

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL J. BRISKIN

Appeal 2007-3891
Application 08/523,004
Technology Center 1600

Decided: April 24, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 103-105, 109-112, 115, 116, 118-120, 123, 125-127, 130, 131, 133, and 134. The Examiner indicated that claims 106, 107, 117, and 124, the only remaining pending claims, are allowable (May 3, 2005 Office Action 8: ¶ 6). We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to an isolated nucleic acid which encodes a naturally occurring primate MAdCAM, a recombinant nucleic acid construct comprising this nucleic acid, and a host cell comprising this nucleic acid (claims 103-105, 115, 116, and 123); an isolated nucleic acid encoding a naturally occurring primate MAdCAM or variant thereof which binds an $\alpha 4\beta 7$ integrin, a recombinant nucleic acid construct comprising this nucleic acid, and a host cell comprising this nucleic acid (claims 109, 110, 118-120, and 125); an isolated nucleic acid encoding a naturally occurring primate MAdCAM-1 or variant thereof, a recombinant nucleic acid construct comprising this nucleic acid, and a host cell comprising this nucleic acid (claims 111, 112, 119, 126, and 127); and an isolated nucleic acid encoding a fusion protein comprising a naturally occurring primate MAdCAM or variant thereof and a host cell comprising this nucleic acid (claims 130, 131, 133, and 134). Claims 103, 109, 111, and 112 are illustrative:

103. An isolated nucleic acid which encodes a naturally occurring primate MAdCAM, wherein said nucleic acid encodes the polypeptide shown in Figure 1 (SEQ ID NO: 2), the polypeptide shown in Figure 2 (SEQ ID NO: 4), or the polypeptide shown in Figure 3 (SEQ ID NO:6).

109. An isolated nucleic acid encoding a naturally occurring primate MAdCAM or variant thereof which binds an $\alpha 4\beta 7$ integrin, wherein said nucleic acid hybridizes under wash conditions of 0.1X SSC, 0.1% SDS at 65°C with a second nucleic acid selected from the group consisting of:

- a) the nucleic acid of Figure 1 (SEQ ID NO: 1);
- b) the nucleic acid of Figure 2 (SEQ ID NO: 3);
- c) the nucleic acid of Figure 3 (SEQ ID NO:5); and

d) a nucleic acid having a sequence complementary to the strand shown in Figure 1 (SEQ ID NO: 1), Figure 2 (SEQ ID NO: 3), or Figure 3 (SEQ ID NO: 5).

119. A recombinant nucleic acid construct comprising a nucleic acid encoding a naturally occurring primate MAdCAM or variant thereof, wherein said variant has at least about 75% amino acid sequence similarity to the sequence of a protein shown in Figure 1 (SEQ ID NO: 2), Figure 2 (SEQ ID NO: 4) or Figure 3 (SEQ ID NO: 6), and said variant mediates $\alpha 4\beta 7$ -dependent adhesion.

120. The recombinant nucleic acid construct of Claim 119, wherein said variant has at least about 90% amino acid sequence similarity to the sequence of a protein shown in Figure 1 (SEQ ID NO: 2), Figure 2 (SEQ ID NO: 4), or Figure 3 (SEQ ID NO:6)

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

| | | |
|--|--------------|---------------|
| Vonderheide | US 5,599,676 | Feb. 4, 1997 |
| Butcher | WO 94/13312 | Jun. 23, 1994 |
| David J. Erle et al., "Expression and Function of the MAdCAM-1 Receptor, Integrin $\alpha 4\beta 7$, on Human Leukocytes," 153 <i>J. Immunology</i> 517-528 (1994). | | |

The rejections as presented by the Examiner are as follows:

1. Claims 111, 112, 119, 120, 126, 127, 130, 131, 133, and 134 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

2. Claims 103-105, 109-112, 115, 116, 118-120, 123, 125-127, 130, 131, 133, and 134 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle.

We affirm the rejection of claim 119 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 111, 126, 130, and 133 fall together with claim 119.

We affirm the rejection of claim 120 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 112, 127, 131, and 134 fall together with claim 120.

