

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte BENJAMIN J. LUFT, JOHN J. DUNN,
SHOHEI KOIDE, and CATHERINE L. LAWSON

Appeal 2007-2717
Application 10/369,339
Technology Center 1600

Decided: February 20, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a variant of the Osp A protein of *Borrellia burgdorferi*, which the Examiner has rejected as failing to enable the full scope of the claims, as indefinite and as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Background

“Lyme disease begins at the site of a tick bite, producing a primary infection with spread of the organism to secondary sites occurring during the course of infection. The causative bacterial agent of this disease is the spirochete *Borrelia burgdorferi*” (Spec. 1). The Specification discloses that “*B. burgdorferi* has an outer membrane whose major protein constituents are the outer surface proteins A and B (OspA and OspB)” (Spec. 2). The Specification separately notes that “a vaccine that consists of recombinant OspA may require frequent booster immunizations. An additional concern of OspA-based vaccines is the recent identification of a putative autoreactive OspA domain with a high degree of similarity to a region of human leukocyte function-associated antigen- 1” (Spec. 2-3).

Appellants teach that the “present invention is drawn to altered forms of OspA from *Borrelia burgdorferi* that have increased conformational stability while maintaining at least some of the antigenicity of wild type OspA. In some embodiments, the altered OspA polypeptide has decreased cross-reactivity with hLFA- 1, as compared to the corresponding unaltered OspA polypeptide.” (Spec. 3).

Statement of the Case

The Claims

Claims 16 and 18-21 are on appeal¹. We will focus on claim 16 which is representative and reads as follows:

¹ Claims 18-21 were not separately argued. These claims therefore stand or fall together with claim 16. *See* 37 C.F.R. § 41.37(c)(1)(vii).

16. A polynucleotide encoding amino acids comprising from about residue 139 to about residue 273, inclusive and in consecutive order, of an OspA protein from *Borrelia burgdorferi*, wherein the polynucleotide encodes at least one alteration selected from the group consisting of: codon 139 encoding methionine, codon 160 encoding tyrosine, codon 189 encoding methionine and combinations thereof, wherein the numbering corresponds to the numbering of SEQ ID NO: 7.

The Examiner relies on the following prior art references to show unpatentability:

Richards et al., "Protein Stability: still an unsolved problem," 53 *Cellular Molecular Life Sci.* 790-802 (1997).

Ding et al., "Structural Identification of a Key Protective B-cell Epitope in Lyme Disease Antigen OspA," 302 *J. Molecular Biology* 1153-1164 (2000).

Purcell et al., "Dissecting the Role of Peptides in the Immune Response: Theory, Practice and the Application to Vaccine Design," 9 *J. Peptide Sci.* 255-281 (2003).

Arioli WO 98/00549 Jan. 8, 1998

The rejections as presented by the Examiner are as follows:

A. Claims 16 and 18-21 stand rejected under 35 U.S.C. § 112, first paragraph as being nonenabled.

B. Claims 16 and 18-21 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

C. Claims 16 and 18-21 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Arioli.²

A. *35 U.S.C. § 112, first paragraph Enablement rejection*

Claims 16 and 18-21 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification

while being enabling for a nucleic acid comprising SEQ ID NO: 6, 8 and 10 and complementary fragments thereof that specifically hybridize with the nucleic acids set forth as SEQ ID NO: 6, 8 or 10, does not reasonably provide enablement for the broad scope of what is presently claimed.

(Ans. 6.)

The Examiner reasons that

although some polynucleotides within the scope of the claims could be used to detect the presence of OspA polynucleotides in a biological sample, the majority of the polynucleotides within the broad scope of what is claimed would not have sufficient sequence identity to allow for specific hybridization of said nucleic acid with a native OspA nucleic acid such that the nucleic acid could be used as a diagnostic as contemplated in the specification.

(Ans. 11.)

