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Paper 113
Entered: October 25, 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*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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.”). On October 26, 2021, we instituted the petitioned review (Paper 13, “Institution Decision” or “Inst. Dec.”).

Novartis Pharma, AG, et al., (“Patent Owner” or “Novartis”)² filed a Patent Owner Response (Papers 35, 40³ “PO Resp.”) to oppose the Petition. Regeneron filed a Reply (Papers 72, 73 “Pet. Reply”) to the Patent Owner Response. Patent Owner filed a Sur-reply (Papers 92, 93 “Sur-reply”) to the Reply. We conducted an oral hearing on July 21, 2022. A transcript has been entered into the record (Paper 112, “Tr.”).

We have jurisdiction under 35 U.S.C. § 6(b)(4) and § 318(a). This Decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of claims 1–26 of the ’631 patent. We determine Petitioner has shown by a preponderance of the evidence that those claims are unpatentable.

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.

³ Two papers listed include both the public, redacted, version and the sealed confidential version.

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 complaint⁴ 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 complaint⁵ 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 infringes 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

⁴ Novartis Pharma AG et al. v. Regeneron Pharms., Inc., No. 20-cv-690 (N.D.N.Y.) (filed Jun. 19, 2020).

⁵ Regeneron Pharms., Inc. v. Novartis Pharma AG et al., No. 20-cv-5502 (S.D.N.Y.) (filed July 17, 2020).

the '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 2012⁶ (*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.

⁶ Patent Owner contends that the claims are entitled to a priority date of July 3, 2012. PO Resp. 7. Whether the claims are entitled to the July 3, 2012 priority date, or to the date of October 23, 2012 (Ex. 1003 ¶ 20) alleged by Petitioner, makes no difference in our ultimate patentability determination.

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

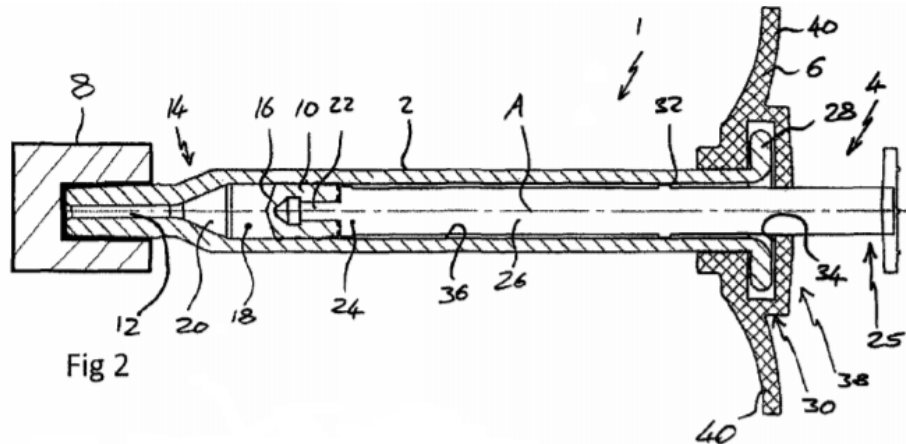


Figure 2 (above) depicts a cross section of a top down view of a syringe. *Id.* at 10:48–49.

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 through 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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