We affirm the rejection of claim 119 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 111, 126, 130, and 133 fall together with claim 119.

We affirm the rejection of claim 120 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 112, 127, 131, and 134 fall together with claim 120.

We affirm the rejection of claim 109 as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 110, 118, and 125 fall together with claim 109.

We reverse the rejection of claims 103-105, 115, 116, and 123 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle.

DISCUSSION

Written Description:

Claims 111, 112, 119, 120, 126, 127, 130, 131, 133, and 134 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

The Examiner finds that the claims encompass nucleic acids that encode primate MAdCAM “from any primate or alleles of said molecules wherein the nucleic acids encode proteins that have a particular degree of amino acid sequence similarity recited in the claims” (Ans. 4). The Examiner finds that Appellant’s “specification discloses one nucleic acid sequence encoding macaque MAdCAM [(SEQ ID NO: 5)] and two different nucleic acid sequences encoding human MAdCAM [(SEQ ID NOS: 1 and 3)] as well as amino acid sequences for said molecules” (*id.*). From this the Examiner concludes that “[w]ith the exception of the aforementioned nucleic acid sequences, the skilled artisan cannot envision the detailed structure of the encompassed nucleic acids” (*id.*).

In addition, the Examiner finds that “there are 11 families, 52 genera and 181 species encompassed by the term primate. Thus, [A]ppellant has not provided a description of the vast majority . . . of the amino acid sequences (or nucleic acids encoding said molecules) of primate MAdCAM” (Ans. 10). Further, the Examiner asserts that “[i]f each species had multiple alleles or polymorphic variants than [sic] the potential number of MAdCAM sequences would vastly increase from the 181 sequences number” (Ans. 10-11).

Regarding the percent similarity limitations in the claims, the Examiner finds that the “claims do not specify what particular regions of the

sequence are similar and do not specify the identity of the nonsimilar portion, it is unclear as to how this provides a further description of the sequence encoding other primate variants” (Ans. 11). In addition, the Examiner finds that

there is no disclosure in the specification as to what particular amino acids can or cannot be substituted wherein the fusion protein would maintain all of the required functions of MAdCAM and there is no disclosure as to what particular amino acids [sic] substitutions could be tolerated in any particular section of the sequence with the retention of MAdCAM function.

(Ans. 13.)

Appellant provides separate arguments for the following groups of claims: I. claims 111, 119, 126, 130, and 133; and II. claims 112, 120, 127, 131, and 134. Accordingly, we limit our discussion to representative claims 119 and 120. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 119:

Claim 119 is drawn to an isolated nucleic acid encoding a naturally occurring primate Mucosal Addressin Cell Adhesion Molecule¹ (MAdCAM) or variant thereof. In addition, claim 119 requires that the variant:

- a. has at least about 75% amino acid sequence similarity to the sequence of a protein shown in Figure 1 (SEQ ID NO: 2), Figure 2 (SEQ ID NO: 4) or Figure 3 (SEQ ID NO: 6); and
- b. mediates $\alpha 4\beta 7$ -dependent adhesion.

¹ Spec. 9: 16-17 (“MAdCAMs (Mucosal Addressin Cell Adhesion Molecules”).

We note that while claim 119 requires the MAdCAM variant to mediate $\alpha 4\beta 7$ -dependent adhesion, claim 119 does not require the MAdCAM, encoded by the claimed recombinant nucleic acid, to mediate $\alpha 4\beta 7$ -dependent adhesion.

According to Appellant's Specification:

1. "[S]ome proteins of the present invention can selectively bind to an $\alpha 4\beta 7$ integrin and thereby mediate $\alpha 4\beta 7$ -dependent cellular adhesion to cells bearing the $\alpha 4\beta 7$ integrin, such as leukocytes" (Spec. 9: 26-29).