² The statement of the rejection in the Examiner's Answer applies this rejection only to claims 16 and 21, but in a footnote, the Examiner states that the rejection was "subsequently applied to claims 18-20 in the Office Action mailed 12 January 2006" (Ans. 13). Appellants understood the rejection to apply to claims 16 and 18-21 (App. Br. 7) and the Examiner agreed with Appellants' statement of the rejections on appeal (Ans. 2-3). We therefore understand the rejection to apply to claims 16 and 18-21.

The Examiner cites Purcell and Richards to demonstrate the unpredictability of immune response of peptides which differ in structure from the native molecules (*see* Ans. 9-10).

The Examiner concludes that, because of the vast breadth of the claims and unpredictability of the art, undue experimentation would be required to “determine how to use the vast majority of nucleic acids within the scope of the claim” (Ans. 12).

Appellants state that the “present invention pertains to OspA polypeptides having an 'alteration'” (App. Br. 8). Appellants focus attention on three specific changes (*see* App. Br. 8). However, Appellants further argue that the “language of the specification indicates that fragments, derivatives, analogs, variants and mutants, as well as [proteins] fragmented, derivatized, or otherwise altered after having the alterations described, are ‘modified OspA.’” (App. Br. 9). Appellants note that “OspA proteins are extremely well characterized proteins of *Borrelia*. As indicated in the Specification at page 15, line 25 et seq., for example, the structure of OspA is very well known, having been determined to 1.95 Å resolution” (App. Br. 10). Appellants conclude that “one of ordinary skill in the art, understanding the close relationship between OspA proteins, would understand what is encompassed by the term, ‘OspA of *Borrelia burgdorferi*’ and would be able to prepare nucleic acids encoding the specific amino acids as described in the claims without undue experimentation” (App. Br. 11).

In view of these conflicting positions, we frame the enablement issue before us as follows:

Would it have required undue experimentation to use the full scope of the claimed Osp A nucleic acid of claim 16?

Findings of Fact

Breadth of the Claims

1. Claim 16 is not limited to SEQ ID NO: 7, but encompasses any nucleic acids which encode OspA polypeptides that are about 135 amino acids in length or longer (*see* Claim 16).

2. As interpreted in light of the Specification, claim 16 requires that the sequence of only one amino acid out of three possible variant amino acids is present. “The altered OspA polypeptides of the present invention can be derived from OspA molecules comprising fragments, derivatives, analogs, variants and mutants of the OspA protein (modified OspA) or can be fragmented, derivatized, or otherwise altered after having the alterations described herein inserted.” (Spec. 18:15-19). Thus, in the entire length of the claimed OspA protein, “about” 135 amino acids, the specific amino acid alterations are the only amino acids which are expressly required. The remaining sequence is open to any other amino acids (*see* Claim 16).

3. Claim 16 imposes no functional or biological test to determine whether or how the resultant protein is an Osp A protein (*see* Claim 16).

4. The Specification expressly teaches that the OspA polypeptides “can comprise additional modifications. Such additional modifications include conservative and/or non-conservative amino acid substitutions, additions of one or more amino acids, and/or deletions of one or more amino acids. Such additional modifications should also preserve at least some activity of the encoded protein or polypeptide” (Spec. 22:20-24).

Presence of Working Examples

5. The Specification discloses six specific amino acid variants, which fall within the scope of the claims, as working examples. The Specification does not teach other variants (*see* Spec. 70-73).

Amount of Direction or Guidance Presented

6. The Specification does identify certain antigenic regions of Osp A (*see* Spec. fig. 2). These antigenic regions do not comprise codons 139, 160 and 189 of SEQ ID NO: 7 (*see* Spec. fig. 2).

7. The Specification teaches that “a limited set of conservative changes at these sites were not sufficient to abolish binding of all of the agglutinating MAbs. These results suggested that the agglutinating epitopes of OspA are distinct, yet may have some overlap” (Spec. 46: 22-25).

