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3 Ways to Meet Biotech Patent Written Description Standards

From the Experts

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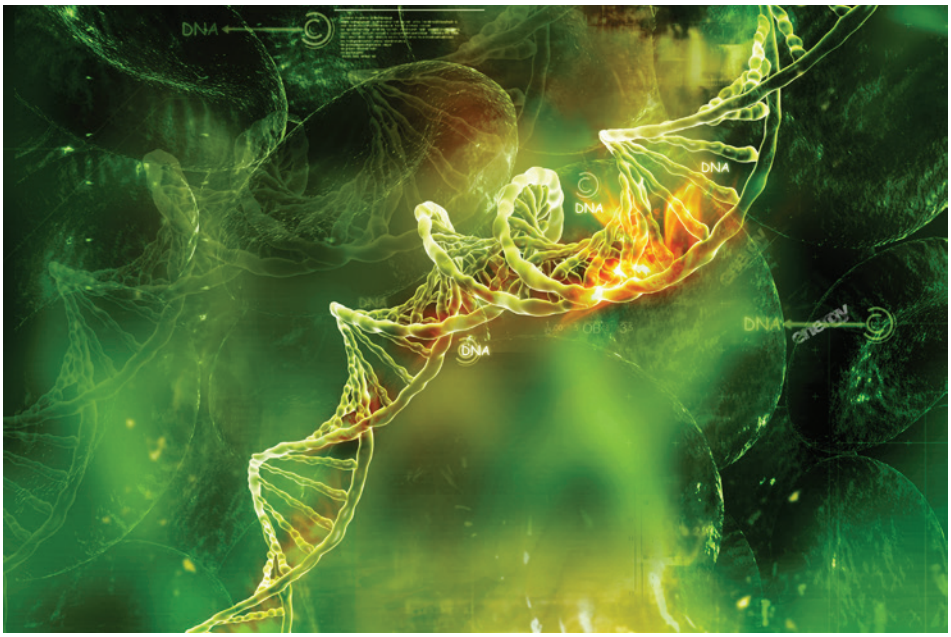

In recent years the U.S. Court of Appeals for the Federal Circuit, in reviewing both litigation and prosecution decisions, has revived the doctrine of written description under 35 U.S.C. § 112. The court has applied the doctrine to biotechnology patents—specifically those claiming genuses of antibodies, DNA sequences or other biologic molecules (i.e., molecules made by processes occurring in living cells). These claims are frequently the target of written description attacks by both the U.S. Patent and Trademark Office (PTO) and by private litigants. Several recent Federal Circuit opinions offer the same guidance on how such claims might be better drafted to satisfy this requirement and avoid the attacks.

For a genus claim generally to satisfy the written description requirement, the specification of the patent generally must permit someone who has skill in the art to "visualize or recognize" the claimed genus based on the specification's disclosure. *Centocor Ortho Biotech Inc. v. Abbott Labs.* (Fed. Cir. 2011). Patents in the biotechnology arts hypothetically can meet this "visualize or recognize" standard by disclosing in their specifications one of the following:

1. A representative number of species in the genus.
2. Relevant identifying characteristics of the genus, such as common structural features of the genus or other physical or chemical properties.
3. Functional characteristics coupled with a known or disclosed correlation between function and structure.

Notably, while the law suggests that each of these criteria by itself is sufficient to satisfy the written description requirement, all of these criteria at a minimum seem to require the disclosure of a common structural property that is shared by the entire genus.

In practice, it is often difficult to discern from Federal Circuit decisions where the line between a satisfactory and an unsatisfactory written description lies for biotechnology patents. For example, the Federal Circuit on the one hand has said that the written description requirement is "rigorous, but not exhaustive: it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention." *In re Alonso* (Fed. Cir. 2008). Accordingly, the Federal Circuit has indicated that compliance with § 112 does not mandate that the patentee disclose any examples or an actual reduction to practice.

On the other hand, the Federal Circuit also has indicated that biotechnology patentees must do more than simply sketch out an invention's boundaries. And even proof of a reduction to practice by itself may not be enough. In addition, the Federal Circuit has held that disclosing "a method of making and identifying compounds capable of being used to practice the claimed invention" is not necessarily enough.

Billups-Rothenberg Inc. v. Associated Reg'l and Univ. Pathologists Inc. (Fed Cir. 2011).

In view of decisions such as these, there remains significant ambiguity regarding what level of disclosure is required to meet the written description requirement for biotechnology inventions. Despite that ambiguity, the Federal Circuit's decisions offer the following guidelines explaining how biotechnology patentees can satisfy the written description requirement.

1. Describe a Representative Number of Species

In assessing whether biotechnology patents meet the written description requirement, the Federal Circuit has found the following passage from the Guidelines for Examination of Patent Applications instructive: "[f] or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus."

In view of that guidance, the Federal Circuit has held that a patent must disclose a broader number of species when there is unpredictability in the results of species not specifically disclosed, or when the species in the claimed genus demonstrate substantial structural variation. There is no bright-line rule for determining whether a specification discloses a sufficiently representative number of species within a claimed genus. While "the number of species that must be disclosed to describe a genus claim . . . necessarily changes with each invention, and it changes with progress in a field," the specification must disclose species representing the genus throughout its scope.

Applicants for biotechnology patents thus should consider either claiming subgenuses that are tailored to the representative species described by the patent's specification or, alternately, including in their patent specifications descriptions of species that represent the full range of the claimed genus. Although the Federal Circuit has counseled that exhaustive disclosures are not required, disclosing the broadest structural variety of species in the claimed genus will better support genus claims.

2. Identify Physical or Chemical Characteristics Common to the Claimed Genus

The Federal Circuit looks to see whether a patent specification has adequately characterized representative species by their physical or chemical properties; a description of the functional properties of the species may not necessarily be sufficient to satisfy the written description requirement. The court's decisions suggest that patent applicants should not simply stop at describing what their inventions do (even in quantitative terms) or how they are made; rather, the patent specifications also should include some description of the shared structural characteristics of the genus they are claiming.

3. Avoid Functionally Defined Genus Claims, When Possible

As described above, the Federal Circuit generally has demanded that patents disclose physical or chemical features common to the claimed genus, or a representative number of species as defined by their structures. This is because "[f]unctionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus." *Abbvie Deutschland and GmbH & Co. v. Janssen Biotech Inc.* (Fed. Cir. 2014).

Arguably making matters more complicated for biotechnology patentees is the fact that determinations by the courts or by the PTO concerning predictability rest not just on the adequacy of the disclosure of the patent, but upon findings regarding the predictability of the state of the art to which the patent belongs. Those factors largely are beyond the patentee's control and can vary considerably depending on the time frame in question.

Nevertheless, this aspect of the law also highlights potential advantages to present-day drafters of biotechnology patents that were not previously available to patentees in cases like *Centocor* and *Billups-Rothenberg*. As the biotechnology field matures, more precise characterizations of the structural features that unite the members of a broad claimed genus may become possible. Moreover, the burden of crafting an adequate written description may be alleviated somewhat as once-novel technology evolves into the common knowledge in the art, and thus no longer must be taught by the patentee as part of his or her patent specification.

Time will tell whether biotechnology patents of more recent vintage will benefit from these advantages. In the meantime, patent practitioners may be able to better guard biotechnology patents against written description attacks by including in their applications descriptions of more than one species (preferably several species that exemplify the full scope of the claim); by including a description of the physical or chemical properties shared by the members of the genus; and by avoiding (when possible) specifications that include only functional descriptions of the claimed subject matter.

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