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An Old Trap in the New 'First-to-File' Era

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On March 16, the U.S. patent system will change from a "first-to-invent" to a "first-to-file" system under the Leahy-Smith America Invents Act (AIA). This will trigger a race to the U.S. Patent and Trademark Office (USPTO) with every new idea and invention. Beginning on that date, or even now, the new norm for inventors will be to file early and file often. With the new norm, there are many traps, new and old, for the unwary. One of the most discussed new traps is the effective filing date. Yet another elephant in the room is the old written description requirement, which should not be ignored when the race is on.

To obtain a patent, an applicant must meet a number of requirements, including the "written description" and "enablement" requirements under 35 U.S.C. §112. The two requirements serve two different policy purposes of patent law. The enablement requirement allows for weeding out inventions that cannot be made or used by a hypothetical person in a relevant art, known as a person skilled in the art. In contrast, the written description requirement, by requiring "possession," serves to eliminate protection for inventions not made by the inventors themselves and give others incentive to continue to invent. For inventors, especially those in the biotech/pharmaceutical field, these two requirements are tricky and sometimes confusing. Indeed, some used to call the written description requirement a "super enablement" in the chemical and biotechnology art and believed that an enabling disclosure should satisfy both requirements. Yet, this belief creates a "written description" trap, which can be very costly, as evidenced by *Centocor Ortho Biotech v. Abbott Laboratories,* 636 F.3d 1341 (Fed. Cir. 2011), its predecessors and, most recently, *Helicos Biosciences* v. *Illumina*, case number 10-CV-00735, (D. Del. 2012).

At stake in *Centocor* was about $13 billion involving two blockbuster drugs. One was Abbott's best-selling rheumatoid arthritis drug Humira, which posted $6.5 billion global sales in 2010, accounting for 18 percent of Abbott's revenue. The other was Centocor's (a subsidiary of Johnson & Johnson) Remicade, which had $4.61 billion in sales, making up 7.5 percent of Johnson & Johnson's sales. On top of these numbers was $1.67 billion in damages previously awarded to Centocor by a Texas jury. The patent at issue is U.S. Patent No. 7,070,775 (the '775 patent) co-owned by Centocor Ortho Biotech and New York University (collectively, "Centocor"). Centocor sued Abbott Laboratories, Abbott Bioresearch Center and Abbott Biotechnology Ltd. (collectively, "Abbott"), alleging that Abbott's Humira antibody infringes claims 2, 3, 14 and 15 of the patent. After a trial in the district court, the jury found Abbott liable for willful infringement. Yet, on appeal, the Federal Circuit reversed and ruled that the claims were invalid since they did not meet the "written description" requirement.

Both Humira and Remicade are anti-TNF-α antibodies. In developing those drugs, Centocor and Abbott took different approaches. Centocor started by identifying a mouse antibody to human TNF-α and then modified the mouse antibody to make it look like a human antibody. The resulting product was a chimeric antibody having a mouse variable region and therefore was not considered to be "fully human." Nevertheless, Centocor filed a patent application disclosing both its mouse antibody and the chimeric antibody in 1991, followed by a number of continuation-in-part applications. One of them issued into the '775 Patent with claims covering fully human antibodies. Abbott, on the other hand, worked with collaborators to construct a fully-human antibody from scratch using a phage display library containing a spectrum of human variable regions. In the end, Abbott successfully obtained a fully-human antibody, a related patent

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and FDA approval in 2002. After Abbott's success, Centocor filed its claims to fully-human antibodies and obtained the '775 patent.

In the lawsuit, the Federal Circuit agreed with Abbott that the asserted claims were invalid for failure to meet the written description requirement. In particular, despite the testimony that general library technologies could be used to make antibodies, including human antibodies, the Federal Circuit stated that, "[T]he fact that a fully-human antibody could be made does not suffice to show that the inventors of the '775 patent possessed such an antibody." The court further stated: "The specification at best describes a plan for making fully-human antibodies and then identifying those that satisfy the claim limitations. But a 'mere wish or plan' for obtaining the claimed invention is not sufficient."

