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## *Client Alert*: Can Post-Filing Evidence be used to Invalidate a Patent?

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This past October, in *Amgen v. Sanofi* (Fed. Cir. 2017), the Federal Circuit sent shivers down the spine of the biotechnology industry when it overturned a district court decision confirming the validity of two patents that claim antibodies for lowering cholesterol. One of the issues litigated was whether or not a court may rely on post-priority-date, i.e., post-filing, evidence to determine if a patent discloses a representative number of species to satisfy the written description requirement. To the surprise and dismay of many innovators, the Court held that post-filing evidence may be relied upon to determine if a specification provides a sufficient number of species that fall within the scope of the genus claimed.

Amgen owns U.S. Patent Nos. 8,829,165 and 8,859,741 (collectively, the Amgen patents), which cover therapeutic monoclonal antibodies marketed as Repatha® (evolocumab). Briefly, the Amgen patents claim monoclonal antibodies that bind to proprotein convertase subtilisin kexin type 9 (PCSK9) at specific residues or epitopes on a protein, which blocks the binding of PCSK9 to low density lipoprotein receptors (LDLR).

Sanofi US and Regeneron Pharmaceuticals, Inc. developed their own monoclonal antibody product—Praluent® (alirocumab), which also binds to PCSK9 and prevents binding of PCSK9 to LDLR. In July of 2015, the FDA approved Praluent® for the US market. However, just prior to the FDA approval, Amgen brought an infringement action in the District Court for the District of Delaware against Sanofi and Regeneron alleging patent infringement and seeking a permanent injunction to prevent Praluent® from entering the US market until the Amgen patents expire.

In the District Court, the defendants argued that the Amgen patents were invalid because the claims were not enabled and lacked written description under 35 USC § 112, and were further obvious under 35 USC § 103. With regard to the written description, the defendants stipulated that the Amgen patents failed to provide a sufficient number of species that fall within the scope of the genus claimed, and offered evidence that certain antibodies, including Praluent® itself, were not known or

described until after the priority date of the Amgen patents, and that those antibodies allegedly fall within the scope of the claims. In refusing to admit the post-filing evidence, the District Court upheld the validity of the Amgen patents on all grounds and granted a permanent injunction.

On appeal, the Federal Circuit acknowledged that it had not previously considered whether post-filing evidence can be used to challenge written description. Disagreeing with the District Court, the Federal Circuit reasoned that:

> ...the district court and Appellees misread *In re Hogan* by conflating the difference between post-priority-date evidence proffered to illuminate the post-priority-date state of the art, which is improper, with post-priority-date evidence proffered to show that a patent fails to disclose a representative number of species. *In re Hogan* prohibits the former but is silent with respect to the latter. (Slip Op. at p. 10.)

The Court expressly held that using post-priority-date evidence to show that a patent does not disclose a representative number of species of a claimed genus is proper. The District Court decision was, therefore, vacated and remanded.

## Practice Note

Regardless of technology, all patent owners and applicants, especially those that draft broad genus-type patent claims, may be affected by this decision as it opens the door to new patent validity challenges based on post-filing evidence. Patent owners must now consider the risk of their own post-filing disclosures, which may conceivably be used as evidence against the validity of their granted claims.

Amgen has a fairly robust disclosure for an antibody patent, so there is a reasonable possibility that the claims will survive on remand. Unsurprisingly, Amgen has petitioned the Court for *en banc* review, and unless the decision is overturned on *en banc* review or possibly by the Supreme Court, several issued patents may be subject to challenges on the basis of lack of written description.

Applicants should take extra care in preparing a comprehensive patent filing strategy that weighs the advantages of quickly filing a patent application to secure a priority date against the potential disadvantage of being limited to narrow claims that may only protect the specific embodiments disclosed. While this has always been advisable, *Amgen v Sanofi* highlights the importance of drafting a robust specification at the earliest possible date and avoiding hastily filed applications.