The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DAVID H. WALKER, XUE-JIE YU, and JERE W. McBRIDE

Appeal 2007-1032
Application 10/062,920
Technology Center 1600

Decided: June 15, 2007

Before ERIC GRIMES, NANCY J. LINCK, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of inducing an immune response against *Ehrlichia canis*. The Examiner has rejected the claims as nonenabled. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

BACKGROUND

"Canine ehrlichiosis, also known as canine tropical pancytopenia, is a tick-borne rickettsial disease of dogs. . . . The etiologic agent of canine

ehrlichiosis is *Ehrlichia canis*, a small, gram-negative, obligate intracellular bacterium . . ." (Specification 2).

Analysis of *E. canis* "has resulted in the identification of numerous immunodominant proteins . . . , including a 30-kDa protein" (*id.* at 4). This protein is homologous to "28-32kDa immunodominant proteins encoded by multigene families . . . in related organisms" including *E. chaffeensis*, the causative agent of human monocytic ehrlichiosis (*id.*). In recombinant form, the *E. chaffeensis* 28-kDa outer membrane protein "appeared to provide protection against homologous challenge infection in mice, and antisera produced against the recombinant protein cross reacted with a 30-kDa protein of *E. canis*" (*id.* at 5).

The Specification discloses "the molecular cloning, sequencing, characterization, and expression of homologous mature 28-kDa immunoreactive protein genes of *Ehrlichia canis*" (*id.* at 6). The Specification discloses that administering a 28-kDa *E. canis* antigen can inhibit infection by the organism, for example by "stimulat[ing] . . . the subject's humoral or cellular immune responses" (*id.* at 8).

DISCUSSION

1. CLAIMS

Claims 17, 19, and 20 are pending and on appeal (Br. 2). Claim 17 is representative and reads as follows:

> 17. A method of inducing an immune response against *Ehrlichia canis* in a subject comprising the steps of:
> identifying a subject prior to exposure or suspected of being exposed to or infected with *Ehrlichia canis*; and
> administering a composition comprising a 28-kDa antigen of *Ehrlichia canis*, wherein said 28-kDa antigen is a

> recombinant protein comprising an amino acid sequence selected from the group consisting of SEQ ID No. 2, 4, 6, 40, 42, 44 and 46 in an amount effective to induce said immune response against *Ehrlichia canis* in said subject.

Thus, claim 17 is directed to a method of inducing an immune response against *Ehrlichia canis* by administering a recombinant protein having one of seven specified amino acid sequences to a subject.

The breadth of the term "immune response" is an issue in this case. The Examiner argues that "the Specification teaches that inducing an immune response was intended as a means to inhibit *E. canis* infection" (Answer 5). The Examiner argues that "[s]ince the Specification teaches that inducing an immune response against *E. canis* is one way to inhibit infection, the claims encompass methods of inhibiting *E. canis* infection" (*id.* at 6, citations omitted).

Appellants argue that it is improper for the Examiner to interpret the claims as requiring the use of the 28-kDa protein to inhibit infection (Br. 8).[1] Appellants argue that "[i]t is improper for the Examiner to interpret the claims in any way other than methods for inducing an immune response" (*id.*; Reply Br. 3).

It is well settled that, "in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art."

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[1] Appeal Brief filed May 19, 2006.

In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983) (citation omitted).

We agree with the Examiner that the Specification discusses using the 28 kDa protein to induce an immune response to *E. canis* in the context of inhibiting *E. canis* infection (Specification 8, 31). Claim 17, however, requires only that the designated protein be "administer[ed] . . . in an amount effective to induce said immune response against *Ehrlichia canis* in said subject." Thus, by its language, claim 17 does not require inducing an immune response that will prevent *E. canis* infection.

Moreover, it is improper to read limitations from the Specification into the claims. *See Sjolund v. Musland*, 847 F.2d 1573, 1581, 6 USPQ2d 2020, 2027 (Fed. Cir. 1988) ("[W]hile it is true that claims are to be interpreted *in light of* the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."); s*ee also In re Van Geuns*, 988 F.2d 1181, 1184, 26 USPQ2d 1057, 1059 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification."). We therefore interpret claim 17 as encompassing processes that induce any degree of immune response to *E. canis*.

2. REFERENCES

The Examiner relies on the following references:

Norio Ohashi et al., *Cloning and Characterization of Multigenes Encoding the Immunodominant 30-Kilodalton Major Outer Membrane Proteins of Ehrlichia canis and Application of the Recombinant Protein for Serodiagnosis*, 36 J. Clin. Microbiol. 2671-2680 (Sept. 1998).

Jere W. McBride et al., *Molecular Cloning of the Gene for a Conserved Major Immunoreactive 28-Kilodalton Protein of Ehrlichia canis: a Potential Serodiagnostic Antigen*, 6 Clin. Diag. Lab. 392-99 (May 1999).

Norio Ohashi et al., *Immunodominant Major Outer Membrane Proteins of Ehrlichia chaffeensis Are Encoded by a Polymorphic Multigene Family*, 66 Infect. Immun. 132-39 (Jan. 1998).

3. ENABLEMENT

Claims 17, 19, and 20 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled on the basis that "undue experimentation would be required to practice a method of inhibiting *E. canis* infection" (Answer 4).

