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Expert Analysis

Court Reemphasizes Importance Of Written Description for Patents

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Difficult economic times force companies to reevaluate current and future business opportunities. For many companies, one of the most valuable ways to secure a stable future is to obtain a solid patent portfolio. In order for a company to have a strong patent portfolio it must first, of course, be innovative. But also important, it must prepare and prosecute patent applications that support the full scope of the claims to capture and protect all to which the inventors should be due.

To assist their clients, many patent lawyers are tempted to draft very broad patent claims. Should the Patent and Trademark Office (PTO) deem these broad claims patentable over the prior art and the patent proceed to issuance, the patentee may seemingly appear able to enjoy a right to prevent others from making, using, and selling a broad class of products or services. The Court of Appeals for the Federal Circuit (CAFC), however, recently reminded patentees that in addition to having claims directed to subject matter that is novel and non-obvious,[1] a patent application must satisfy the requirements of 35 U.S.C. §112, which include the written description requirement.

The written description requirement is rarely discussed outside of the patent bar. However, as clients try to reinforce their competitive positions, they (and their lawyers) need to be cognizant of the fact that even the most innovative of companies will not be able to obtain a valuable competitive advantage if they do not sufficiently focus on this issue. In *ICU Medical Inc. v. Alaris Medical Systems Inc.*,[2] the CAFC recently reemphasized that they need to pay close attention to the exacting written description requirement, and invalidated claims that might have been patentable had the underlying specification been properly drafted.

One of the requirements for obtaining a valid patent claim is that it is supported by the specification, and in fact the first requirement noted in 35 U.S.C. §112 is that "[t]he specification shall contain a written description of the invention."[3] In order to satisfy the written description requirement, the CAFC has stated that the specification must describe the invention in sufficient detail so that one of ordinary skill in the art could clearly conclude that the inventor invented the claimed subject invention as of the filing date of the application.[4] Although this standard imposes a certain requirement on the specification, it must be considered by comparing the invention as it is claimed with the disclosure of that specification.

> The first requirement noted in 35 U.S.C. §112 is that '[t]he specification shall contain a written description of the invention.'

The written description requirement is part of a "quid pro quo" in which the federal government grants the inventor the right to prevent others from making, using and selling an invention for a limited time period in exchange for a meaningful disclosure of the invention such that the public can, after the patent expires, use the invention, and during the life of the patent benefit from a thorough disclosure of how the invention works. Although others are not permitted to practice (even most experimental uses) the claimed technology during the life of the patent, they can use the disclosure to spark ideas and to design around the claimed technology.

Thus, the written description requirement ensures that the scope of the patent right to exclude, as set forth in the claims, is commensurate with, not broader than, the scope of the inventor's contribution to the field of the art as described in the patent specification. Although the specification does not need to recite the claimed invention verbatim as it appears in the patent claims, it must do more than merely disclose that which would have rendered the claimed invention obvious.[5]

'ICU Medical v. Alaris'

In *ICU Medical v. Alaris*, the technology at issue involved medical valves that are used in the transmission of fluids to or from a patient when using an IV. The inventors developed a medical valve that received fluid from a medical implement, such as a syringe, without using external needles. The medical implement compressed a seal on the valve to create a fluid pathway from the medical implement through the valve and into a patient's IV line.

The CAFC grouped the asserted claims into three types, which it defined as: (1) the spike claims; (2) the spikeless or spike-optional claims; and (3) tube claims. The spike claims required that there be a body, a spike and a seal. By contrast, the spikeless or spike-optional claims required only that there be a needle-less connector valve comprising a body and a seal. By using the term "comprising" the claim was open ended, meaning that a valve could, but did not need to, contain additional elements and still be within the scope of the claim.

The claims that were directed to embodiments that did not require the spike were not filed as part of the original application.[6] Rather, they were added years later during prosecution.

The defendant argued that the specification limited the invention to valves that contained a spike, and consequently, did not demonstrate, at the time of invention, that the inventor possessed a medical valve without a spike. The plaintiff

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(patent holder) responded that the claims were spike-optional and thus covered valves with or without the spike. The plaintiff elaborated that the disclosure in the specification of valves with a spike support claims that are neutral regarding whether the valve must include a spike.

The trial court and the CAFC disagreed with the patent holder. The CAFC determined that the claims that did not require the use of a spike were invalid, emphasizing that the specification described only medical valves with spikes. The patentee had argued that in addition to being a spike neutral disclosure, the specification described a preslit or precut seal that would permit fluid transmission without the piercing of a spike.[7] The CAFC disagreed, and also emphasized that "it is not enough that it would have been obvious to person of ordinary skill that a preslit trampoline seal could be used without a spike."[8]

Accordingly, the CAFC found the spikeless or spike optional claims to be invalid for failing to comply with the written description requirement. This finding of invalidity was based on a failure of the disclosure; had the disclosure been drafted differently, the claim might have survived.