The *Centocor* case is not the first time that the Federal Circuit used the written description requirement to invalidate biotech/pharmaceutical patents. In fact, there seems to be a trend that the Federal Circuit is increasingly willing to use this requirement for that purpose. Another three prominent biotech/pharmaceutical cases are *Regents of the Univ. of California v. Eli Lilly,* 119 F.3d 1559 (Fed. Cir. 1997), *Univ. of Rochester v. G.D. Searle,* 358 F.3d 916 (Fed. Cir. 2004), and *Ariad Pharm. v. Eli Lilly*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)).

In *Regents of the Univ. of California v. Eli Lilly*, the district court held that one of the University of California patents failed to meet the written description requirement for a claimed broader genus of vertebrate and mammal insulin cDNAs since it only described a rat proinsulin cDNA. The Federal Circuit affirmed that a genus is not adequately described by simply describing a species of that genus but "a description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs." A notable point of this case is that the Federal Circuit singled out chemical and biotechnology patents, requiring that the written description provide "a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." This case is often said to be the first using written description as independent requirement to invalidate patents.

In *Univ. of Rochester v. G.D. Searle,* scientists at the University of Rochester developed a screening assay for determining whether a particular drug selectively inhibited the activity of COX-2, a type of cyclooxygenase. They eventually obtained a U.S. patent covering methods for selectively inhibiting COX-2 activity in a human host by administering a nonsteroidal compound that selectively inhibits the activity. After knowing that the anti-inflammation drugs Celebrex and Bextra targeted COX-2, the university sued G.D. Searle, Monsanto, Pharmacia and Pfizer (collectively, "Pfizer") who marketed the drugs. Again, like the University of California's patent, the University of Rochester's patent was invalidated for failing to comply with the written description requirement.

Fast forwarding to March 2010, 10 months before *Centocor*, the Federal Circuit invalidated another high-profile biotech patent (*Ariad Pharm. v. Eli Lilly*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)) for not meeting the same requirement. Although the dollar amount in the *Ariad* case was not as large (about $65 million in back royalties and 2.3 percent on future sales of Eli Lilly's drugs Evista and Xigris), the patent was granted to a group of inventors, including several Nobel laureates and co-owned by famous research institutions such as Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research and Harvard College.

Most recently, on Aug. 28, in *Helicos Biosciences* v. *Illumina,* a Delaware federal judge invalidated Helicos' patent also for lack of written description regarding a particular focusing light source in its claimed apparatus for analyzing biological samples.

The mantra in these cases is that a patent claim can be invalidated for failing the written description requirement even though it complies with the enablement requirement. The aftermath of these cases shows that the written description requirement is distinct from the enablement requirement and can be harder to meet.

In *Ariad*, the Federal Circuit made that clear and devised a "four-corner"/"four-factor" test for the written description requirement. That is, the test for sufficiency of the written description of a patent specification is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. The test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art, and for generic claims, four factors are used for evaluating the adequacy of the disclosure: (1) the existing knowledge in the particular field; (2) the extent and content of the prior art; (3) the maturity of the science or technology; and (4) the predictability of the aspect at issue. Although these four factors to some degree resemble some factors for the enablement requirement, limiting the inquiry into the four corners of the specification leaves a patent applicant little wiggle room once an application has been filed and therefore makes the written description requirement stricter to meet than the enablement requirement.

Given the stricter written description requirement, the timing of filing patent applications will become even more critical in the AIA "first-to-file" era. On one hand, not filing until after all products or uses are ascertained and possessed would incur a substantial amount of resources and, more seriously, lose the race to the USPTO against competitors. On the other hand, filing too early in the research discovery process risks an outcome like that in the *Regents of the Univ. of California, Univ. of Rochester, Ariad, Centocor* and *Helicos* cases. Striking the right balance in the new era requires even higher commitment and collaboration than before by researchers, technology transfer officers, investors, corporate partners and their patent counsels so as to make sure that possession of a claimed invention is demonstrated in the four corners of the specification. ■