State of the Prior Art and Unpredictability of the Art

8. Ding teaches that “heterogeneity across the three genospecies precludes broad protection with a vaccine based on OspA from a single strain” (Ding 1154, col. 1).

9. Ding teaches that OspA “[c]onservation may also result from functional requirements, but this is hard to evaluate, since OspA's natural role in *B. burgdorferi* has yet to be elucidated” (Ding 1159, col. 2).

10. Purcell teaches

In the case of antibody recognition, the biggest obstacle to induction of antibody of relevant specificity is conformational integrity of the peptide representing the epitope; in order to induce antibody that will recognize the parent antigen, the epitope needs to possess a conformation that is similar to that assumed by the same sequence within the native antigen. In some cases relatively short peptide sequences will adopt conformations that mimic those

assumed by the peptide sequence within the native antigen but in most cases a relatively short sequence of amino acids (10-40 in length) will rarely result in a peptide that folds into the correct conformation. Thus, while it is a relatively simple matter to elicit antibodies to a peptide, the resulting antibodies are unlikely to cross-react with the parent antigen.

(Purcell 264, col. 2).

11. Richards teaches that “[i]n terms of structural alterations and thermostability, responses to genetic mutations are context dependent and remain difficult to predict with confidence” (Richards 790, abstract).

12. Richards teaches regarding single point mutations in the ribonuclease S protein that “[e]ven the small changes are so complex that the linkage relations do not allow assignments of the energetic changes to unique parts of the altered residue and its immediate contacts” (Richards 796, col. 2).

13. Richards teaches that “[a]lmost all mutations are accompanied by some conformational change, making prediction of the effects on stability difficult. In most cases mutations lead to lowering of the stability” (Richards 793, col. 2).

Quantity of Experimentation necessary

14. The Specification teaches that “Variants” and “mutants” of OspA can be produced using *in vitro* and/or *in vivo* techniques well-known to those of skill in the art, for example, site-specific mutagenesis, and oligonucleotide mutagenesis. Manipulations of the OspA polypeptide sequence can be made at the protein level as well. Chemical modifications can be carried out using known techniques including but not limited to, specific chemical cleavage using cyanogen bromide, trypsin and/or

papain. OspA can also be structurally modified and/or denatured, for example, using heat. In general, mutations can be conservative or non-conservative amino acid substitutions, amino acid insertions or amino acid deletions.

(Spec. 23:16-24).

15. “To test the antigenicity of the altered OspA polypeptides, mice can be immunized with OspA polypeptides or proteins containing the polypeptide sequences in aluminum hydroxide. Mice are then bled and tested for antibody responses against OspA derived from various strains of *Borrelia*” (Spec. 31:23-26).

16. “In additional experiments, these immunized mice can be challenged with ticks infected with *Borrelia burgdorferi* and transmission of infection can be assessed as described in the Exemplification[s] which use OspA, OspC and OspC/OspA chimeric molecules” (Spec. 31:26-29).

Discussion of 35 U.S.C. § 112, first paragraph Enablement rejection

We agree with the Examiner that the Specification does not provide sufficient guidance to enable practice of the full scope of the claimed invention without undue experimentation. The nature of the invention places it in the class of invention which the Federal Circuit has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The Specification expressly teaches that the OspA polypeptides “comprise fragments, derivatives, analogs, variants and mutants of an OspA protein (modified OspA) and/or can be fragmented, derivatized or otherwise altered after having the alterations described herein inserted (also referred to as modified OspA). Such modified OspA molecules possess at least some

OspA antigenic activity” (Spec. 22:14-18). However, the Specification further expands the genus of OspA proteins, noting that the OspA proteins “can comprise additional modifications. Such additional modifications include conservative and/or non-conservative amino acid substitutions, additions of one or more amino acids, and/or deletions of one or more amino acids. Such additional modifications should also preserve at least some activity of the encoded protein or polypeptide” (Spec. 22:20-24). However, the Specification does not teach what activity is required of the OspA protein and the prior art of Ding notes that “OspA's natural role in *B. burgdorferi* has yet to be elucidated” (Ding 1159, col. 2).

