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PATENTS

The Supreme Court's New Definiteness Standard And Its Effect on Medical Device Patents

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The current intellectual property environment is trending against patents in many arenas. Congress recently proposed legislation aimed at making it harder for non-practicing entities to assert patents. The U.S. Patent and Trademark Office's Patent Trial and Appeal Board is canceling a staggering percentage of claims for which trial is instituted—about 81 percent. And recently, the Supreme Court decided two cases that some commentators have characterized as anti-patent decisions—*Alice Corp. Pty. Ltd. v. CLS Bank International*[1] and *Nautilus, Inc. v. Biosig Instruments, Inc.*[2] In *Alice Corp.*, the Supreme Court determined that a computer-implemented method of mitigating settlement risk was not eligible for patenting, and in *Nautilus*, the Supreme Court lowered the standard for finding claims indefinite and, thus, made it easier to invalidate a patent. The *Nautilus* decision has many implications on the medical device community.

[1] No. 13-298, slip op. (U.S. June 19, 2014).

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Supreme Court's Nautilus Decision

A patent's claims define the metes and bounds of an invention. U.S. patent law requires that the claims ''particularly point[] out and distinctly claim[]'' the invention—the statutory definiteness requirement.[3] (The America Invents Act did not alter the wording of this statutory requirement.) The *Nautilus* decision involved this definiteness requirement.

In *Nautilus*, the patent claimed a heart rate monitor for use with an exercise apparatus that included a live electrode and a common electrode mounted on an elongate member ''in a spaced relationship with each other.''[4] At the district court, Nautilus moved for summary judgment, arguing that *spaced relationship* was indefinite. The district court granted the motion and reasoned that *spaced relationship* did not sufficiently convey what the space between the electrodes could be.[5] Biosig appealed to the Federal Circuit.

On appeal, the Federal Circuit applied its definiteness standard: a claim is indefinite only when it is ''not amenable to construction'' and is ''insolubly ambiguous.''[6] Applying this insolubly-ambiguous standard, the Federal Circuit reversed the district court and held that the patent was not indefinite. The Federal Circuit explained that the intrinsic evidence—the claim language, the specification, and the prosecution history—would allow a person of ordinary skill in the art to understand the

[2] No. 13-369, slip op. (U.S. June 2, 2014).
[3] 35 U.S.C. § 112(b).
[4] *Nautilus*, slip op. at 3-4.
[5] *Id.* at 6-7.
[6] *Id.* at 7.

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metes and bounds of the claimed invention.[7] Particularly, the Federal Circuit noted that the electrodes could not be farther apart than the width of the user's hands because the electrodes detect electrical signals at two distinct points of a hand, and that the electrodes could not be so close together to form a single electrode with one detection point. Nautilus appealed to the Supreme Court.

The Supreme Court vacated the Federal Circuit's decision. To start, the Supreme Court highlighted three well-settled points regarding the definiteness analysis. First, definiteness is determined from the perspective of a person skilled in the relevant art.[8] Second, definiteness is determined in light of the patent's specification and prosecution history.[9] And third, definiteness is determined at the time the patent was filed.[10]

Next, the Supreme Court noted that the statutory definiteness requirement delicately balances two considerations: (1) language has inherent limitations that will always lead to a degree of imprecision and (2) the claims must be precise enough to provide clear notice to the public.[11] Subsequently, the Supreme Court rejected the Federal Circuit's insolubly-ambiguous definiteness standard and instead articulated a new standard based on reasonable certainty: ''a patent's claims, viewed in light of the specification and prosecution history, [must] inform those skilled in the art about the scope of the invention with *reasonable certainty*.''[12] The Supreme Court explained that the Federal Circuit's insolubly-ambiguous definiteness standard lacked the precision that the U.S. patent law required.[13] Particularly, the U.S. patent law does not allow imprecision that falls just short of being ''insolubly ambiguous,'' which the Federal Circuit's standard would have allowed, because such impreciseness fails to provide notice to the public and creates a zone of uncertainty about what is the claimed invention.[14]

Accordingly, the Supreme Court remanded the case to determine whether *spaced relationship* in the asserted patent's claims informed those skilled in the art about the scope of the invention with reasonable certainty in view of the specification and prosecution history.

Practical Considerations for Medical Device Patents

The *Nautilus* decision is a warning that courts may no longer tolerate the same degree of imprecision in patent claims that they once did. And medical device patent claims will likely be challenged on indefiniteness grounds more often during district court litigation and the Patent Office's newly established post-grant review proceedings[15] since the standard for finding claims indefinite was lowered from an insolubly-ambiguous standard to a reasonable-certainty standard. Medical device patent claims often include two feature types that are susceptible to indefiniteness challenges. Particularly, medical device claims often include language that identifies a position of a device component relative to an anatomical feature and pseudo-functional language that denotes device structure.

