

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 KEVIN P. BAKER, DAVID BOTSTEIN, LUC DESNOYERS,
DAN L. EATON, NAPOLEONE FERRARA, SHERMAN FONG,
WEI-QIANG GAO, AUDREY GODDARD, PAUL J. GODOWSKI,
J. CHRISTOPHER GRIMALDI, AUSTIN L. GURNEY, KENNETH J. HILLAN,
JAMES PAN, NICHOLAS F. PAONI, MARGARET ANN ROY, VICTORIA SMITH,
TIMOTHY A. STEWART, DANIEL TUMAS, COLIN K. WATANABE,
P. MICKEY WILLIAMS, and WILLIAM I. WOOD

Appeal No. 2006-2892
Application No. 10/012,237

ON BRIEF

Before MILLS, GRIMES, and LINCK, *Administrative Patent Judges*.
LINCK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of all of the pending claims in Application No. 10/012,237, filed December 7, 2001.¹ We affirm.

¹ The real party in interest is Genentech, Inc. There is a priority claim dating back to September 9, 1998.

Claims on Appeal

Claims 28-32, all the pending claims, are rejected under 35 U.S.C. § 102(e).

These claims have been argued together and thus stand or fall together. Claim 28 is the only independent claim.

It reads:

28. An isolated antibody that specifically binds to the polypeptide of SEQ ID NO:227.

The Examiner has rejected all the claims under § 102(e) over the following reference: Lal et al. (Lal), U.S. 5,932,442, filed Sep. 23, 1997.²

DISCUSSION

The single issue in this case is whether the antibodies of Lal “bind specifically to SEQ ID NO:227, as recited in the claims.” Br. 5. SEQ ID NO:227 is also referred to as PRO1325. According to the specification, Appellants identified and characterized PRO 1325, a transmembrane protein. Specification at 18. Such membrane proteins can act as signal receptors and thus play a regulatory role in multicellular organisms. *Id.* at 1.

Claim Interpretation

The Examiner and Appellants appear to disagree as to the meaning of the functional term “specifically binds.” Appellants do not define “specifically binds” in their specification but rather rely on what is “well known” in the antibody art. Br. 5. Lal defines this term as follows: “The terms ‘specific binding’ or ‘specifically binding,’ as used herein, refer to that interaction between a protein or peptide and an agonist, an antibody and an antagonist. The interaction is dependent upon the presence of a

² Appellants have not attempted to antedate this date. Thus, in spite of Appellants’ argument to the contrary (Reply at 5), Lal is prior art under 35 U.S.C. § 102(e).

particular structure (i.e., the antigenic determinant or epitope) of the protein recognized by the binding molecule.” Col. 10, ll. 31-36. Lal’s definition comports with art-recognized definitions. Additionally, we interpret the term “specifically binds” to mean binding with high affinity, as compared to “nonspecific binding.” Lodish et al., CELL BIOLOGY 538-39 (5th ed. 2004). We do not interpret “specifically binding” to require that binding is only to a specific protein, as Appellants urge. Rather, as the Examiner found and consistent with Lal’s definition, “antibodies can cross-react with different proteins having the same epitope/antigens.” Advisory Action at 3 (mailed Apr. 7, 2005).³

The Cited Prior Art

Like Appellants, Lal discloses regulatory proteins, referred to by Lal as “human regulatory molecules” or HRM, “having at least one of the amino acid sequences selected from the group consisting of SEQ ID NOS:1-48.” Col. 4, ll. 25-30. The reference also discloses “a purified antibody which binds to an HRM.” Col. 4, ll. 65-67. According to Lal, the term ““antibody’ is a reference to one or more antibodies.” Col. 5, ll. 63-67. Relevant to this case, Lal’s SEQ ID NO:24 is 431 amino acids in length and is 52.1% identical to Appellants’ SEQ ID NO:227; of the 431 amino acids in Lal’s sequence, 430 match those on the carboxy terminal half of SEQ ID NO:227 without interruption (except for a single mismatch). Sequence Comparison attached to non-final Office Action, mailed May 10, 2004. *See also* Lal, cols. 95-97 (sequence for SEQ ID NO:24).

³ During examination, “claims are given their broadest reasonable interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000), quoted with approval in *In re Bigio*, 381 F.3d 1320, 1324, 72 USPQ2d 1209, 1210-11 (Fed. Cir. 2004).

The Disputed Claim Limitation: “Specifically Binds”

Appellants take the position that ““an isolated antibody that specifically binds to the polypeptide of SEQ ID NO:22’ . . . refers to an antibody that binds to a particular epitope without binding to another epitope.” Br. 4 (emphasis in original). Thus, according to Appellants:

Claim 28 . . . clearly refer[s] to an antibody that is able to bind to a specific epitope of the PRO 1325 polypeptide of SEQ ID NO:227 *without* cross reacting with other epitopes, including those found in the sequence disclosed in Lal. . . . As a result of the requirement of specific binding, the claims pending in this application do not encompass antibodies that specifically bind to epitopes found in the polypeptide of Lal. [Id.]