The only constraints on the polynucleotide of claim 16 are that the polynucleotide have a triplet which can encode one of methionine or tyrosine at one of three specific positions and that the polynucleotide encode a protein of about 135 amino acids in length or longer (FF 1-2). The “of an OspA protein from *Borrelia burgdorferi*” language in claim 16 imposes no particular sequence requirement since the Specification fails to delimit what sequences are necessary to function as an “OspA protein” (FF 3-4).

Consequently, the breadth of these claims arguably reads on any polynucleotide encoding a 135 or longer amino acid protein which contains methionine or tyrosine at particular codon numbers, “wherein the numbering corresponds to the numbering of SEQ ID NO:7.” Thus, the breadth of the claims is not commensurate in scope with disclosure of the Specification.

While there are a limited number of working examples in the Specification, the guidance of the Specification on specific alterations other than the three specific alterations disclosed is minimal (FF 5). The

Specification does not identify any other alterations, deletions, derivatives, analogs or mutants which would be useful in an OspA detection system or vaccine, the uses disclosed for OspA in the Specification (FF 8-13).

The prior art demonstrates that mutations in OspA, a protein whose function is unknown, would yield unpredictable results (FF 8-13). In particular, Ding notes that there is heterogeneity among OspA species (FF 8). Purcell and Richards evidence the high level of unpredictability in mutations which was well known in the art at the time of Appellants' invention (FF 9-13).

Purcell's teaching is significant because the overwhelming majority of embodiments of claim 16 would have limited regions of homology with OspA and Purcell demonstrates that regions of 10-40 amino acids are insufficient, in general, to function as antigens (FF 10). This directly supports the "how to use" enablement issue since Purcell shows that for the vast majority of the claimed embodiments, it is unpredictable whether they will function as OspA antigens (*see* FF 10). As the Examiner noted, "the ability of any individual embodiment of the polypeptide encoded by the claimed polynucleotide to provide an immune response capable of recognizing an OspA protein is unpredictable and must be determined experimentally" (Ans. 10).

The Examiner based this conclusion on evidence such as "[e]ven the small changes are so complex that the linkage relations do not allow assignments of the energetic changes to unique parts of the altered residue and its immediate contacts" (Richards 796, col. 2). The prior art also noted that "[a]lmost all mutations are accompanied by some conformational change, making prediction of the effects on stability difficult. In most cases

mutations lead to lowering of the stability” (Richards 793, col. 2). These statements provide strong support for a conclusion that the the mutations encompassed by the scope of claim 16, as discussed above, would have an unpredictable effect on the encoded protein.

The Specification provides some discussion showing that a large quantity of experimentation would be required in order to perform the claimed method (FF 14-16). In particular, after making any particular mutant, it would require a series of experiments using mice to determine whether the OspA mutant that was generated had antigenic effect. In view of the immense number of mutations encompassed by claim 16, this represents a large quantity of experimentation (FF 15-16).

We are not persuaded by Appellants’ conclusion that “one of ordinary skill in the art, understanding the close relationship between OspA proteins, would understand what is encompassed by the term, ‘OspA of *Borrelia burgdorferi*’ and would be able to prepare nucleic acids encoding the specific amino acids as described in the claims without undue experimentation” (App. Br. 11). Appellants’ argument focuses on the question of whether the nucleic acids of the invention could be prepared without undue experimentation while the rejection focuses on whether the nucleic acids could be used without undue experimentation. While we would agree with Appellants that generation of any particular mutation is routine in the PCR world, the same does not hold true for the use of that mutation. As the prior art of Purcell and Richards exemplify, there remains significant unpredictability in the effect of even small changes to protein structure (FF 8-13). Appellants’ claims broadly encompass not only small

conservative or nonconservative changes, but the Specification indicates that the claims expressly encompass fragments, derivatives and other large changes to the protein structure (FF 5-7). It is the use of proteins with these changes with which the rejection is concerned, not the molecular biology required to make the proteins.

