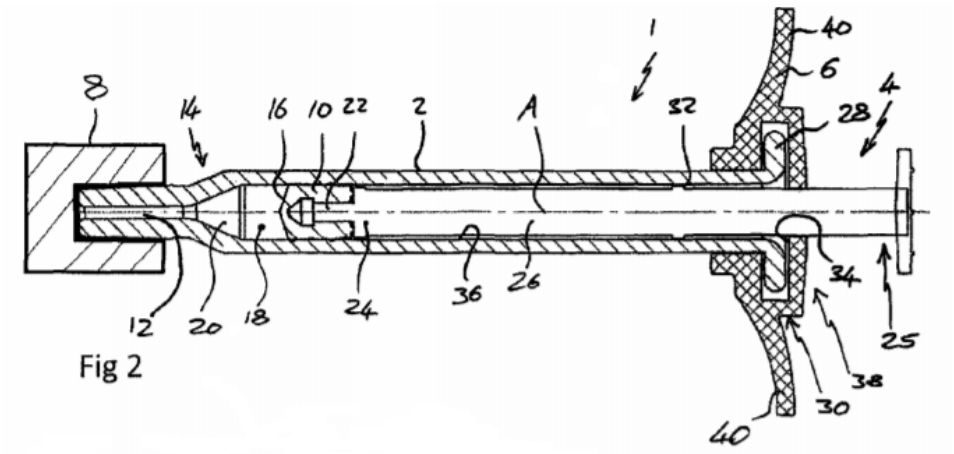

Figure 2 (above) depicts a cross section of a top down view of a syringe. *Id.* at 10:48–49.

As described, syringe 1 comprises body 2, stopper 10 and plunger 4. *Id.* at 10:61–67. Syringe 1 extends along first axis A, and body 2 comprises outlet 12 at outlet end 14. *Id.* Stopper 10 is arranged within body 2 such that front surface 16 of stopper 10 and body 2 define variable volume chamber 18. *Id.* Variable volume chamber 18 contains injectable medicament 20 comprising an ophthalmic solution comprising a VEGF antagonist. *Id.* at 10:67–11:2. Injectable fluid 20 can be expelled though outlet 12 by movement of stopper 10 towards outlet end 14 thereby reducing the volume of variable volume chamber 18. *Id.* at 11:3–5.

C. Challenged Claims

The '631 patent includes twenty-six claims, and Petitioner challenges each claim. Claim 1 is illustrative and reads as follows:

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