Appellants further argue:

[T]here may be antibodies that are capable of binding to epitopes present in both the PRO1325 polypeptide and the Lal protein. However, the present invention does not claim such antibodies. It is, again, emphasized that the claimed antibodies would only bind to those epitopes which are present in PRO1325 and not any other proteins, including the Lal protein. Therefore, any antibody capable of specifically binding to epitopes found in both PRO1325 and the protein of Lal is not encompassed by the presently claimed antibodies. [Br. 6 (emphasis in original).]

With respect to this issue, the Examiner responds:

It is well-known in the art that antibodies cross-react with antigens on more than one protein and this would need to be determined by a competitive binding assay. . . . Two proteins which share almost 100% identity over 431 residues [such as is the case here] would be expected to bind some of the same antibodies. . . .

. . . . The crux of Appellant's argument appears to be that if a given antibody binds to a protein other than that of SEQ ID NO:227 then it is not encompassed by the claims. However, this is, respectfully, not how "specific binding" is interpreted. Specific binding cannot be viewed as an antibody which only binds a given protein, but, if anything, one that has a higher affinity for one protein over another.

. . . The fact that an antibody binds to other proteins with a given epitope does not make it non-specific for that protein. The antibody is still specific, but for a given epitope. [Answer at 3-4.]

Analysis

We agree with Appellants that specific binding is dependent upon the presence of a particular epitope. However, we also agree with the Examiner that at least some antibodies would be expected to specifically bind to both SEQ ID NO:227 *and* Lal's SEQ ID NO:24 as both likely have such an epitope in common, given the very large overlap of 430 amino acids (substantially 100% of Lal's sequence is found in that of Appellants). Thus, unless some unidentified secondary or tertiary structure interfered with such binding, any antibody that specifically binds to an epitope of SEQ ID NO:24 would likely specifically bind to SEQ ID NO:227.

As Appellants argue, there may be antibodies that specifically bind to SEQ ID NO:227 and not to SEQ ID NO:24. Br. 6; Reply 4 (“specific epitopes in the SEQ ID NO:227 protein that are not found in the Lal protein clearly exist . . . in the amino terminal half of SEQ ID NO:227”). However, that fact is not relevant to deciding this case, in view of Appellants’ claim language. As we interpret the claims, they include *all* antibodies that specifically bind to SEQ ID NO:227, *including* any that also specifically bind to SEQ ID NO:24.⁴ And to the extent “specific epitopes . . . exist . . . in the amino terminal half of SEQ ID NO:227,” its fair to conclude other specific epitopes exist in the

⁴ While not necessary for our determination, we interpret the term “antibody” to include polyclonal antibodies, given the additional limitations in dependent claim 29 to “monoclonal.” *See also* Specification at 373, l. 7 (“anti-PRO antibodies may . . . be monoclonal antibodies”).

carboxy terminal half, i.e., the half that is substantially identical to SEQ ID NO:24.⁵

Thus, we find that the Examiner has made a *prima facie* case of anticipation—Lal’s antibodies to SEQ ID NO:24 would be expected to specifically bind SEQ ID NO:227.

Appellants . . . argue that it may be difficult to predict the binding characteristics of a protein once it has folded since the tertiary structure of a protein is unpredictable. However, since the Office does not have the facilities for examining and comparing Appellant's protein/antibody with the protein/antibody of the prior art, the burden is on Appellants to show a novel or unobvious difference between the claimed product and the product of the prior art See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922, 1923 (PTO Bd. Pat. App. & Int.). As of now, since there is such a high degree of overlap between the protein of Lal and that of SEQ ID NO:227 it would be expected that the antibodies would cross-react.

[Answer 3.]

As the Examiner explained, the burden shifted to Appellants to overcome the Examiner’s *prima facie* case. Specifically, it is Appellants’ burden to show that antibodies do not specifically bind to both the protein of SEQ ID NO:24 and that of SEQ ID NO:227. *See, e.g., In re Swinehart*, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971) (“where the Patent Office has reason to believe that a functional limitation [such as ‘specifically binds’] asserted to be critical for establishing novelty . . . may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.”), quoted with approval in *In re Best*, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1977). To date, Appellants have not met this burden.

⁵ Appellants admit “there may be antibodies that are capable of binding to epitopes present in both the PRO 1325 polypeptide and the Lal protein.” Br. 6. According to Appellants, their claims do not cover such antibodies. *Id.* (“any antibody capable of specifically binding to epitopes found in both PRO1325 and the protein of Lal is not encompassed by the presently claimed antibodies”). We disagree. There is nothing in the claim language to support Appellants’ position.

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Conclusion

We affirm the Examiner's rejection of claims 28-32.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv) (2004).

AFFIRMED

DEMETRA J. MILLS
Administrative Patent Judge

ERIC GRIMES
Administrative Patent Judge

NANCY J. LINCK
Administrative Patent Judge

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INTERFERENCES

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