2. "In another embodiment, proteins of the present invention can bind a primate $\alpha 4\beta 7$ integrin from the same or a different primate species, *and/or* have cellular adhesion molecule function (e.g., the ability to mediate cellular adhesion such as $\alpha 4\beta 7$ -dependent adhesion in vitro and/or in vivo)" (Spec. 10: 1-6 (emphasis added)). Appellant identifies human and macaque MAdCAM-1 proteins as an example of MAdCAM proteins that "can selectively bind to $\alpha 4\beta 7$ integrin present on human lymphocytes, *and* can function as cellular adhesion molecules capable of mediating selective adhesion to cells bearing the $\alpha 4\beta 7$ integrin" (Spec. 10: 8-11 (emphasis added)).

Appellant's Specification discloses the nucleotide and amino acid sequence of two human (Spec. 6: 29 - 7: 9) and one macaque MAdCAM-1 (Spec. 7: 15-19). Appellant's Specification also provides some structural characterization of the human and macaque MAdCAM-1 protein in relation to murine MAdCAM-1 (Spec. 7: 14-19).

Appellant asserts that the Specification "contains a detailed description of the structure of naturally occurring primate MAdCAM and variants thereof and the relationship between structure and $\alpha 4\beta 7$ -dependent

adhesion function, that is sufficient to demonstrate that Appellant was in possession of the claimed subject matter at the time the application was filed” (App. Br. 10-11). We disagree. Appellant has provided a disclosure of MAdCAM-1 but not the broader genus encompassed by MAdCAM, which according to Appellant’s Specification can, *inter alia*, bind a primate $\alpha 4\beta 7$ integrin from the same species, a different primate species, *or* have cellular adhesion molecule function (*see* Spec. 10: 1-6). Appellant’s arguments focus on a species of MAdCAM protein – the MAdCAM-1 protein, particularly those MAdCAM-1 proteins from human and macaque that have SEQ ID NOs: 2, 4, and 6 (*see* App. Br. 7-20).

Appellant does not identify and we find no disclosure of a nucleotide or amino acid sequence of a non-MAdCAM-1 nucleic acid or protein that falls within the genus of MAdCAM, or a disclosure of a correlation between the structure and function of a non-MAdCAM-1 protein that falls within the MAdCAM genus. Further, while Appellant discloses that “as shown herein, human and macaque MAdCAM-1 proteins . . . can selectively bind to $\alpha 4\beta 7$ integrin present on human lymphocytes, *and* can function as cellular adhesion molecules capable of mediating selective adhesion to cells bearing the $\alpha 4\beta 7$ integrin”², Appellant does not identify and we find no disclosure that all MAdCAM proteins within the claimed genus exhibit a similar function and selective binding ability.

Accordingly, we disagree with Appellant’s argument that his disclosure “of three species of nucleic acids which encode naturally occurring primate MAdCAM[-1]” and “a correlation between [MAdCAM-1] structure and $\alpha 4\beta 7$ -dependent adhesion function, are adequate to convey to

² Spec. 10: 8-11 (emphasis added).

the person of skill in the art that Appellant was in possession of the claimed invention at the time the application was filed” (App. Br. 12).

On facts similar to those here, the U.S. Court of Appeals for the Federal Circuit has held claims to lack adequate description. In *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997), the court held that claims generically reciting cDNA encoding vertebrate or mammalian insulin were not adequately described by the disclosure of cDNA encoding rat insulin. *Id.* at 1568. The court held that

a generic statement such as “vertebrate insulin cDNA” or “mammalian insulin cDNA,” without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. The court held that a

description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

(*Id.* at 1569.)

We are not persuaded by Appellant’s assertion that the disclosure of nucleotide and amino acid sequences for three MAdCAM-1 proteins, or that the alleged structure and functional relationship of MAdCAM-1 protein disclosed in Appellant’s Specification is sufficient to provide an adequate

written description of the genus of MAdCAM recombinant nucleic acid constructs encompassed by Appellant's claim 119.

We are also not persuaded by Appellant's assertion that the "specification contains extensive disclosure and exemplification of the claimed subject matter" (App. Br. 15). Assuming, arguendo, that Appellant's disclosure of the nucleotide and amino acid sequences of three MAdCAM-1 proteins and a structure-function relationship for MAdCAM-1 proteins provides adequate written description of a recombinant nucleic acid construct comprising a nucleic acid encoding a naturally occurring primate MAdCAM-1; we find that such a disclosure fails to provide adequate written descriptive support for the entire genus encompassed by claim 119.

