

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 JENNIFER L. HILLMAN and SURYA K. GOLI

Appeal 2006-3288
Application 10/316,761
Technology Center 1600

DECIDED: May 16, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and LORA M. GREEN,
Administrative Patent Judges.

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal involves claims to antibodies specific for a human pancreatitis-associated (PAP) protein, termed PAP-2. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 134. We affirm.

BACKGROUND

“The reg/PSP multigene family comprises genes encoding secretory proteins which are expressed in the pancreas” (Specification 2: 9-10), and “include[s] genes encoding pancreatitis-associated proteins (PAPs), which

have been identified in humans, mice and rats” (*id.* at 3: 1-2). The PAP proteins, “like other members of the reg/PSP family, share[] sequence similarity with the carbohydrate-binding domain of C-type lectins, which likely explains the ability of PAP to induce aggregation of bacteria” (*id.* at 3: 8-10). “The PAP proteins are secretory proteins which are stored in zymogen granules prior to secretion” (*id.* at 3: 6-7), and are “present at low levels in normal pancreas but [are] rapidly overexpressed during the acute phase of pancreatitis” (*id.* at 3: 7-8).

“The present invention features a . . . C-type lectin protein hereinafter designated human PAP-2 and characterized as having a similarity to the human PAP 1 protein” (*id.* at 4: 10-11). The claims at issue in this appeal are directed to “a purified antibody which binds specifically to a polypeptide comprising at least a portion of the amino acid sequence of SEQ ID NO:1” (*id.* at 5: 25-26).

DISCUSSION

Claims 11, 31, 32, 34, 42, and 43 are pending and the subject of appeal. Appellants do not argue the claims separately. Therefore, the claims subject to each rejection will stand or fall together, as provided in 37 CFR § 41.37(c)(1)(vii). Claims 11 and 31 are representative and read as follows:

11. An isolated antibody which specifically binds to a polypeptide of SEQ ID NO:1.
31. The antibody of claim 11, wherein the antibody is:
 - a) a chimeric antibody,
 - b) a single chain antibody,
 - c) a Fab fragment,
 - d) a F(ab')₂ fragment, or
 - e) a humanized antibody.

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

Iovanna	U.S. 5,436,169	Jul. 25, 1995
Queen	U.S. 5,530,101	Jun. 25, 1996

The amino acid sequence of PAP-2 is represented by SEQ ID NO:1. SEQ ID NO:1 is a 175 amino acid sequence representing both the “secretory (*i.e.*, the signal peptide is cleaved; E27-D175 of SEQ ID NO:1) and non-secretory (*i.e.*, signal peptide remains) forms of . . . human PAP-2 as well as any proteolytic fragments thereof” (Specification 4: 10-20).

According to the Specification, “[t]he terms ‘specific binding’ or ‘specifically binding’, as used herein, in reference to the interaction of an antibody and a protein or peptide, mean that the interaction is dependent upon the presence of a particular structure (*i.e.*, the antigenic determinant or epitope) on the protein; in other words, the antibody is recognizing and binding to a specific protein structure rather than to proteins in general” (*id.* at 13: 14-18).

ANTICIPATION

Claims 11, 32, 34, 42, and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Iovanna.

“[I]n an *ex parte* proceeding to obtain a patent, . . . the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty.” *See In re Wilder*, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). Nevertheless, “when the PTO shows *sound basis* for

believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (emphasis added).

Iovanna describes a human PAP protein represented by the amino acid sequence A3, i.e., SEQ ID NO: 7 (Iovanna col. 6). There is no dispute that “Iovanna’s SEQ ID NO: 7 and Appellants’ SEQ ID NO: 1 differ by 27 amino acids” and “[t]hese differences are not localized in a particular region but are distributed throughout the sequence” (Brief 4). However, a direct comparison of the amino termini of Iovanna’s SEQ ID NO: 7 and Appellants’ SEQ ID NO: 1 reveals that the first 28 amino acids, at least, are identical.

Iovanna also describes polyclonal and monoclonal antibodies raised against “the protein corresponding to the A3 amino acid sequence” that recognize the human PAP protein of SEQ ID NO: 7 (Iovanna col. 9, l. 51 to col. 10, l. 30).

The Examiner contends that Iovanna anticipates the claimed invention because “antibodies to the protein of . . . SEQ ID NO: 7 of the reference would bind the protein of . . . SEQ ID NO: 1 of the instant application” (Answer 3).

