SUTHERLAND

LEGAL ALERT

February 28, 2011

The Written Description Requirement Revisited, Giving Caution to Biotech Patent Owners

On February 23, 2011, in *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, No. 2010-1144, a three-judge panel of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) applied the written description requirement set forth in 35 U.S.C. § 112, first paragraph, to invalidate Centocor's U.S. Patent No. 7,070,775 (the '775 patent).

The case came before the Federal Circuit on appeal after the district court granted Abbott's motion for judgment as a matter of law (JMOL) to set aside the jury's finding of willfulness damages in the amount of $1.67 billion, but denied Abbott's JMOL motions on the issues of infringement and validity. The Federal Circuit reversed the district court's denial of JMOL as to the validity of the '775 patent, holding that claims 2, 3, 14, and 15 (the asserted claims) were invalid.

In 1991, Centocor filed a patent application disclosing two therapeutic antibodies (the A2 mouse and chimeric antibodies) for neutralizing tumor necrosis factor α (TNF-α), the overproduction of which can lead to autoimmune conditions such as arthritis. The A2 mouse and chimeric antibodies contain mouse variable regions and human constant regions, and are not considered "fully-human" because the variable region is determinative of antibody type. The patent application described the difficulties associated with making a fully-human antibody to a human protein like TNF-α.

Centocor subsequently filed a series of continuation-in-part (CIP) applications in 1994 that added new matter which Centocor relied on as evidence of the written description for the asserted claims. After Abbott was granted a patent in 2000 and received regulatory approval in 2002 of Humira®, a fully-human antibody to TNF-α, Centocor filed claims to human variable regions and fully-human antibodies as part of a thirteenth application in the still-pending patent family disclosing the A2 mouse and chimeric antibodies. The subject '775 patent issued in 2006, and shortly thereafter, Centocor filed this action alleging that Humira® infringed the asserted claims.

At trial, the jury rejected Abbott's arguments that the asserted claims were invalid, finding no invalidity for anticipation, lack of enablement, or lack of written description and also finding willful infringement on the part of Abbott. After the district court denied its JMOL motions on infringement and validity, Abbott appealed.

On appeal, the Federal Circuit asked "whether the '775 patent provides adequate written description for the claimed human variable region." Because the '775 patent relied on a priority claim to the 1994 CIP applications to pre-date Abbott's 1996 filing date, the court looked "to the four corners of the CIP applications," which described the A2 mouse antibody and the chimeric antibody Centocor had made based on the A2's mouse variable region in detail. The court determined, however, that "the mouse variable region sequence does not serve as a stepping stone to identifying a human variable region within the scope of the claims" and found that "very little in the '775 patent supports that Centocor possessed a high affinity, neutralizing, A2 specific antibody that also contained a human variable region."

In holding that the '775 patent "specification does not describe a single antibody that satisfies the claim limitations," the court relied on testimony from Abbott's expert that "the mere fact that the 'words appear'

does not reasonably suggest to one of skill in the art that Centocor was in possession of such antibodies." The court stated that the "asserted claims to fully-human antibodies 'merely recite a description of the problem to be solved while claiming all solutions to it.'" In addition, the court noted that the asserted claims constituted a wish list of properties that a fully-human TNF-α antibody should have while the specification at best described a plan for making fully-human antibodies and then identifying those that satisfy the claim limitations. "Claiming antibodies with specific properties, e.g., an antibody that binds to human TNF-α with A2 specificity, can result in a claim that does not meet written description even if the human TNF-α protein is disclosed because antibodies with those properties have not been adequately described."

The court subsequently noted that Centocor's reliance on the U.S. Patent and Trademark Office (PTO) Written Description Guidelines (the PTO Guidelines) was based on an unduly broad characterization of both the PTO Guidelines and court's precedent. While the PTO Guidelines dictate that some antibodies to a well-characterized protein may be adequately described even when they are functionally claimed and not actually produced, the court noted that this reasoning may not apply to obtaining *human* antibodies to a *human* protein, particularly those with specific claimed properties. Moreover, although "precedent suggests that written description for certain antibody claims can be satisfied by disclosing a well-characterized antigen, that reasoning applies to disclosure of newly characterized antigens where creation of the claimed antibodies is routine." Quoting *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).

In finding that Centocor's asserted claims lacked written description, the court reaffirmed that adequacy of the written description is measured by whether the disclosure of the application reasonably conveys to one skilled in the art that the inventor had possession of the claimed invention as of the filing date. Specifically, the court stated that the written description requirement demands that one of skill in the art be able to "visualize or recognize" the claimed invention based on the specification. Although possession can be demonstrated constructively, an applicant cannot merely recite a description of a problem to be solved while claiming all solutions to it.

The Federal Circuit's opinion largely reaffirms previous decisions in which it was held that the written description and enablement requirements are distinct. Although the practical effect of the court's decision remains to be seen, the court's dicta may suggest that the reasoning of the PTO Guidelines and its prior decision in *Noelle* should be narrowly applied in biological arts, where a description of animal antibodies and antigens may not be sufficient to support claims to the human counterparts. Thus, practitioners should remain cautiously aware of the adequacy of the written description when preparing a patent application in the biological arts, especially a provisional application, to avoid potential rejections for lack of written description during patent prosecution or later challenges to a patent's validity.

■ ■ ■

If you have any questions about this Legal Alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

Peter G. Pappas	404.853.8064	pete.pappas@sutherland.com
William L. Warren	404.853.8081	bill.warren@sutherland.com
Stacy D. Fredrich	404.853.8112	stacy.fredrich@sutherland.com
Elizabeth Ann Lester	404.853.8012	elizabeth.lester@sutherland.com