

## Written Description Guidelines Detail USPTO Requirements For Genus Claims

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In the Written Description Guidelines<sup>1</sup> issued January 5, 2001, the United States Patent and Trademark Office (USPTO) succeeds in providing examiners with a helpful roadmap through the difficult genus-species precedent set by the Federal Circuit in recent years. The Written Description Guidelines reinforce the notion that, in predictable and unpredictable arts alike, disclosure of more embodiments and reference to ample alternatives and variations is advisable when seeking generic coverage. In other words, a more developed and carefully considered disclosure is more likely to yield greater claim scope for the applicant

### *Written Description Requirement*

The first paragraph of 35 U.S.C. § 112 requires, *inter alia*, that the “specification shall contain a written description of the invention.”<sup>2</sup> To be adequate, the written description must describe the *claimed* invention in sufficient detail for one skilled in the art to reasonably conclude that the inventor had possession of the claimed invention at the time the patent application was filed.<sup>3</sup> Notably, the written description requirement is distinct from the added requirements that the applicant provide an enabling disclosure<sup>4</sup> and set forth the best mode<sup>5</sup> of the invention.

As policy objectives, the written description requirement is intended to ensure that (a) the applicant possesses the subject matter for which patent protection is sought, and (b) the public receives a sufficient understanding of the invention to promote further scientific progress.

In light of the written description requirement, the Federal Circuit has held that claims directed to a broad genus may not be adequately supported when the applicant describes only a small number of species.<sup>6</sup> In particular, in such a case, it may be unclear whether the applicant was actually in possession of any of the remaining species at the time of filing. In addition, the Federal Circuit has held that claims may not satisfy the written description requirement when they omit a feature characterized as critical or essential to the invention.<sup>7</sup>

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<sup>1</sup> Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, “Written Description Requirement.” 66 Fed. Reg. 1099 (Jan. 5, 2001).

<sup>2</sup> 35 U.S.C. § 112, ¶ 1.

<sup>3</sup> *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

<sup>4</sup> As another requirement of 35 U.S.C. § 112, ¶ 1, the disclosure must be sufficient to enable one skilled in the art to make and use the *claimed* invention.

<sup>5</sup> The best mode required by 35 U.S.C. § 112, ¶ 1 is the best embodiment for making and using the claims invention, in the subjective belief of the inventor, at the time of filing.

<sup>6</sup> See, e.g., *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

<sup>7</sup> See, e.g., *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998); see also *Johnson Worldwide Associates v. Zebco Corp.*, 175 F.3d 985 (Fed. Cir. 1999).

### ***Representative Number of Species***

With explicit deference to the Federal Circuit's decision in *Regents of the Univ. of Cal. v. Eli Lilly & Co.*<sup>8</sup>, the Written Description Guidelines advise the examiner to resolve the genus-species dilemma in part by determining whether the disclosure sets forth a "representative number" of species encompassed by the genus at issue. Specifically, according to the Written Description Guidelines:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, . . . reduction to drawings, . . . or by disclosure of relevant, identifying characteristics, i.e., structure of other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

The "representative number of species" must be representative of the *entire* genus and, reflect variation between the species of the genus.

Rather than issue one set of guidelines for biotechnology and chemical inventions, and another for the electrical and mechanical arts, the USPTO indicates that the Written Description Guidelines are "applicable to all technologies."<sup>9</sup> This is notable because the case law with respect to the written description requirement is often marked by different outcomes for different technology types. The Written Description Guidelines take this into account, however, pointing out that the "representative number of species" is an inverse function of the skill and knowledge in the art. Thus, for the "more predictable" electrical and mechanical arts, the representative number ordinarily would be much less than in the biotechnology and chemical arts.

### ***Essential Features***

In addition to the quest for a "representative number" of species, the examiner must identify any structure, feature, or characteristic described in the specification as essential. According to the Written Description Guidelines, a claim that does not include such an essential feature fails to live up to the written description requirement. For example, if a particular ingredient is described as essential for the preparation of an adhesive compound, whether in fact it is essential in practice, the applicant may be limited to claims for a compound that includes the ingredient.

The Written Description Guidelines cite the Federal Circuit's controversial decision in *Gentry Gallery*<sup>10</sup> in support of the essential feature inquiry. However, the Written Description Guidelines also make reference to *Johnson Worldwide Associates Inc. v.*

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<sup>8</sup> 119 F.3d 1559 (Fed. Cir. 1997).

<sup>9</sup> 66 Fed. Reg. 1099.

<sup>10</sup> 134 F.3d 1473 (Fed. Cir. 1998).

*Zebco Corp*<sup>11</sup>, which clarified the extent of the *Gentry Gallery* holding. In particular, the *Johnson* case highlighted the fact that, in *Gentry Gallery*, the Court found clear statements in the written description mitigating against coverage for a broad genus. Thus, the Written Description Guidelines seem to suggest that the Examiner should take a measured view toward invocation of the essential feature requirement, and be more attentive to affirmative statements of criticality in the specification.

### ***Practice Tips***

Rather than suggest new prosecution tactics, the Written Description Guidelines generally reinforce the best practices already used by competent patent prosecutors. For example, we already knew it was good practice, for purposes of both favorable claim construction and written description, to provide a number of alternative embodiments. The Written Description Guidelines should instill a heightened awareness, however, and cause patent practitioners to consider whether they have satisfied the “representative number of species” threshold. It will be advisable to spend more time digging into alternative embodiments, as well as variations in materials, temperatures, processing techniques, and the like, to better fortify the breadth of the genus sought in the claims. In light of the Written Description Guidelines, it also may be advisable to incorporate statements that demonstrate the disclosure of a representative number of species and the manner in which they reflect variation across the entire genus.

With respect to the essential features problem, most astute patent prosecutors already avoid statements of criticality and importance when describing a particular feature. Instead, the features of the inventions are usually described as exemplary and merely representative of one embodiment of the invention. Nevertheless, it will pay to be even more explicit in downplaying the significance of particular features that could be seized upon by the Examiner as essential, and provide alternatives and variations in the body of the specification. Again, these are tactics already practiced by most patent prosecutors, but it may be necessary to exercise even greater vigilance. Then, when faced with a written description rejection by an examiner, the patent prosecutor can point to conspicuous statements in the specification rather than rely on “mere attorney argument.”

In summary, the Written Description Guidelines appear to be a welcome development for examiners, patent prosecutors and applicants alike. They provide not only a guideline for the examiner in assessing compliance with the written description requirement, but also an inside track for the patent prosecutor in avoiding written description rejections and assuring claim scope. In this sense, the Written Description Guidelines are another helpful attempt by the USPTO to define the rules of the game.

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<sup>11</sup> 175 F.3d 985 (Fed. Cir. 1999).