Appellants argue that “Iovanna’s hypothetical antibody does not necessarily specifically bind Appellants’ SEQ ID NO: 1” (Brief 4), because “Iovanna’s SEQ ID NO: 7 has only 84% sequence identity to Appellants’ SEQ ID NO: 1” (*id.* at 5), and “these differences in sequence mean that the epitopes in each sequence may be different” (*id.*). Thus, Appellants contend

“it is a mere possibility that Iovanna’s hypothetical antibody specifically binds Appellants’ SEQ ID NO: 1” (*id.* at 5-6).

Nevertheless, while it is true that antibodies raised against Iovanna’s *whole* protein might not bind Appellants’ protein, we note that Iovanna explicitly teaches that “[p]articularly useful monoclonal antibodies . . . are those which recognize specifically the NH₂-terminal portion of the human PAP” (Iovanna col. 9, ll. 65-68). As discussed above, the NH₂-termini of SEQ ID NO: 7 and SEQ ID NO: 1 are identical for a stretch of 28 amino acids. Appellants have not explained why antibodies raised against this portion of SEQ ID NO: 7 would not be expected to specifically bind SEQ ID NO: 1.

In any case, we note that the present claims do not require antibodies specific for portions of PAP-2 that differ from PAP-1. Nor do we find any basis in the Specification for interpreting “specifically binds” as requiring an antibody that binds Appellants’ SEQ ID NO: 1, but not Iovanna’s SEQ ID NO: 7. As discussed above, the Specification merely states that the term “specifically binds” “mean[s] that the interaction is dependent upon the presence of a particular structure (i.e., the antigenic determinant or epitope) on the protein” (Specification 13: 14-18).

Finally, it is irrelevant that a person of ordinary skill in the art might raise *other* antibodies within the broad disclosure of Iovanna that would not bind SEQ ID NO: 1. That is, it is irrelevant that antibodies raised against other portions of Iovanna’s SEQ ID NO: 7 might not specifically bind a polypeptide of Appellants’ SEQ ID NO: 1.

In summary, Iovanna explicitly describes antibodies raised against the NH₂-terminal portion of Iovanna's SEQ ID NO: 7, and this portion is identical to the NH₂-terminal portion of Appellants' SEQ ID NO: 1. Therefore, we find that the Examiner has established a sound basis for believing that antibodies raised against the NH₂-terminal portion of Iovanna's SEQ ID NO: 7 would specifically bind a polypeptide of SEQ ID NO: 1, and Appellants have not explained why this would not be the case.

We find that the Examiner has established a *prima facie* case of anticipation, which Appellants have not adequately rebutted by argument or evidence. Accordingly, we affirm the anticipation rejection claim 11.

Claims 32, 34, 42, and 43 fall with claim 11.

OBVIOUSNESS

Claim 31 stands rejected under 35 U.S.C. 103(a) as unpatentable over Iovanna in view of Queen.

Claim 31 depends from claim 11. The Examiner acknowledges that Iovanna does not describe the humanized PAP antibodies of claim 31, and relies on Queen as evidence that "it would have been *prima facie* obvious to a person of ordinary skill in the art to obtain humanized antibodies as taught by Queen [], to the PAP protein [] as taught by Iovanna" (Answer 5).

Appellants do not dispute that it would have been obvious for one skilled in the art to make a humanized version of Iovanna's antibodies. Rather, Appellants argue that the obviousness rejection "must fail for the same reason that the rejection of claims 11, 32, 34, 42, and 43 . . . must fail" (Brief 6).

Thus, Appellants do not argue the patentability claim 31 separately from the patentability of claim 11. Inasmuch as we have already determined that the Examiner has established a prima facie case that Iovanna anticipates claim 11, and Appellants do not dispute the Examiner's conclusion with respect to the combined teachings of Iovanna and Queen, we will affirm the obviousness rejection of claim 31 as well.

SUMMARY

Because the Examiner has established a prima facie case that Iovanna describes antibodies which specifically bind a polypeptide of SEQ ID NO: 1, which Appellants have not adequately rebutted by argument or evidence, we affirm the anticipation rejection of claims 11, 32, 34, 42, and 43. Because Iovanna and Queen together teach or suggest all of the limitations recited in claim 31, we affirm the obviousness rejection of claim 31 as well.

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

AFFIRMED

dm

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