We also reject Appellants' argument that "one of ordinary skill in the art, given the claim language, would understand what is encompassed by this term. The language of the claims indicates that the amino acids comprise a certain specific string (i.e., from about residue 139 to about residue 273, inclusive and in consecutive order) of an OspA protein" (Reply Br. 4). As the court noted,

as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Appellants' argument presupposes limitations on the sequence of the OspA protein which are expressly rejected by the Specification (FF 6-8). No specific string is necessarily required since the Specification notes that an OspA protein may "comprise fragments, derivatives, analogs, variants and mutants of an OspA protein (modified OspA) and/or can be fragmented, derivatized or otherwise altered after having the alterations described herein inserted" (Spec. 22:15-17). We think that the person of ordinary skill, reading claim 16 with the

enlightenment of the Specification, would interpret the claim to broadly encompass an immense variety of embodiments.

We affirm the rejection of claim 16 under 35 U.S.C. § 112, first paragraph, as it would require undue experimentation to use the full scope of OspA proteins encompassed by claim 16 in protein analysis or vaccine generation or other contemplated uses. Claims 18-21 fall with claim 16.

B. 35 U.S.C. § 112, second paragraph indefiniteness rejection

The Examiner's position is that "it is unclear from the disclosure exactly how the correspondence to the numbering of SEQ ID NO: 7 limits the structural properties of the amino acid sequence encoded by the nucleic acid that is actually being claimed" (Ans. 12). The Examiner argues that "[t]here are at least two ways that the numbering of the polypeptide set forth as SEQ ID NO: 9 might correspond to the numbering disclosed for SEQ ID NO: 7" (Ans. 28). In the first way, the Examiner notes that the "numbering of amino acids in SEQ ID NO: 7 is in consecutive order commencing at amino acid residue 1. Therefore, a corresponding numbering of SEQ ID NO: 9 might be considered a numbering that also commences at amino acid residue 1 and proceeds in consecutive order" (Ans. 28). "An alternative interpretation, and the interpretation apparently promoted by Appellant, is that number correspondence actually refers to functional correspondence and allows for small sequence variations among strains of *B. Burgdorferi*" (Ans. 29).

The Appellants contend that the "boundaries of what is an OspA protein are well defined" (App. Br. 11). Appellants further argue that

All of these genospecies or strains are very closely related to one another, and their OspA proteins are correspondingly

similar. Because the nucleotide numbering for strains with small insertions in OspA protein will differ slightly from those without such insertions, the language, ‘corresponding to’, in the claims, is used to take these and other such small differences into consideration.

(App. Br. 11).

In view of these conflicting positions, we frame the indefiniteness issue before us as follows:

Is the phrase “numbering corresponds to the numbering of SEQ ID NO: 7” in claim 16 indefinite when read in light of the Specification?

Discussion of 35 U.S.C. § 112, second paragraph indefiniteness rejection

The Federal Circuit has noted that “[t]he standard of indefiniteness is somewhat high; a claim is not indefinite merely because its scope is not ascertainable from the face of the claims.” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003). Rather, “[a] claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention.” *Id.*

We agree with the Examiner that in this particular situation, the phrase “numbering corresponds to the numbering of SEQ ID NO: 7” is insolubly ambiguous when read in concert with the statement at the beginning of claim 16 that the amino acids are “in consecutive order”. In the figure 4 and in figures 17A-17P of the Specification, the alignment of the various OspA proteins and nucleic acids was performed in consecutive order. However, as the Examiner demonstrated with the alignment of SEQ ID NO 7 and 9, consecutive order does not necessarily produce the best alignments.

