

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte

DANIEL JOSEPH O'MAHONY, VERNON L. ALVAREZ,
and MICHELA SEVESO

Appeal 2008-2117
Application 10/104,603
Technology Center 1600

Decided: August 14, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and MELANIE L.
McCOLLUM, *Administrative Patent Judges*.

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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a peptide. The Examiner has rejected the claims as not being supported by an adequate written description. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 14-16, 19-25, 36 and 37 are on appeal. Claims 38-45 are also pending but have been indicated to be allowable.

The claims on appeal have not been argued separately¹ and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 14, the broadest claim on appeal, which reads as follows:

14. A peptide which permits or facilitates the transport of an active agent through an epithelial cell layer lining a luminal side of a human or animal gastro-intestinal track,² the peptide being identified by a method comprising the steps of:

- (a) administering in vivo or in situ to the luminal side of the gastro-intestinal track in an animal a predetermined amount of phage from a random phage library or a preselected phage library;
- (b) at a predetermined time harvesting phage from the animal to select transported phage, wherein the harvesting site is separated from the luminal side of the gastro-intestinal track by an epithelial cell layer;
- (c) amplifying the transported phage in a host;
- (d) repeating in order step (a) using the transported phage obtained in step (b) and amplified in step (c) and steps (b) and (c) a predetermined number of times to obtain a selected phage library containing phage which

¹ With regard to claims 15, 16, 19-25, 36 and 37, which depend from claim 14, Appellants argue that the Specification provides written description for the additional features recited in these claims (App. Br. 14-17). However, Appellants have not provided arguments that any of these claims would be patentable even if claim 14 is not patentable. Thus, Appellants have not provided arguments that these claims are separately patentable.

² As amended on February 26, 2007, claim 14 recites a “gastro-intestinal track.” However, the Claims Appendix included with the Appeal Brief indicates that claim 14 recites a “gastro-intestinal tract.”

can be transported from the luminal side of the human or animal gastro-intestinal track to the site of harvesting; and

(e) determining the identity of at least one peptide coded by phage in the selected phage library to identify a peptide which permits or facilitates the transport of an active agent through an epithelial cell layer lining the luminal side of the human or animal gastro-intestinal track.

Claims 14-16, 19-25, 36, and 37 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 3). The Examiner finds that the “claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention” (*id.*). In particular, the Examiner finds that “the claims are drawn to a huge genus of peptides with only a common function, and not common structure, wherein said peptides are identified and claimed via a product-by-process approach” (*id.*). The Examiner also finds that, although Appellants describe eight species, these “disclosed peptides do not share a common structure that contribute to the common desired activity of the peptides” (*id.* at 4-5). Therefore, the Examiner concludes that “the other species within the diverse genus also would be expected to have diverse structures” and “the only means of identifying them is by a common function” (*id.* at 5).

Appellants contend that, based on the large amount of information provided in the Specification, “one of ordinary skill would recognize that Applicants were in possession of the claimed invention at the time of filing the application” (App. Br. 12). In particular, Appellants argue that, “[g]iven that phage display technology was routine at the time Applicants filed the instant application, and the specification provided a clear-cut method by

which the claimed genus of peptides may be obtained, the claimed genus of peptides was adequately described by the specification” (*id.* at 13 (emphasis omitted)). Appellants also argue that, from their disclosure, “the skilled artisan could readily identify the genus of peptides capable of transporting an active agent through an epithelial cell layer lining a luminal side of a human or animal gastro-intestinal tract” (*id.*). Additionally, Appellants argue that they “have disclosed a representative number (8) of peptides derived by the method outlined in the Specification, which entitles Applicants to be able to claim the genus of peptides obtained by the outlined method” (*id.*).

ISSUE

The issue is whether the disclosure of a method for identifying a peptide having a specified function, together with the disclosure of eight specific peptides having the function, which were identified by the method, is sufficient to support a generic claim directed to peptides having the function, which were identified by the method, where neither the Examiner nor Appellants have identified structural characteristics common to the eight species.

FINDINGS OF FACT

1. The Specification discloses “a method of identifying a peptide which permits or facilitates the transport of an active agent through a human or animal tissue,” specifically epithelial cells lining the luminal side of a gastro-intestinal tract (Spec. 4).

2. Claim 14 requires a peptide that “permits or facilitates the transport of an active agent through an epithelial cell layer lining a luminal

side of a human or animal gastro-intestinal track.” It is undisputed that this function is not correlated to a particular, known structure (Ans. 3-5; App. Br. *passim*; Reply Br. *passim*).

3. Claim 14 also requires that the peptide be identified by a particular method. This method does not require hybridization of the nucleic acids encoding the peptides to a common oligonucleotide.

4. In Example 4, the Specification describes the identification of peptide sequences from transported phage in colon tissue segments (Spec. 33). The method includes sequencing clones from the sixth cycle of a screening process (*id.*). It was determined that:

[a] number of clones/DNA sequences [were] present more than once. . . .