Tips for Compliance

ICU Medical should be a reminder to patent practitioners that the written description requirement can and will be used against an applicant or patent holder who deviates too far from the specification as filed. Accordingly, when considering compliance with the written description requirement, practitioners and inventors should be mindful of at least three things.

First, a patent application should not be drafted merely to provide foundation to cover an anticipated commercial embodiment. Rather, the specification should be drafted to provide the foundation to make claims as broad as is justifiable for a given invention. The specification must include embodiments that are within the scope of what the inventor may intend to commercialize, as well as embodiments that differ from the intended commercial embodiment. The more specific embodiments with different features that are disclosed, the broader the genus will be for which the applicant can assert that he or she has an adequate disclosure. Further, there should be explicit language stating that in different embodiments, the invention is directed to different genuses and sub-genuses.

This caution is well-known to those who practice in the biological arts, where claims to broad genuses are difficult to obtain. This, in the biological arts, in part rests on the judicial notice of the alleged unpredictability of the chemistry and biotechnology. However, *ICU* is a reminder that the written description requirement is not technology specific.

Second, the practitioner should be aware that the written description requirement is not symmetrical with the non-obviousness requirement. As the CAFC in *ICU Medical* emphasized, the question before it was not whether the claims at issue would have been obvious, but rather the issue was whether the disclosure indicated devices commensurate with the claims scope, i.e., whether their was any disclosure of a spikeless device. Thus, although there was not support for the broad claim, had someone else tried to make the claim to a device that not only let the presence of the spike be optional, but required its absence, the PTO might have been justified in holding that other party's claim to a spikeless invention was obvious over ICU Medical's patent. This is because when evaluating the written description requirement, one does not ask if the claimed subject matter is an obvious variant of what is disclosed.[9] Additionally, it should be noted that the PTO did not say that the inventors would not have been entitled to the broader claim had they drafted an adequate specification to support it.

This new reality will place additional pressure on patent practitioners to draft claims at the start of prosecution that are adequately supported by the specification, that cover the desired subject matter and that can get through prosecution with limited numbers of amendments.

Third, in a separate case a few days after *ICU Medical* was decided, the CAFC vacated much of the injunction against the PTO's implementation of rules for limiting continuation practice.[10] Beginning in 2006, the PTO underwent its rule making process to institute a series of rules that would make it difficult for patent applicants to take more than what the PTO thought would be a reasonable number of attempts to prosecute patent applications.

The rules issued on Aug. 21, 2007 were intended to address what the PTO thought were excessive or abusive practices with respect to the use of continuation applications and requests for examination, and to address the backlog of applications at the PTO. The new rules were set to go into effect on Nov. 1, 2007. However, on Oct. 31, 2007, they were preliminarily enjoined and on April 1, 2008 they were permanently enjoined. The CAFC vacated the injunction with respect to three rules, thereby paving the way for the PTO to reinstitute rule 114, which would limit the number of requests for continued examination that are permitted per patent family as a matter of right, and require an additional showing as to why a request for continued examination is necessary if the applicants want to file additional requests for continued examination, and rules 75 and 265, which in combination would limit the number of claims that an applicant may include in an application absent taking on an additional burden of conducting their own prior art search and identifying both how each independent claim is patentable over the prior art and where the specification supports the claims.[11]

These rules are highly technical, and should they ultimately go into effect, it is unlikely that many people other than patent practitioners, will become intimately familiar with them. Nevertheless, the long and short of them is that they will force applicants either to face significant increase in patent prosecution costs or to accept limitations on the number of back and forth that their attorneys may have with the PTO. This new reality will place additional pressure on patent practitioners to draft claims at the start of prosecution that are adequately supported by the specification, that cover the desired subject matter and that can get through prosecution with limited numbers of amendments. Thus, the written description requirement will likely become both a more heavily litigated issue and a subject of more appeals in the PTO.

Conclusion

The written description requirement focuses on the adequacy of the disclosure of a patent application as compared to scope of the patent claims at issue. During prosecution of a patent, practitioners and their clients are often tempted to reach into the specification and pull out features to be included in broad claims. However, the applicant does not have an endless right to claims to inventions whose breadth are not adequately supported by the specification, and particularly in view of the continuation rules that will likely go into effect in the near future, an applicant should be wary of reaching for too large of a grant of patent right when he or she has only provided a description of narrow embodiments.

1. 35 U.S.C. §§102, 103.
2. 2008-1077 Slip. Opinion (Fed. Cir. March 13, 2009).
3. 35 U.S.C. §112, ¶1.
4. *In re Alonso*, 2008 U.S. App. LEXIS 24320 6-7 (Fed. Cir. Oct. 30, 2008).
5. *ICU Medical v. Alarnis*, at 9-10.
6. Id. at 10.
7. Id. at 12-13.
8. Id. at 13.
9. *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. GE*, 264 F.3d 1111, 1119-20 (Fed. Cir. 2001).
10. *Tafas v. SmithKline Beecham*, 2008-1352 Slip Opinion (Fed. Cir. March 20, 2009).
11. Id. at 3.