IN THE SUPREME COURT OF THE UNITED STATES

17A ____

AMGEN INC., AMGEN MANUFACTURING LIMITED, AMGEN USA, INC.,

Petitioners,

v.

SANOFI, AVENTISUB LLC, REGENERON PHARMACEUTICALS INC., SANOFI-AVENTIS U.S., LLC,

Respondents.

APPLICATION FOR AN EXTENSION OF TIME
IN WHICH TO FILE A PETITION FOR A WRIT OF CERTIORARI
TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

Amgen Inc., Amgen Manufacturing Limited, and Amgen USA, Inc. ("Amgen") respectfully request a 60-day extension of time, to and including July 23, 2018, within which to file a petition for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Federal Circuit in *Amgen Inc.* v. *Sanofi*, No. 17-1480 (Fed. Cir.). The court of appeals entered judgment on October 5, 2017, and denied rehearing and rehearing *en banc* on February 23, 2018. Unless extended, the time for filing a petition for a writ of certiorari will expire on May 24,

2018. Pursuant to this Court's Rule 13.5, this application is being filed at least 10 days before that date. This Court has jurisdiction under 28 U.S.C. §1254(1). A copy of the court of appeals' opinion is attached as Exhibit 1, and a copy of the court of appeals' order denying rehearing and rehearing *en banc* is attached as Exhibit 2.

As explained below, the extension is necessary to permit counsel of record—who was not retained until after merits briefing in the Federal Circuit—to familiarize himself with the voluminous record, to determine whether to file a petition for a writ of certiorari, and, if one is to be filed, to see to its preparation and submission. Counsel of record also has been heavily engaged with the press of other matters.

1. The patents at issue in this case—U.S. Patent Nos. 8,829,165 and 8,859,741—disclose Amgen's invention of monoclonal antibodies that have proven useful in therapeutic treatment. Those novel antibodies reduce low-density lipoprotein ("LDL") cholesterol or "bad cholesterol" levels in the blood. Ex. 1, Op. at 3-4. Typically, high cholesterol is treated using molecules called statins. *Id.* at 4. The antibodies that Amgen invented operate through an entirely different mechanism of action. *Ibid.* In particular, they target a naturally occurring protein in the body known as PCSK9. *Ibid.*

Receptors in the liver ("LDL-receptors") ordinarily extract LDL-cholesterol from the blood. Ex. 1, Op. at 4. But PCSK9 binds to the LDL-receptors,

interfering with their ability to remove bad cholesterol. *Id.* at 4, 6. The relevant claims of the two Amgen patents cover monoclonal antibodies that bind at an area on the PCSK9 protein, informally dubbed the "sweet spot." Binding with PCSK9 at the sweet spot blocks PCSK9 from binding with LDL-cholesterol receptors; it thereby prevents PCSK9 from interfering with the receptors' removal of LDL-cholesterol. *Id.* at 4-5. Amgen's patents describe the generation of hundreds of antibodies that bind to the sweet spot and block PCSK9. *Ibid.* The patents also provide the amino-acid sequences for 24 claimed antibodies that bind at the sweet spot. *Id.* at 5-6. This research resulted in the development of Amgen's drug Repatha. *Id.* at 4. The FDA approved Repatha in August 2015. *Ibid.*

Respondents (Sanofi-Regeneron) also explored monoclonal antibodies that target PCSK9. Ex. 1, Op. at 6. Sanofi-Regeneron's research culminated in the development of the drug Praluent. *Ibid.* Like Repatha, Praluent targets the sweet spot on PCSK9 to prevent PCSK9 from binding to and destroying cholesterol receptors. *Ibid.* Sanofi-Regeneron sought FDA approval of Praluent in November 2014, and the FDA approved it in July 2015. *Ibid.*

2. In October 2014, Amgen filed suit against Sanofi-Regeneron, alleging that Praluent infringed Amgen's two patents in suit. Ex. 1, Op. at 6. Sanofi-Regeneron stipulated to infringement, but challenged the validity of the patents asserted by Amgen. *Ibid.* Among other things, Sanofi-Regeneron asserted that the patents failed to provide an adequate written description. *Ibid.* Under § 112 of

the Patent Act, patents must include "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same." 35 U.S.C. § 112(a).

The district court held a five-day jury trial. Before and during trial, Sanofi-Regeneron sought to introduce evidence of PCSK9 antibodies, created after Amgen's priority date, as evidence in support of their argument that the patents did not meet the written-description requirement. See Ex. 1, Op. at 6. Sanofi-Regeneron argued that Praluent, and other antibodies developed after the priority date of Amgen's patents, supported their argument that the monoclonal antibodies disclosed in Amgen's patents were not sufficient for written-description purposes because they were not "representative" of the genus of monoclonal antibodies Amgen had claimed as its invention. See *id.* at 8-9. The district court excluded that evidence. The evidence, it ruled, did not "illuminate[] the state of the art *at the time of [the patent's] filing*" and thus was not relevant "to determine whether there is sufficient disclosure of the claimed invention." *Id.* at 7 (first alteration in original).

