United States Court of Appeals for the Federal Circuit

IN RE BIMEDA RESEARCH & DEVELOPMENT LIMITED

2012-1420

Appeal from the United States Patent and Trademark Office, Board of Patent Appeals and Interferences No. 90/010,445.

Decided: July 25, 2013

TROY E. GRABOW, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for appellant. With him on the brief was SARAH E. CRAVEN. Of counsel was JENNIFER ROBINSON.

MEREDITH H. SCHOENFELD, Associate Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia, argued for appellee. With her on the brief was ROBERT J. MCMANUS, Associate Solicitor. Of counsel was NATHAN K. KELLEY, Deputy Solicitor.

Before RADER, *Chief Judge,* CLEVENGER, and PROST, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* CLEVENGER

Opinion concurring filed by *Chief Judge* RADER

Bimeda Research & Development Limited ("Bimeda") appeals a decision by the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences, now known as the Patent Trial and Appeal Board ("Board"), in *Ex Parte Bimeda Research & Development Limited*, No. 2011-010507, 2011 WL 3754635 (B.P.A.I. Aug. 19, 2011) ("*Board Opin.*"), which affirmed an examiner's rejection of certain claims introduced in the context of ex parte reexamination of Bimeda's U.S. Patent No. 6,506,400 (issued Jan. 14, 2003) ("the '400 patent"). For the reasons set forth below, we affirm.

I

The '400 patent concerns methods for preventing the onset of bovine mastitis, i.e., the inflammation of udder tissue in cows. The patent is entitled "Antiinfective free intramammary veterinary composition," and the summary of the invention describes how the composition employs a physical barrier within the teat canal to block the introduction of mastitis-causing organisms without requiring the use of antiinfectives such as antibiotics:

> We have found that if a physical barrier is provided within the teat canal and/or the lower teat sinus during the dry period without the use of antibiotics, the incidence of mammary disorders is substantially reduced. . . . This non-antibiotic approach to preventing new dry period infection in dairy cows has major potential for the dairy industry as it results in the reduction of the incidence of antibiotic contamination in early season milk production. Thus the invention provides a quality improvement to dairy production and will

> facilitate farmers meeting consumer preferences for reducing the level of antibiotics used in food production.

'400 patent col.1 ll.23–42.

As originally issued, claim 1 of the patent recited a method for sealing the teat canal of a cow's mammary gland with a seal formulation so as to provide a physical barrier that blocks mastitis-causing organisms from reaching the canal:

> 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.

'400 patent col.5 l.52–col.6 l.2.

The PTO ordered ex parte reexamination of the '400 patent on March 13, 2009, to reevaluate patentability in light of prior art teachings of teat seal formulations utilizing a physical barrier in conjunction with certain antiinfective agents such as antibiotics and the antiseptic acriflavine.[1] In response, Bimeda cancelled claims 1–8 and added new claims 18–39.[2]

Three of Bimeda's new claims were independent: claims 18, 26, and 32. Claim 18 recited the method of claim 1 "wherein the seal formulation is free of an agent

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[1] The class of antiinfectives covers all agents capable of fighting infections, but can be divided into subclasses such as antiseptics and antibiotics based upon, for instance, how the agents fight infections or what types of infections the agents are capable of preventing.

[2] Bimeda originally added and then cancelled new claims 9–17, for reasons not relevant here.

that is antiinfective . . . ." Claim 26 recited the same method using a seal formulation that "has no bacterial action." The examiner allowed these two claims along with their related dependent claims.

Claim 32 recited the method of claim 1 wherein the teat seal canal had an "an acriflavine-free" formulation. Acriflavine was a well-known antiseptic antiinfective agent which had long been used to treat mastitis. Nevertheless, the examiner rejected claims 32–39 under § 112, ¶ 1, reasoning that "acriflavine" was not mentioned anywhere in the original disclosure of the '400 patent and so therefore the disclosure did not demonstrate possession of an acriflavine-free composition. *Board Opin*. at *2.