As discussed above, Appellant's Specification contemplates MAdCAM proteins to be associated with a variety of functions. Accordingly, we are not persuaded by Appellant's reliance on Example 14 of the Written Description Guidelines, which discusses a single protein whose function is to "catalyze the reaction $A \rightarrow B$ " (App. Br. 15).

For the foregoing reasons, we affirm the rejection of claim 119 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 111, 126, 130, and 133 fall together with claim 119.

Claim 120:

Claim 120 depends from and further limits the variant of claim 119 to have at least about 90% amino acid sequence similarity to the sequence of a protein shown in Figure 1 (SEQ ID NO: 2), Figure 2 (SEQ ID NO: 4) or Figure 3 (SEQ ID NO: 6). Appellant's arguments with regard to claim 120 are substantially the same as those for claim 119 with the exception that

Appellant emphasizes that claim 120 requires that the variant of claim 119 exhibit at least about 90% amino acid sequence similarity to one of the stated sequences.

Claim 120 further limits only the variant portion of claim 119. Claim 120 does nothing to further limit the claimed recombinant nucleic acid construct comprising a nucleic acid encoding a naturally occurring primate MAdCAM. Accordingly, for the same reasons as set forth above with regard to claim 119, we affirm the rejection of claim 120 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 112, 127, 131, and 134 fall together with claim 120.

Obviousness:

Claims 103-105, 109-112, 115, 116, 118-120, 123, 125-127, 130, 131, 133, and 134 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle.

The Examiner makes the following findings:

1. Butcher teaches vectors and host cells containing a nucleic acid sequence of murine MAdCAM (Ans. 7).
2. Butcher teaches complementary nucleic acids to those encoding MAdCAM nucleic acids (*id.*).
3. Butcher does “not teach nucleic acids encoding primate MAdCAM” (*id.*).
4. Erle teaches “human MAdCAM binds to $\alpha 4\beta 7$ ” (*id.*).
5. Erle teaches “that MAdCAM is found in mucosal lymphoid organ HEV and gut lamina propria venules” (*id.*).
6. Erle teaches “human cell lines expressing $\alpha 4\beta 7$ and MAdCAM” (*id.*).
7. Erle teaches “a source of human MAdCAM nucleic acids” (*id.*).

8. Vonderheide teaches “methods to isolate nucleic acids encoding molecules that bind $\alpha 4\beta 7$ ” which require “human cell lines expressing $\alpha 4\beta 7$ and human cells expressing MAdCAM” (*id.*).
9. Vonderheide teaches “nucleic acids encoding molecules that bind $\alpha 4\beta 7$ ” (*id.*).
10. Vonderheide “teach that molecules that bind $\alpha 4\beta 7$ can be used for a variety of art recognized purposes . . . and the art recognizes that nucleic acids encoding said molecules . . . can be used to recombinantly produce said molecule” (Ans. 8).

Based on these findings the Examiner concludes that

[i]t would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Butcher et al. teach murine nucleic acids encoding MAdCAM, Erle et al. teach that human MAdCAM binds to $\alpha 4\beta 7$ and human cell lines expressing $\alpha 4\beta 7$ and MAdCAM, while Vonderheide et al. teach methods to isolate nucleic acids encoding molecules that bind $\alpha 4\beta 7$ wherein said methods require human cell lines expressing $\alpha 4\beta 7$ and MAdCAM.

(Ans. 7-8.)

