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Intellectual Property Law

Keywords: **claim construction, written description**

General: **There must be adequate support within the description of a patent to claim a genus when a species is described.**

In re Bimeda & Development Limited
U.S. Court of Appeals Federal Circuit
107 USPQ2d 1619
Decided July 25, 2013

I. Facts

Bimeda Research & Development Limited ("Bimeda") was issued U.S. Patent No. 6,506,400 ("the '400 patent") on January 14, 2003. Generally, the '400 patent describes techniques for preventing mastitis (i.e., udder infection) in dairy cows by providing a physical barrier within the teat canal and/or the lower teat sinus during a dry period. Independent claim 1, as originally issued, is reprinted below:

> 1. A prophylactic method of controlling infection in a mammary gland by a mastitis-causing organism, comprising sealing a teat canal of a mammary gland with a seal formulation so as to provide a physical barrier in the teat canal.

More specifically, the '400 patent describes that the mastitis is prevented without the use of antibiotics (e.g., antiinfective-free), but does not provide any specific examples of antiinfectives that can be avoided. In other words, the '400 patent broadly excludes the use of the genus of antiinfectives.

In 2009, a competitor (i.e., Merial Limited) filed an *ex parte* reexamination request. During reexamination, Bimeda cancelled the original claims and added new claims 18-39, in which claims 18, 26, and 32 were independent. More specifically, independent claim 18 recited the method of claim 1, "wherein the seal formulation is free of an agent that is antiinfective …." Similarly, independent claim 26 recited the method of claim 1 "wherein the seal formulation has no bacterial action …." Independent claim 32 recited the method of claim 1 "with an acriflavine-free seal formulation." The Examiner allowed both independent claims 18 and 26, as well as the claims that depend therefrom. However, the Examiner rejected independent claim 32 under 35 U.S.C. § 112, paragraph 1 as failing to comply with the written description requirement.

Bimeda appealed the Examiner's rejection to the Board of Patent Appeals and Interferences ("the Board"). Bimeda argued that disclosing the exclusion of antiinfectives also

disclosed the exclusion of acriflavine, which was a known antiinfective used in teat seals. However, the Board affirmed the Examiner's rejection on two grounds. First, the Board held that the '400 patent failed to demonstrate possession of a formulation that specifically excluded the acriflavine species of the antiinfectives genus because the disclosure did not offer guidance or "blaze marks" to guide a skilled artisan towards excluding the particular species. Second, the Board held that the disclosure failed to convey the full scope of what was affirmatively claimed in independent claim 32, which is a formulation that excluded acriflavine but could include other antibiotics.

II. Issue

Does substantial evidence support the Board's interpretation that "an acriflavine-free seal formulation" is not supported by the general exclusion of antiinfectives?

III. Discussion

Yes. Disclosing the exclusion of the antiinfectives genus does not provide support for excluding the acriflavine species.

The written description requirement under 35 U.S.C. § 112, paragraph 1 is a question of fact and is reviewed on appeal under the substantial evidence standard. The substantial evidence standard is met if a reasonable mind can find the relevant evidence adequate to support the conclusion.

The Federal Circuit found that substantial evidence supported the Board's finding that the disclosure failed to convey the full scope of what was affirmatively claimed. More specifically, the Federal Circuit noted that the disclosure distinguishes the invention due to the ability to prevent mastitis without using antiinfectives, which is inconsistent with a formulation that excludes acriflavine but could include other antiinfectives, as generally recited by independent claim 32.

IV. Conclusion

The Federal Circuit affirmed the Board's finding that the '400 patent's disclosure did not convey possession of the literal scope of independent claim 32. Additionally, the Federal Circuit decided not to reach the merits of the Board's alternative holding that the '400 patent failed to guide a skilled artisan towards excluding acriflavine.

V. Concurring

Judge Rader agreed with the majority. However, Judge Rader noted that the alternative rationale provided by the Board that the patentee did not show possession of a formulation that specifically excluded acriflavine is problematic because "the Board places the patentee into a Catch-22: to satisfy written description, the patentee must show possession of something it specifically claims it does not possess."

VI. Practice Tips

- Negative claim limitations are acceptable.
- Best practice: provide examples and alternatives in the specification to allow for clear support
- Caution: when wanting to broadly exclude a genus as well as a specific species in the genus, it may be insufficient to merely list example species in the genus. Instead, broadly exclude the genus in a first embodiment and exclude a specific species in a second embodiment.

MPEP § 2173.05

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

MPEP § 2163

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.