Bimeda appealed the rejection of claims 32–39 to the Board. It argued that that the '400 patent's disclosure broadly described an invention that was free from antiinfectives, and also noted that Example 1 described an exemplary embodiment which did not include acriflavine as an ingredient. It therefore contended that an ordinary artisan, who would have been well aware that acriflavine could be used to prevent mastitis, would understand that its antiinfective-free invention could also be acriflavine-free.

In response to the appeal, the examiner reiterated the original basis for rejection and further argued that the '400 patent's disclosure failed to describe formulations which (like claim 32) could exclude acriflavine but include other antiinfectives:

> [T]he specific exclusion of acriflavine introduces a new concept, as [it] implies inclusion of one or more undisclosed antiinfectives other than acriflavine. Such a concept is not supported in the disclosure as originally filed. The original disclosure only contemplates the general concept of antiinfective-free formulations and does not contem-

> plate inclusion or exclusion of particular species of antiinfectives from the formulations.

Board Opin. at *5–6.

The Board affirmed the examiner's rejection on two grounds. First, it agreed with the examiner's finding that the disclosure failed to demonstrate possession of a formulation that specifically excluded the acriflavine species of antiinfectives. *Board Opin.* at *5. Citing *In Re Ruschig et al.*, 379 F.2d 990 (CCPA 1967), the Board held that where the patent's disclosure describes the exclusion of a broad genus, claims to embodiments which exclude particular species are only supported if the disclosure offers some guidance or "blaze marks" to guide the skilled artisan towards excluding that particular species. *Id.* In the case of the '400 patent, the Board found that the disclosure lacked such guidance because it did not contemplate the exclusion of any single specific antiinfective, much less acriflavine. *Id.* Rather, the Board found, the '400 patent described inventions that were free of entire classes of agents such as antibiotics. *Id.*

Second, the Board agreed with the examiner that the disclosure failed to convey the full scope of what was affirmatively claimed by claim 32—namely, a formulation which excluded acriflavine but could include other antiinfective agents. *Board Opin.* at *5–6. The Board believed that Example 1 of the patent was consistent with this finding because it contained no antiinfectives at all, and therefore did not disclose a formulation which excluded a specific species of the antiinfective genus but permitted the presence of others. *Id.* at *6.

Accordingly, the Board affirmed the examiner's rejection. *Board Opin.* at *6. Bimeda sought rehearing before the Board, which was denied, and then timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141.

II

Written description under § 112, ¶ 1,[3] is a question of fact, and on appeal from the Board, we review such questions for substantial evidence. *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). Substantial evidence means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. Nat'l Labor Relations Bd.*, 305 U.S. 197, 229 (1938).

In this case, the Board found, *inter alia*, that claim 32 failed the written description requirement because the disclosure did not "describe[] a formulation excluding a specific species of the anti-infective genus, while permitting others to be present." *Board Opin.* at *6. On appeal, Bimeda counters this finding by arguing that the disclosure broadly claims a teat seal formulation utilizing a physical barrier, yet does not expressly exclude any particular antiinfective agents. Bimeda interprets this as tacit indifference to the presence or absence of specific antiinfectives, and contends that the disclosure therefore supports a claim which excludes one particular antiinfective (such as acriflavine) but permits the use of others (such as antibiotics).

Substantial evidence supports the Board's contrary interpretation because the disclosure is generally inconsistent with a formulation which, like claim 32, excludes acriflavine but could include antibiotics. As noted above, the summary of the invention describes the invention's

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[3] Paragraph 1 of 35 U.S.C. § 112 was replaced with newly designated § 112(a) when § 4(c) of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, took effect on September 16, 2012. Because this case was filed before that date, we will refer to the pre-AIA version of § 112.

"non-antibiotic approach" to preventing mastitis, and explains how this approach achieves the benefit of "meeting consumer preferences for reducing the levels of antibiotics used in food production." '400 patent at col.1 ll.35-42.