Butcher teaches “[m]ammalian purified nucleic acids and proteins encoding mucosal addressins” (Abstract). In this regard, Butcher discloses “the cDNA sequence of murine MAdCAM-1 . . . and the encoded amino acid sequence” (Butcher 3: 11-12). According to Butcher

[n]ucleotide sequences are provided encoding mammalian mucosal addressin, where the sequences can be used for expressing the addressin or fragments thereof. The addressin or fragments thereof may be used to produce antibodies which may find therapeutic purposes. The addressin or fragments thereof, by themselves or joined to other molecules, may find

use in tagging leukocytes, inhibiting leukocyte binding to endothelial cells, in isolating leukocytes, in transporting various agents to leukocytes, and the like. Also as a tool for screening to identify molecules that bind to the mucosal addressins, that might themselves find therapeutic uses in inhibiting MAd functions, or might be used to target other agents to MAdCAM-1 and endothelial cells (“EC”) for therapeutic purposes. Methods are provided for isolating or synthesizing DNA which encodes at least a portion of the mucosal addressin, for introducing the DNA into host cells, and for expression of the addressin or fragments thereof. In addition, the addressin can serve as a source of the carbohydrate side chains which serve as binding entities to the leukocytes.

(Butcher 2: 28 - 3: 8.) In addition, Butcher teaches that the addressin peptide or protein may be fused to other proteins to provide a fusion protein. However, as the Examiner recognizes, Butcher does “not teach nucleic acids encoding primate MAdCAM” (Ans. 7). The Examiner relies on Erle and Vonderheide to make up for this deficiency.

Erle teaches that MAdCAM-1 is “expressed selectively on mucosal lymphoid organ HEV and on gut lamina propria venules” (Erle 518: col. 1, ll. 13-16). In addition, Erle teaches that human $\alpha 4\beta 7$ “mediates adhesion to MAdCAM-1 in vitro” (Erle 518: col. 1, ll. 48-50). Vonderheide teaches “a method for isolating a novel receptor for $\alpha 4$ integrins” including “[i]solated nucleic acids encoding the receptor” (Vonderheide, Abstract). Vonderheide defines “[t]he term ‘ $\alpha 4$ integrins’ as . . . molecules comprising the $\alpha 4$ integrin subunit, including but not limited to VLA-4 ($\alpha 4\beta 1$), $\alpha 4\beta 7$, and the $\alpha 4$ subunit itself” (Vonderheide, col. 4, ll. 27-30). Based on this evidence the Examiner concludes that an isolated nucleic acid encoding a naturally occurring primate MAdCAM or MAdCAM-1 and fusion protein thereof would have been prima facie obvious to a person of ordinary skill in the art

as Butcher teaches a murine MAdCAM nucleic acid and fusion protein, Erle teaches the source of primate MAdCAM and Vonderheide teaches the methodology of obtaining $\alpha 4$ integrin receptors, including $\alpha 4\beta 7$ receptors such as MAdCAM-1 (Ans. 7-8 and 15-18). We find no error in the Examiner's conclusion that claims 111, 112, 119, 126, 127, 130, 131, 133, and 134 are prima facie obvious in view of the combination of Butcher, Vonderheide, and Erle.

In response, Appellant asserts that Butcher "does not suggest the claimed nucleic acids to the person of ordinary skill in the art or provide a reasonable expectation of success, because murine MAdCAM and primate or human MAdCAM have a very low degree of sequence similarity" (App. Br. 22). We are not persuaded. Claims 111, 112, 119, 126, 127, 130, 131, 133, and 134 do not require any amount of sequence similarity to a particular nucleic acid sequence. These claims only require an isolated nucleic acid encoding a (1) naturally occurring primate MAdCAM or MAdCAM-1; or (2) fusion protein comprising a naturally occurring primate MAdCAM. As Vonderheide teaches a method of obtaining nucleic acids for $\alpha 4$ integrin receptors that does not involve hybridization, we are not persuaded by Appellant's reliance on Shyjan (App. Br. 22-23).

We are also not persuaded by Appellant's assertion that the combination of Vonderheide and Erle fails to make up for the deficiency in Butcher because "at best Vonderheide *et al.* discloses a method suitable for isolating a cDNA that encodes an $\alpha 4$ integrin receptor, and Erle *et al.* demonstrates that primate or human MAdCAM was not known, but believed to exist" (App. Br. 23; see also *id.* at 26-30). Erle identifies the cellular source of MAdCAM which can be used in Vonderheide's methodology to

obtain the primate homologue of the murine MAdCAM identified by Butcher.