Based on the recurrent random peptide sequences . . . , two synthetic oligonucleotides were constructed and used to screen phage populations representing colon screening cycles 1-6 in a series of oligonucleotide hybridization reactions to determine whether these phage and corresponding peptides were being selected during the screening process. . . . [I]t appears that there is a gradual selection of phage which hybridize to [these] oligonucleotide[s].

(*Id.* at 34.)

5. In Example 6, the Specification describes the transport of phage from rat lumen into portal and systemic circulation (*id.* at 40). “In this study, phage from random phage display libraries . . . were injected into the lumen of the rat gastro-intestinal tract[,] . . . [b]lood was collected over time from either the systemic circulation or portal circulation and the number of phage which were transported to the circulation was determined” (*id.*) From this study, “[e]ight DNA sequences . . . with corresponding peptide

sequences SEQ. NOS. ID: 19, 21, 23, 25, 27, 29, 31 and 33 were discovered” (*id.* at 45). The Specification states that these peptides “are capable of facilitating the transport of an active agent . . . through a human or animal tissue” (*id.*).

6. It is undisputed that the eight peptide sequences identified in Example 6 have no common structure (Ans. 3-5; App. Br. *passim*; Reply Br. *passim*).

ANALYSIS

The first paragraph of 35 U.S.C. § 112 “requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). An adequate written description of a chemical invention “requires a precise definition, such as by structure, formula, chemical name, or physical properties.” *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004); *Regents of the Univ. of Cal. v. Eli Lilly & Co., Inc.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). “A description of what a material does, rather than of what it is, usually does not suffice.” *Rochester*, 358 F.3d at 923; *Eli Lilly*, 119 at 1568. Instead, the “disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.” *Id.* However, not all functional descriptions “necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003).

In the present case, claim 14 is directed to any peptide having a particular function, which is identified by a particular method (Findings of Fact (FF) 2-3). It is undisputed that the disclosed function is not correlated with a known structure (FF 2). Thus, we agree with the Examiner that the mere recitation of peptides having this function is insufficient to show possession thereof.

The Specification (and the claims) also provides a method for identifying peptides having the claimed function (FF 1-3). However, “[p]ossession may not be shown by merely describing how to obtain possession of members of the claimed genus.” *Ex parte Kubin*, 83 USPQ2d 1410, 1417 (BPAI 2007) (citing *Rochester*, 358 F.3d at 927).

Appellants argue that “the manner in which the peptides were isolated provides a structural link between the claimed peptides” (Reply Br. 4). In particular, based on Specification Example 4, Appellants argue:

The isolated peptides share a commonality of structure by virtue of the homology shared by their underlying nucleotide sequences. Since the peptides are isolated based on a commonality of function . . . , as well as commonality of structure, *i.e.*, ability of the nucleotide sequences that encode the peptides to hybridize to a common oligonucleotide, they are encompassed within a defined genus.

(*Id.*)

We are not persuaded by this argument. In Example 4, the Specification describes conducting “a series of oligonucleotide hybridization reactions to determine whether these phage and corresponding peptides were being selected during the screening process” (FF 4). However, the method recited in claim 14 does not require hybridization to a common

oligonucleotide (FF 3). Thus, we do not agree with Appellants that the method of claim 14 provides a structural link between the claimed peptides. Instead, we agree with the Examiner that the disclosure of this identification method is insufficient to show possession of the claimed peptides.

It is also not disputed that the Specification discloses eight peptides (SEQ ID NOs: 19, 21, 23, 25, 27, 29, 31 and 33) identified by the claimed method that have the claimed function (FF 5). In addition, possession of a genus “may be achieved by means of a recitation of a representative number of [compounds] . . . falling within the scope of the genus.” *Eli Lilly*, 119 at 1569. However, it is undisputed that there is no structure common to these eight peptides (FF 6).³ Thus, we agree with the Examiner that “other species within the diverse genus also would be expected to have diverse structures” (Ans. 5) and that therefore the disclosed species are not representative of the broad genus (*id.* at 9).

CONCLUSION

We conclude that the Examiner has set forth a *prima facie* case that claim 14 is not supported by an adequate written description, which Appellants have not rebutted. We therefore affirm the rejection of claim 14

³ As discussed above, Appellants argue that “the manner in which the peptides were isolated provides a structural link between the claimed peptides” (Reply Br. 4). However, based on Appellants’ reliance on Specification Example 4 rather than Specification Example 6, which discloses the identification of these eight peptides (FF 5), Appellants do not appear to be arguing that the nucleic acids encoding these eight peptides hybridize to a common oligonucleotide. However, even if they did, they would not be representative of the genus encompassed by claim 14, which does not require hybridization to a common oligonucleotide (FF 3).

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under 35 U.S.C. § 112, first paragraph. Claims 15, 16, 19-25, 36 and 37 fall with claim 14.

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

cdc

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON DC 20004