The remainder of the disclosure similarly distinguishes the invention due to its ability to prevent mastitis without using antibiotics. For instance, Example 2 of the patent utilizes a seal formulation made from liquid paraffin, Alugel 30 DF (aluminum stearate), and bismuth subnitrate, all mixed in a sterile bioprocess container or "B.P.C." '400 patent col.2 ll.61-64 (utilizing same formulation as Example 1). Although this exemplary formulation does not expressly exclude any particular class of antiinfective, one nevertheless comes away with the clear understanding that it cannot include antibiotics because it is described as realizing results "comparable with that achieved by prophylactic antibiotic treatment" and as "very surprisingly offer[ing] a non-antibiotic approach" to mastitis prevention. *Id*. at col.3 ll.16–19. Examples 3 and 4 used the same seal formulation as Examples 1 and 2, so the observation that the exemplary seal is "non-antibiotic" applies to those Examples as well. *Id.* at col.3 l.23, col.3 l.63. The fifth and final Example compares the invention with other formulations and concludes that "there was no significant difference between the antibiotic based treatments and the antibiotic-free treatment of the invention." *Id*. at col.5, ll.9–11. Importantly, the patent discloses that the invention presents "no risk of antibiotic residues after calving," *id*. at col.5, ll.16–17, which seemingly can only be true if the formulation excludes all antibiotics. The specification thus leaves no room for argument that the inventor possessed a formulation that excludes only acriflavine while permitting the use of antibiotics.

The '400 patent's disclosure is therefore inconsistent with a claim which "excludes acriflavine, but *not* the presence of other anti-infectives or antibiotics." *Board*

Opin. at *5 (emphasis in original). Because substantial evidence supports the Board's finding that the patent's disclosure does not convey possession of the literal scope of claim 32, we need not reach the merits of the Board's alternative finding that the disclosure insufficiently led an artisan to target acriflavine for exclusion.

CONCLUSION

For the reasons set forth above, we affirm the Board's decision that claims 32–36 of the '400 patent lack written description support under § 112, ¶ 1.

AFFIRMED

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RADER, *Chief Judge,* concurring.

The undisputed claim construction in this case is a formulation which excludes a specific species of the anti-infective genus but permits the presence of other species. As the specification does not sufficiently disclose this dual-natured formulation, I join my colleagues. I write separately to highlight the problematic alternative rationale advanced by the Board of Patent Appeals and Interferences (Board).

The Board stated that the patentee did not show possession of a formulation that specifically excluded acriflavine as a species of antiinfectives. J.A. 14–15. The repeated references to "possession," i.e. the traditional nomenclature for discussing written description, illustrate the weakness in using this framework for all written description cases.

"The name of the game is the claim." *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998) (quoting Giles Sutherland Rich, *Extent of Protection and Interpretation of Claims-American Perspectives,* 21 Int'l Rev. Indus. Prop. & Copyright L. 497, 499 (1990)). Here, the Board refused to wrestle with the fact that the claim at issue (and the patent as a whole) focuses on negative claiming. That is, the claim at issue specifically *excludes* an element, acriflavine, from the claimed formulation. J.A. 9. Yet the Board discusses written description in the context of claiming the inclusion, not the exclusion, of a particular element. *See* J.A. 15 (noting that when a patentee claims a species, the broad naming of the genus in a specification is likely insufficient); J.A. 15–16 (citing *In Re Ruschig*, 379 F.2d 990 (CCPA 1967) for the proposition that the specification must provide "blaze marks" which guide the skilled worker from the broadly disclosed genus to the claimed species). Thus, 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.

The adequacy of written description must be determined on the facts of each case. *In re Jolley*, 308 F.3d 1317, 1323 (Fed. Cir. 2002). Here, the specification clearly supports a formulation which excludes all antiinfectives. Acriflavine was a well-known species of antiinfective that had been used in teat seals to treat bovine mastitis for over 75 years. J.A. 15; 2418–53. Some of the Board's analysis of possession ignored these facts and ignored the nature of the claims.