The Examiner reasons that the claims encompass processes in which administration of the *E. canis* protein results in inhibition of subsequent infection by the organism (*id.* at 4-6). The Examiner states that the Specification "provides general guidance that a 28 kDa protein would be administered to a subject but does not provide any guidance with any specifics as to how much of the protein should be administered or how many times the protein should be administered in order to be effective" (*id.* at 6). The Examiner notes that the Specification "does not have any examples of a method of inducing an immune response to *E. canis* to inhibit infection" (*id.*).

The Examiner urges that while "[s]everal of the proteins used in the method claims were known at the time of the invention" the art "do[es] not teach or suggest that any of the proteins disclosed therein could be used successfully in a method of treating *E. canis*" (*id.* at 7). The Examiner argues that "determining what 28 kDa proteins of *E. canis* could be used to successfully inhibit *E. canis* infection or to induce an immune response

against *E. canis* infection is highly unpredictable" because the proteins' functions were not known, and because the art does not disclose any previous methods in which *E. canis* infection was inhibited (*id.* at 8).

Thus, the Examiner argues, "the claimed method is not one where a routine method known in the art is practiced with unknown proteins" (*id.*). Instead, because the Specification "and the prior art lack any evidence that any *E. canis* proteins could induce an immune response against *E. canis* in vivo to effectively treat or protect a subject from infection[,] and lack any guidance as to how any 28 kDa *E. canis* proteins are related to infection," the Examiner concludes that practicing the claimed method would require undue experimentation (*id.* at 9).

Appellants argue that the Examiner has interpreted the claims too narrowly (Br. 8) and has not made out a prima facie case of lack of enablement (*id.* at 6-8). Appellants argue that the Specification meets the enablement requirement by providing the amino acid sequences for the proteins, and methods for enhancing their immunogenicity (*id.* at 9). Appellants argue that one of the claimed proteins has been demonstrated to react with antiserum from a dog previously infected with *E. canis*, and that "therefore it is not undue to demonstrate that giving the recombinant protein to an uninfected dog would produce antibodies to the recombinant protein" (*id.* at 10). Moreover, Appellants argue, in view of the high skill level in the immunological arts, the experimentation required to practice the claimed method would be routine, rather than undue (*id.* at 11).

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention

without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). However, "[t]he scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill without undue experimentation." *National Recovery Technols. Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1228, 1232, 49 USPQ2d 1671, 1675-76 (Fed Cir. 1999).

Moreover, a claim does not lack enablement merely because it encompasses inoperative embodiments. *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984). Thus, claims to a method do not lack enablement merely because a difficult-to-achieve outcome is encompassed, but not required, by the claims. *See In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (claims encompassing achieving full head of hair held enabled by evidence showing three-fold increase in hair number, filling-in, and fuzz).

We agree that the claims encompass inhibiting infection by *E. canis*. All that they *require*, however, is inducing some degree of immune response, such as generating antibodies.

The Specification provides the amino acid sequences of the proteins recited in the claims. One of the claimed proteins has been demonstrated to react with antiserum from a previously infected dog (Specification 42; Figure 2), thus suggesting that it would elicit an immune response in a subject. The Specification discloses that all of the proteins recited in the claims "are homologous to the *omp-1* multiple gene family of *E. chaffeensis*" (Specification 50:11-12), and that this "family of homologous genes encoding outer membrane proteins with molecular masses of 28-kDa

have been identified in *E. chaffeensis*, and mice immunized with recombinant *E. chaffeensis* P28 appeared to have developed immunity against homologous challenge" (*id.* at 54:10-14).

In addition, the Specification discusses methods for enhancing the immunogenicity of the proteins, including conjugation with suitable carriers, and combination with suitable adjuvants (Specification 25-26). Appellants point out, and the Examiner does not dispute, that the level of skill in the immunological arts is high, and that it would have been routine to determine suitable methods for administering the claimed proteins to generate an immune response, and assay the results of that administration (Br. 11).

We therefore agree with Appellants that the Examiner has not adequately shown that one skilled in the art would not have been able to induce an immune response to the proteins recited in the claims, based on the disclosure in the Specification, without undue experimentation.

The Examiner argues that, in interpreting the claims to require a method of treatment, the claims have been given their broadest reasonable interpretation (Answer 14). The Examiner urges that "if inducing an immune response was intended for making antibodies, then . . . exposure of the subject to E. canis would not be important and the claim would recite a step of recovering the antibodies (for a useful method)" (*id.* at 15). The Examiner concludes that when the claims are given their broadest reasonable interpretation in light of the Specification, "the intended use of the claimed methods is to inhibit infection. No other utility for inducing an immune response has been provided by Appellants arguments or the specification, and the claims as written imply a method of treatment" (*id.*).

We are not persuaded by these arguments. The Specification clearly contemplates using the 28 kDa proteins to generate antibodies (Specification 25-27). Moreover, as discussed *supra,* "limitations are not to be read into the claims from the specification." *In re Van Geuns*, 988 F.2d at 1184, 26 USPQ2d at 1059.

Claim 17 does not state that the immune response induced by administering the protein must prevent or inhibit infection by *E. canis*. Claim 17 is therefore not limited to inducing an immune response that inhibits *E. canis* infection, despite the Specification's disclosure that doing so would be desirable. We agree with Appellants that the Examiner has not shown that undue experimentation would be required to induce an immune response to the claimed proteins based on the disclosures in the Specification and knowledge in the art. We therefore reverse the rejection for nonenablement.

REVERSED

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