As stated in *Ex parte Goldgaber*, 41 USPQ2d 1172, 1176 (BPAI 1995), “[w]e find nothing intrinsically wrong, however, in the application of methodology in rejecting product claims under 35 U.S.C. § 103, depending on the particular facts of the case, the manner and context in which methodology applies, and the overall logic of the rejection.” On this record, the combination of Butcher and Erle provides a road map that would have directed a person having ordinary skill in the art to a nucleic acid meeting the claimed limitations. Vonderheide provides the methodology to obtain that nucleic acid. Here, similar to the facts presented in *Goldgaber*, and in contrast to the facts presented in *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) and *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), “there is something in the prior art to lead to the particular DNA and indicate that it should be prepared.” *Deuel*, 51 F.3d at 1558. Stated differently, the combination of prior art relied upon by the Examiner puts the key in the lock of the door of success. All that remains for a person having ordinary skill is to turn the key and, in so doing, open the lock. That, in our judgment, does not give rise to a patentable invention. *Cf. Goldgaber*, 41 USPQ2d at 1175. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

We are also not persuaded by Appellant’s assertion that “none of the cited references demonstrate that primate or human MAdCAM binds $\alpha 4\beta 7$ integrin, or even that primate or human MAdCAM proteins existed” (App. Br. 24). Claims 111, 112, 119, 126, 127, 130, 131, 133, and 134 do not

require that the primate MAdCAM bind $\alpha 4\beta 7$ integrin. Further, Butcher teaches that “[t]he results of this study support the hypothesis that $\alpha 4\beta 7$ plays a crucial role in mucosal homing of human lymphocytes by mediating adhesion to the mucosal addressin, MAdCAM-1” (Butcher 526: col. 2, ll. 41-44). Thus, contrary to Appellant’s assertion, while the MAdCAM receptor was not isolated, the preponderance of the evidence on this record suggests that a primate MAdCAM receptor existed, provided the cellular source, and the methodology for the isolation of the nucleic acid for this receptor.

In addition, we are not persuaded by Appellant’s assertion that the Examiner’s rejection is based on hindsight reconstruction (App. Br. 31). In this regard, we note that Appellant’s assertion is based on a rejection over a combination of references presented in the “first Office Action on the merits” and later withdrawn by the Examiner (*see* App. Br. 31-32).

Appellant provides separate arguments for the following groups of claims: I. claims 103-105, 115, 116, and 123; II. claims 109, 110, 118, and 125; III. claims 111, 119, 126, 130, and 133; and IV. Claims 112, 120, 127, 131, and 134.

Group III (claims 111, 119, 126, 130, and 133):

We limit our discussion to representative claim 119. Claims 111, 126, 130, and 133 stand or fall with claim 119. 37 C.F.R. § 41.37(c)(1)(vii).

According to Appellant

[a] *prima facie* case has not been established against claims 111, 119, 126, 130 and 133 because the combined teachings of the cited references fail to suggest a nucleic acid that encodes a naturally occurring primate MAdCAM or variant thereof that

mediates $\alpha 4\beta 7$ -dependent adhesion and has at least 75% amino acid sequence similarity to the sequence of a protein[] shown in Figure 1 (SEQ ID NO:2), Figure 2 (SEQ ID NO: 4) or Figure 3 (SEQ ID NO: 6), to a person of ordinary skill in the art.

(App. Br. 25-26.) We are not persuaded.

As discussed above, while Appellant focuses on alternative limitations set forth in claim 119, we note that the scope of claim 119 includes a nucleic acid encoding a naturally occurring primate MAdCAM. For the reasons set forth above, we affirm the rejection of claim 119 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 111, 126, 130, and 133 fall together with claim 119.

Group IV (claims 112, 120, 127, 131, and 134):

We limit our discussion to representative claim 120. Claims 112, 127, 131, and 134 stand or fall with claim 120. 37 C.F.R. § 41.37(c)(1)(vii).

According to Appellant “[t]hese claims are drawn to a smaller subgenus of nucleic acids than claims that recite at least 75% amino acid sequence similarity, and therefore a more precise motivation or suggestion must be found in the prior art to establish a *prima facie* case” (App. Br. 26). We disagree.

