

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,  
Petitioner,

v.

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

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IPR2020-01317  
Patent 9,220,631 B2

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Before ERICA A. FRANKLIN, ROBERT L. KINDER, and  
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

DECISION

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

## I. INTRODUCTION

Regeneron Pharmaceuticals, Inc. (“Petitioner”),<sup>1</sup> on July 16, 2020, 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 3 (“Petition” or “Pet.”). Novartis Pharma, AG, et al., (“Patent Owner”)<sup>2</sup> filed a Preliminary Response to the Petition. Paper 10 (“Preliminary Response” or “Prelim. Resp.”). Pursuant to our authorization, Petitioner filed a Reply (Paper 13, “Reply”) and Patent Owner filed a Sur-Reply (Paper 14, “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 exercise our discretion under 35 U.S.C. § 314(a) to deny institution.

## II. BACKGROUND

### A. *Related Cases and Proceedings*

In addition to IPR2020-01317, the ’631 patent is involved in two district court cases and a proceeding pending before the International Trade

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<sup>1</sup> Petitioner identifies Regeneron Pharmaceuticals, Inc. as the real party in interest. Pet. 4.

<sup>2</sup> Patent Owner identifies the named parties (Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation) as the real parties in interest. Paper 6, 2.

Commission (“ITC”). Petitioner also filed a related petition requesting *inter partes* review in IPR2020-01318, challenging claims of the ’631 patent. We address each below.

*1. ITC Proceeding*

The ’631 patent is asserted in *Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof II*, Inv. No. 337-TA-1207, filed June 19, 2020 (“the ITC Investigation”). Pet. 4; Paper 6, 2. On July 21, 2020, the ITC issued a notice of institution of the investigation. Ex. 2042, 4–5.

The ITC Investigation alleges that Petitioner infringes claims 1–6 and 11–26 of the ’631 patent. Pet. 4. The ITC Investigation has not been stayed and Petitioner did not request a stay. Reply 9. The “Procedural Schedule” sets a hearing for April 19–23, 2021, a final initial determination date of July 29, 2021, and a date of November 29, 2021, for completion of the investigation. Ex. 2002, 3–4. Petitioner notes that a “Presidential review period” will last until approximately January 29, 2022. Reply 13.

*2. Northern District of New York Patent Infringement*

The ’631 patent is asserted in *Novartis Pharma AG v. Regeneron Pharm. Inc.*, 1:20-cv-00690 (N.D.N.Y.). Pet. 4; Paper 6, 2. On June 19, 2020, Patent Owner filed a complaint for patent infringement against Petitioner. Ex. 2043, 2. The complaint alleges that Petitioner infringes at least claim 1 of the ’631 patent. *See* Pet. 4.

The case was stayed pursuant to 28 U.S.C. § 1659 in view of the parallel ITC Investigation. *See* Exs. 2042, 2043.

3. *Southern District of New York Antitrust*

The '631 patent also is involved in *Regeneron Pharmaceuticals Inc. v. Novartis Pharma AG*, 1:20-cv- 05502-AJN (S.D.N.Y.). Paper 6, 2; Ex. 2057. On July 17, 2020, Petitioner filed a complaint against Patent Owner alleging that the '631 patent was “fraudulently procured” and that “Novartis deliberately withheld” key prior art “from the USPTO during prosecution of the '631 Patent.” Ex. 2057, 5, 6, 31.

Petitioner further alleges in this complaint that the '631 patent is unenforceable due to inequitable conduct because material prior art was withheld with an intent to deceive the USPTO. *Id.* at 32–33. Petitioner’s 232-count complaint asserts various antitrust-based harms allegedly caused by Patent Owner, including attempted monopolization through *Walker Process* fraud in violation of Section 2 of the Sherman Act. *See id.* at 73 (asserting that “[t]he '631 Patent is unenforceable because Novartis committed fraud on the USPTO in order to obtain the '631 Patent.”).

As of January 5, 2021, this case has not been stayed by the district court. *See* Ex. 3002.

4. *IPR2020-01318*

Petitioner filed a petition in IPR2020-01318 also challenging all claims of the '631 patent. *See Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG*, IPR2020-01318, Paper 3 (“the IPR1318 proceeding”). On December 7, 2020, we granted Petitioner’s Unopposed Motion to Terminate the IPR1318 proceeding. *Id.*, Paper 17.

*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, and identifies multiple foreign priority applications, the earliest of which was purportedly filed on July 3, 2012. Ex. 1002, 226; Pet. 13–14.

The Specification notes that for small volume syringes intended for eye injections, sterilization can present issues that are not necessarily associated with larger syringes. Ex. 1001, 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.

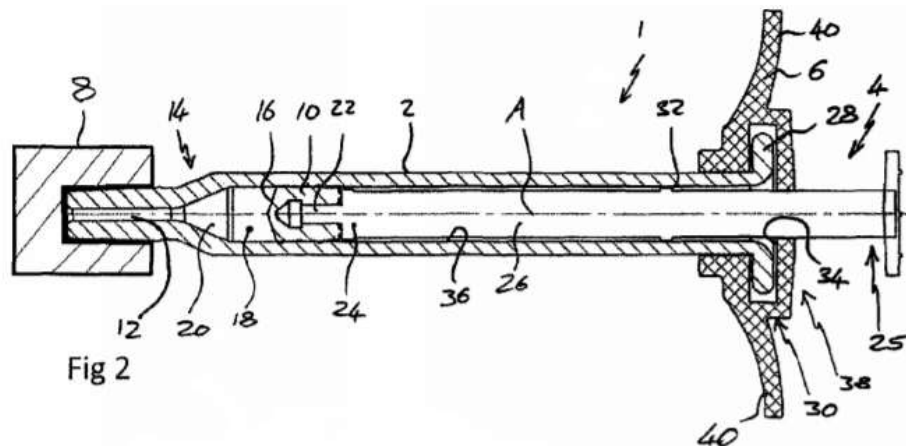


Figure 2 (above) depicts a cross section of a top down view of a syringe. *Id.* at 10:48–49.

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