The consecutive order alignment of SEQ ID Nos 7 and 9 is drawn from the Examiner's Answer and is shown below:

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139
Ser Gly Lys Ala Lys Glu Val Leu Lys Gly Tyr Val Leu Glu Gly Thr Leu Thr Ala Glu Lys
Ser Gly Lys Ala Lys Glu Val Leu Lys Asp Phe Thr Leu Glu Gly Thr Leu Ala Ala Asp Gly

160
Thr Thr Leu Val Val Lys Glu Gly Thr Val Thr Leu Ser Lys Asn Ile Ser Lys Ser Gly Glu
Lys Thr Thr Leu Lys Val Thr Glu Gly Thr Val Val Leu Ser Lys Asn Ile Leu Lys Ser Gly

189
Val Ser Val Glu Leu Asn Asp Thr Asp          SEQ ID NO: 7
Glu Ile Thr Val Ala Leu Asp Asp Ser Asp     SEQ ID NO: 9
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However, a better alignment around position 160 would be to adjust the Gly at position 159 of SEQ ID NO 9, the lower sequence, to not match with any amino acid, resulting in an alignment

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160
Lys Thr Thr Leu Val Val Lys Glu Gly Thr Val . . .
Lys Thr Thr Leu Lys Val Thr Glu Gly Thr Val . . .
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While this alignment would still have mismatches, it would result in a higher overall match through the rest of the sequence.

While the Specification repeatedly uses the phrase, “the numbering of the residues corresponds to the numbering of SEQ ID NO: 7”, the Specification never explains or defines what is meant by “corresponds” (*see* Spec. 5:13-14; 5:21-22; 16:10). We conclude that when this claim is read in the context of this Specification, the ordinary practitioner could not determine which OspA variants are within the scope of the claim. The court noted that “a compound claim, to be definite, must apprise a skilled artisan of the bounds of the claim.” *SmithKline Beecham Corp. v. Apotex Corp.* 403 F.3d 1331, 1340 (Fed. Cir. 2005).

We therefore affirm the rejections of claim 16 for indefiniteness in light of this Specification. Claims 18-21 fall with claim 16.

C. 35 U.S.C. § 102(b) over Arioli

The Examiner finds that

Arioli et al. discloses a nucleic acid encoding the sequence Thr-Met-Ala-Asp-Gly-Thr (i.e., SEQ ID NO: 13 beginning at about nucleotide 1544; page 40 of the sequence listing). The sequence encoded by the nucleic acid of Arioli et al. is the same as the sequence set forth as amino acids 138-143 of the instant SEQ ID NO: 7 except that the amino acid corresponding to position 139 is a methionine as recited in the instant claim. Therefore, the nucleic acid of Arioli et al. anticipates the limitations of the instant claims to the extent that they read on broadly divergent variants of the polypeptide sequences actually disclosed in the application.

(Ans. 32).

Appellants contend that

Arioli et al. describe genes which encode polypeptides involved in cellulose biosynthesis and plants, and particularly nucleic acids encoding an enzyme important in cellulose biosynthesis. In particular, they describe a nucleic acid fragment encoding Thr-Met-Ala-Asp-Gly-Thr. They do not describe any polynucleotides encoding amino acids from about residue 139 to about residue 273, inclusive and in consecutive order, of an OspA protein from *Borrelia burgdorferi*, and also including certain alterations. It is noted particularly that the length of the amino acids, inclusive and in consecutive order, of the claims is significantly longer than the 6 amino acids set forth in Arioli et al.

(App. Br. 12.)

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the Arioli sequence anticipate claim 16 using the broadest reasonable interpretation of claim 16?

Findings of Fact

17. Arioli teaches a nucleic acid sequence which encodes the amino acid sequence of Thr-Met-Ala-Asp-Gly-Thr (Arioli 166:17-20).