Claim 120 limits the variant of claim 119. However, as discussed above, the scope of claim 119 is not limited to a variant. Accordingly, for the reasons set forth above, we are not persuaded by Appellant’s assertion that “there is nothing in the combined teachings of the cited references that suggests a nucleic acid[] that meets the limitations of the claims” (*id.*). For the reasons set forth above, we affirm the rejection of claim 120 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher,

Vonderheide, and Erle. Claims 112, 127, 131, and 134 fall together with claim 120.

Group II (claims 109, 110, 118, and 125):

We limit our discussion to representative claim 109. Claims 110, 118, and 125 stand or fall with claim 109. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 109 is drawn, inter alia, to an isolated nucleic acid encoding a naturally occurring primate MAdCAM that hybridizes under wash conditions of 0.1X SSC, 0.1% SDS at 65°C with a second nucleic acid selected from the group consisting of:

- a) the nucleic acid of Figure 1 (SEQ ID NO: 1);
- b) the nucleic acid of Figure 2 (SEQ ID NO: 3);
- c) the nucleic acid of Figure 3 (SEQ ID NO:5); and
- d) a nucleic acid having a sequence complementary to the strand shown in Figure 1 (SEQ ID NO: 1), Figure 2 (SEQ ID NO: 3), or Figure 3 (SEQ ID NO: 5).

Based on the foregoing discussion we find that the preponderance of evidence on this record supports a conclusion that a nucleic acid encoding a naturally occurring primate MAdCAM would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made. The question then is whether this nucleic acid would have been expected to hybridize under the claimed conditions to a nucleic acid selected from the group consisting of:

- a) the nucleic acid of Figure 1 (SEQ ID NO: 1);
- b) the nucleic acid of Figure 2 (SEQ ID NO: 3);
- c) the nucleic acid of Figure 3 (SEQ ID NO:5); and

d) a nucleic acid having a sequence complementary to the strand shown in Figure 1 (SEQ ID NO: 1), Figure 2 (SEQ ID NO: 3), or Figure 3 (SEQ ID NO: 5).

Appellant does not identify, and we do not find, any evidence on this record to suggest that a nucleic acid taught by the combination of references relied upon by the Examiner would not have been expected to hybridize to any one of the sequences set forth in the claims under the claimed conditions. Instead, Appellant asserts that “the cited references provide a research plan that might have been used to arrive at the claimed invention” (App. Br. 25). For the reasons set forth above, we disagree with this assertion. Accordingly, we affirm the rejection of claim 109 as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 110, 118, and 125 fall together with claim 109.

Group I (claims 103-105, 115, 116, and 123):

Claims 103-105, 115, 116, and 123 stand on a different footing. These claims require a nucleic acid which encodes a naturally occurring primate MAdCAM, wherein said nucleic acid encodes the polypeptide shown in Figure 1 (SEQ ID NO: 2), the polypeptide shown in Figure 2 (SEQ ID NO: 4), or the polypeptide shown in Figure 3 (SEQ ID NO: 6) (*see* claims 103-105, 115, 116 and 123).

The Examiner has failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of successfully isolating a nucleic acid molecule that meets the sequence requirements set forth in claims 103-105, 115, 116, and 123. Accordingly, we reverse the rejection of

claims 103-105, 115, 116, and 123 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle.

CONCLUSION

In summary:

We affirm the rejection of claim 119 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 111, 126, 130, and 133 fall together with claim 119

We affirm the rejection of claim 120 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 112, 127, 131, and 134 fall together with claim 120.

We affirm the rejection of claim 119 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 111, 126, 130, and 133 fall together with claim 119.

We affirm the rejection of claim 120 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 112, 127, 131, and 134 fall together with claim 120.

We affirm the rejection of claim 109 as unpatentable over the combination of Butcher, Vonderheide, and Erle. Claims 110, 118, and 125 fall together with claim 109.

We reverse the rejection of claims 103-105, 115, 116, and 123 under 35 U.S.C. § 103(a) as unpatentable over the combination of Butcher, Vonderheide, and Erle.

Appeal 2007-3891
Application 08/523,004

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-IN-PART

Ssc:

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