To name a few examples of relative positional features used in medical device patents, fifteen medical device patents directed to prostheses (U.S. patent class 623) have issued in 2014 with claims that include the relative positional phrases ''close to'' or ''close proximity to,'' for example, ''close to a subcutaneous area'' and ''close proximity to a cataractous lens of the eye.'' And fifty-eight 2014 prostheses patents include the word ''near'' in the claims, for example, ''near . . . the intervertebral disc'' and ''near . . . an intracranial aneurysm.''[16] Regardless of the particular relative positional features, whether that feature is definite will depend on the knowledge and understanding of one of skill in the relevant art and the disclosure in the patent's specification and prosecution history.

Although relative positional claim features may be definite to a person of skill in the art even if the patent specification does not elaborate on such features, including a section in a medical device patent application that expounds on the claimed relative position would help avoid future indefiniteness challenges during litigation or post-grant review proceedings and their associated costs. The patent's specification could include a section that provides a definition of the relative position feature, exemplary dimensional ranges that are within the recited relative position feature, or provide multiple specific dimensions that are within the recited relative position feature. For example, if the medical device claims recite that a device component is implanted ''near the elbow,'' the patent specification could explain that any position between the shoulder and the finger tips is near the elbow. Alternatively, the specification could explain that any position within six inches of the elbow is near the elbow, or the specification could explain that that positions one, five, and ten inches away from the elbow are near the elbow. Such exemplary explanations would help inform, with reasonable certainty, those skilled in the art about the scope of the invention. Again though, depending on the skill in the relevant art, specific definitions or examples in the patent specification may not be necessary to provide reasonable certainty.

Conversely, when attacking a patent that includes relative positional features, analyze the specification to see if it provides a definition or example of the recited relative position feature. If it does not, this feature may be more susceptible to an indefiniteness challenge.

Turning to pseudo-functional language that denotes device structure, these features are prolific in medical device patents. So far in 2014, over 750 light, thermal, or electrical surgery patents (U.S. patent class 607) issued that include the phrases ''configured to'' or ''adapted to,'' which are typically followed by a desired function or result. Here are a few examples of pseudo-

[7] *Id.*
[8] *Id.* at 8.
[9] *Id.*
[10] *Id.* at 9.
[11] *Id.* at 9-10.
[12] *Id.* at 11 (emphasis added).
[13] *Id.* at 11-12.
[14] *Id.* at 12.
[15] Unlike *inter partes reviews* at the Patent Office, issued claims of first-inventor-to-file patents can be challenged on indefiniteness grounds. *See* 35 U.S.C. §§ 282(b)(3)(A), 321(b).

[16] These phrases are merely examples of relative positional language used in medical device patents. The authors have not analyzed whether these particular phrases are definite in view the knowledge of one of skill in the art, the patent's specification, and the prosecution history.

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functional phrases used in the 2014 medical device patents that describe the device structure: ''a lead . . . configured for deep brain simulation,'' ''a medical lead adapted to be placed within the heart,'' and ''a pore size adapted to promote tissue ingrowth.'' Whether pseudo-functional features that denote structure, such as these, are definite depends on the knowledge and understanding of one of skill in the art and the disclosure in the patent's specification and prosecution history.

So when drafting a medical device patent application that claims pseudo-functional features that denote structure, the patent's specification would prudently explain what the recited function or result includes, if not readily apparent to a person skilled in the art, and identify one or more specific structural examples that are capable of achieving the recited function or result. Like relative positional claim features, pseudo-functional language can be definite to a person of skill in the art even if the patent specification does not elaborate on such features, but including a section in a medical device patent application that expounds on the claimed pseudo-functional features would help avoid future indefiniteness challenges and their associated costs. For example, if the claims recite a pore size adapted to promote tissue ingrowth, the patent specification could explain what it means ''to promote tissue ingrowth'' and then identify a dimensional range or specific dimensions of pore size to promote tissue ingrowth. This description would help inform those skilled in the art about the scope of the invention with reasonable certainty. When attacking a patent that includes pseudo-functional features that denote structure, analyze the specification to see if it provides a definition of the recited function or condition, and whether it provides specific structural examples that achieve the recited function or condition.

In sum, whether preparing a patent application, or attacking a patent in district court litigation or in a post-grant review proceeding at the Patent Office, more attention should be devoted to whether medical device claim terms are definite in view of the Supreme Court's newly articulated standard for definiteness in *Nautilus*.