The district court also instructed the jury that a patentee could satisfy the written-description requirement by disclosing a representative number of species falling within the scope of the genus or structural features common to the members of the genus. Ex. 1, Op. at 12. Based on Federal Circuit precedents, the district

court further instructed the jury that written description can be satisfied by the disclosure of a "newly characterized antigen"—the location where the antibody binds to the targeted pathogen—if "the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine." *Ibid.*

The jury returned a unanimous verdict for Amgen, finding that none of the asserted claims was invalid.

3. Sanofi-Regeneron appealed, and the Federal Circuit reversed in relevant part. Ex. 1, Op. at 7-18.

The court first addressed issues arising from the "written description" requirement under §112. Quoting the Federal Circuit's *en banc* decision in *Ariad Pharmaceuticals, Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the court of appeals held that, "[t]o show invention, a patentee must convey in its disclosure that it 'had possession of the claimed subject matter as of the filing date.'" Ex. 1, Op. at 7. "[F]or a claim to a genus," the court stated, the patent must show that the patentee had possession in one of two ways: It must either (1) "disclose 'a representative number of species falling within the scope of the genus'" or (2) disclose "'structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus.'" *Id.* at 7-8 (quoting *Ariad*, 598 F.3d at 1350).

The court of appeals then turned to the relevance of Sanofi-Regeneron's post-priority-date evidence. The court stated that "written description is judged based on the state of the art as of the *priority date*." Ex. 1, Op. at 8 (emphasis added). But it found that Sanofi-Regeneron's post-priority-date evidence still could have been relevant. Under *Ariad*, the court stated, "a patent claiming a genus must disclose 'a representative number of species falling within the scope of the genus.'" *Ibid.* (quoting *Ariad*, 598 F.3d at 1350). "[E]vidence of species that fall within the claimed genus but are not disclosed by the patent," the court stated, might be relevant as tending to show that "a claimed genus does not disclose a representative number of species." *Id.* at 8-9. Such evidence, the court opined, "is likely to postdate the priority date." *Id.* at 9. As a result, the court of appeals held that the district court improperly excluded Sanofi-Regeneron's post-priority-date evidence. *Id.* at 11.

The court of appeals also held that the district court erred by giving the "newly characterized antigen" instruction. Ex. 1, Op. at 12. The court agreed that, for at least 15 years, Federal Circuit precedent had supported that instruction. *Id.* at 13-15. Those cases had accepted the rule, formulated by the PTO, that the written-description requirement for a novel antibody can be met by fully describing the novel protein or antigen to which it binds, so long as generating that antibody would be routine for anyone skilled in the art. See *id.* at 15. But the court deemed the relevant language in those cases non-binding "dictum." *Id.* at 13-15.

According to the court, the instruction "effectively permitted the jury to dispense with the required finding of a 'written description of the invention.'" *Id.* at 15-16 (quoting 35 U.S.C. §112). "[T]o satisfy the statutory requirement of a description of the invention," the court stated, "it is not enough for the specification to show how to make and use the invention, *i.e.*, to enable it." *Id.* at 16. "Yet the instruction in this case invites just that improper equation," it concluded. *Ibid.* The court of appeals instructed the district court to alter its jury instructions accordingly on remand. *Id.* at 18.

4. On February 23, 2018, the court of appeals denied Amgen's petition for rehearing and rehearing *en banc*. Ex. 2.

5. Amgen respectfully requests that an extension of time be granted. The additional time is needed to determine whether to file a petition for a writ of certiorari and, if one is to be filed, to see to its preparation and submission. Counsel of record was not retained until after the case was fully briefed in the Federal Circuit. Counsel requires additional time to review the extensive trial record and the complex issues involved. Counsel of record also has been heavily engaged with the press of other matters.[1] Accordingly, Amgen respectfully

[1] These include the preparation of an opening brief in *TCL Communication Technology Holdings Ltd.* v. *Telefonaktiebolaget LM Ericsson, Ericsson Inc.*, Nos. 18-1363, -1380, -1382, -1732, due in the Federal Circuit on May 29, 2018; the preparation of a reply brief in *Continental Circuits LLC* v. *Intel Corp.*, No. 18-1076, due in the Federal Circuit on June 8, 2018; the preparation of a response brief in *Comcast Corp.* v. *ITC*, No. 18-1450, due in the Federal Circuit on June 15,

requests a 60-day extension of time within which to file a petition for a writ of certiorari.

Respectfully submitted.

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May 11, 2018

2018; the preparation of an opening brief in *Idenix Pharmaceuticals LLC* v. *Gilead Sciences, Inc.*, No. 18-1691, due in the Federal Circuit on June 28, 2018; the preparation of a response brief in *VirnetX Inc.* v. *Apple Inc.*, No. 18-1197, filed in the Federal Circuit on April 4, 2018; the preparation of a petition for a writ of certiorari in *Weed* v. *United States*, No. 17-1430, filed in this Court on April 13, 2018; the preparation of a petition for a writ of certiorari in *World Programming Ltd.* v. *SAS Institute, Inc.*, No. 17-1459, filed in this Court on April 20, 2018; and the preparation of a petition for a writ of certiorari in *Bank Markazi* v. *Peterson*, No. 17-1534, filed in this Court on May 7, 2018.