18. The Thr-Met-Ala-Asp-Gly-Thr amino acid sequence of Arioli is identical to amino acids 138-143 of SEQ ID NO: 7 of claim 16 except that a methionine is at the position that would correspond to position 139 in SEQ ID NO: 7 (*see* Spec. SEQ ID NO: 7).

19. Arioli teaches that the sequence which encompasses Thr-Met-Ala-Asp-Gly-Thr is 547 amino acids in length and encoded by a polynucleotide 1741 nucleotides in length (Arioli 165-166).

Discussion of 35 U.S.C. § 102(b) anticipation rejection

In analyzing claim 16, our mandate is to give claims their broadest reasonable interpretation.

Giving claims their broadest reasonable construction “serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.” *Yamamoto*, 740 F.2d at 1571; accord *Hyatt*, 211 F.3d at 1372; *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989) (“An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”).

In re American Academy of Science Tech Center, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

In order to interpret claim 16, we must first determine which elements of the claim impose structure on the polynucleotide and which elements

provide no structural information. The requirement that the polynucleotide encode amino acids from about residue 139 to about residue 273 imposes a structural requirement that the polynucleotide encode about 135 amino acids or more and therefore must be about 405 nucleotides in length or longer. The requirement for an alteration at one of codons 139, 160 or 189 requires that one position must be either a methionine or a tyrosine.

However, we do not find that simply stating that a polynucleotide encodes some amino acids of a protein named OspA, without any required structure, imposes any specific sequence requirements on the claim. This is particularly true in this case where the claim does not require that the sequence hybridize to SEQ ID NO: 7, share any level of percent identity with SEQ ID NO: 7, or retain any OspA function. This interpretation of the claim is supported by the Specification, which notes that the OspA polypeptides “comprise fragments, derivatives, analogs, variants and mutants of an OspA protein (modified OspA) and/or can be fragmented, derivatized or otherwise altered after having the alterations described herein inserted (also referred to as modified OspA). Such modified OspA molecules possess at least some OspA antigenic activity” (Spec. 22:14-18). Therefore, an OspA polypeptide in which five amino acids were “of an OspA protein” while the remaining amino acids were variants and mutants would meet the requirements of claim 16 in light of the Specification. Further, the Specification expressly teaches that the OspA polypeptides “can comprise additional modifications. Such additional modifications include conservative and/or non-conservative amino acid substitutions, additions of

one or more amino acids, and/or deletions of one or more amino acids.”
(Spec. 22:20-23).

Applying these interpretations to claim 16, Arioli teaches a polynucleotide sequence which encodes more than 135 amino acids and which comprises a short region of 6 amino acids which share 100% identity with one of the OspA sequences disclosed in figure 7 where codon 139 encodes a methionine (FF 17-19). We therefore conclude that Arioli anticipates claim 16 under its broadest reasonable interpretation.

We reject Appellants’ argument that Arioli only teaches “a six amino acid sequence, which is approximately twenty times shorter than a string [of] amino acids from about residue 139 to about residue 273 (e.g., 135 amino acids), inclusive and in consecutive order, of an OspA protein” (Reply Br. 6). This argument presupposes that the remaining sequence of Arioli is discarded, even though this sequence simply represents a sequence that includes “conservative and/or non-conservative amino acid substitutions, additions of one or more amino acids, and/or deletions of one or more amino acids” (Spec 22:20-23). In fact, Arioli teaches a sequence that meets all of the requirements of claim 16, due to the breadth of that claim.

We therefore affirm the rejections of claim 16 as anticipated by Arioli. Claims 18-21 fall with claim 16.

CONCLUSION

In summary, we affirm the rejection of claim 16 under 35 U.S.C. § 112, first paragraph, scope of enablement and 35 U.S.C. § 112, second paragraph. We also affirm the rejection of claim 16 as anticipated by Arioli.

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Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 18-21 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

Ssc:

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133