Paper No. 41

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BEAT MOLLET, JOHN PEEL, DAVID PRIDMORE, NADJI REKHIF and BRUNO SURI

Appeal No. 2002-1926
Application No. 08/693,353[1]

HEARD: March 6, 2003

Before WILLIAM F. SMITH, SCHEINER and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 23-26, 28, 30, 32, 36, 38, 40, 42-47 and 51-54.[2]

Claims 23, 24, 36, 42, 45 and 46 are representative of the subject matter on

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[1] Application for patent filed August 6, 1996.

[2] Claims 23-54 are pending in the application. Claims 23-47 and 51-54 were finally rejected in paper no. 13, while claims 48-50 were withdrawn from consideration as drawn to non-elected subject matter. An Advisory Action (paper no. 18), mailed May 11, 1998, indicated that claims 23-26, 28, 30, 32, 34, 36, 38, 40, 42-47 and 51-54 were still rejected, but claims 27, 29, 31, 33, 35, 37, 39 and 41 were merely objected to as dependent on a rejected base claim. In the examiner's most recent Advisory Action (paper no. 23) mailed August 17, 1998, the status of the claims was as follows: claims 23-26, 28, 30, 32, 34, 36, 38, 40, 42 and 51-54 stood finally rejected; claims 27, 29, 31, 33, 35, 39 and 41 were objected to as depending from a rejected base claim; claims 43-47 were not addressed. According to the examiner's Answer (paper no. 27), claims 43-47 still stand rejected, but claim 34 does not. Claim 37 is not addressed in the most recent Advisory, nor in the Answer.

appeal and read as follows:

23. A process for preparing a composition having bactericidal activity comprising:

culturing cells of a strain of Micrococcus varians, which upon culturing in a culture medium, produces a bacteriocin which has agar well inhibition test activity against bacterial strains including Listeria monocytogenes to obtain cultured cells in a concentration of from 10^7 to 10^{11} organisms per ml of the medium and a supernatant comprising the bacteriocin; and

separating the supernatant from the cultured cells to obtain the supernatant for obtaining a supernatant composition comprising the bacteriocin.

24. A process according to claim 23 wherein bacteriocin comprises an amino acid sequence selected form the group consisting of SEQ ID NO:1 and a sequence differing from SEQ ID NO:1 by from 1 to 4 amino acids.[3]

36. The supernatant composition of the process of claim 23 or 24.

42. A cell-free Micrococcus varians culture-medium-supernatant composition comprising a bacteriocin which has agar well incubation inhibition test activity against bacterial strains including Listeria monocytogenes.

45. A bacteriocide which comprises a bacteriocin isolated from a bacteria and purified and which comprises an amino acid sequence selected from the group consisting of SEQ ID NO:1 and a sequence differing from SEQ ID NO:1 by from 1 to 4 amino acids.

46. A bacterioside according to claim 45 wherein the bacteriocin comprises amino acid sequence SEQ ID NO:1.

The reference relied on by the examiner is:

Cantoni et al. (Cantoni), "Bacteriocins from Micrococcaceae," Industrie Alimentarie, Vol. 31, pp. 660-665 (July-August 1992)

DISCUSSION

Claims 23-26, 28, 30, 32, 36, 38, 40, 42-47 and 51-54 stand rejected under the

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[3] As explained in the specification (pages 3,14 and 20), concentrated culture supernatants from Micrococcus varians strains CNCM I-1586 and CNCM I-1587 were found to inhibit various species of bacteria, including Listeria monocytogenes, in agar well tests. Inhibitory fractions of the culture supernatants were found to contain a proteinaceous bacteriocin, termed "variacin." SEQ ID NO:1 represents the amino acid sequence of variacin.

first paragraph of 35 U.S.C. § 112, "because the specification, while being enabling for Micrococcus varians strains CNCM I-1586 and CNCM I-1587, does not reasonably provide enablement for bacteriocin . . . production by any other strain of Micrococcus varians. Answer, page 4. According to the examiner (id., page 5),

> Appellants have demonstrated a bacteriocin production by the two strains named above, but have not shown that other strains of Micrococcus varians may reliably be used for production of a bacteriocin effective against Listeria monocytogenes . . . neither of the two (unidentified) strains of Micrococcus varians that Cantoni et al. tested for bacteriocin production had activity against Listeria monocytogenes . . . Thus, based on the art, no other known strain of Micrococcus varians may reliably be used for production of a bacteriocin effective against Listeria monocytogenes; likewise, the specification fails to teach other strains that may be used in the claimed invention.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'" Id. at 1561, 27 USPQ2d at 1513. "That some experimentation may be required is not fatal; the issue is whether the amount of experimentation is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (emphasis in original).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir.

1988). Among these considerations are the so-called Wands factors, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Id.

Appellants argue that "nowhere in the rationale advanced in support of the enablement rejection has the Examiner set forth why the skilled person having appellants' disclosure in-hand would have to engage in undue experimentation to achieve success or otherwise practice the invention as broadly as claimed with [Micrococcus varians] strains other than the deposited strains [CNCM I-1586 and CNCM I-1587]." (Brief, page 9).

In response, the examiner maintains that (Answer, pages 7-8)

> [t]he determination of undue experimentation was based on 1) the breadth of the claims, 2) the available art which observed no strains of Micrococcus varians with bacteriostatic activity against Listeria, 3) the disclosure of only two strains which display the requisite activity and but a single bactericidal protein and 4) the lack of guidance about a) where or how one might isolate other naturally occurring strains which would be expected to show bacteriostatic activity against Listeria and b) structural features expected to be held in common with other bacteriocins of Micrococcus varians.

Nevertheless, we agree with appellants that the reasons given by the examiner are insufficient to establish that "the skilled person would have to engage in undue experimentation to make and use and achieve success with strains other then the deposited strains." Brief, page 11.

Independent claim 23 is directed to a process of preparing a bacteriocin-containing product from Micrococcus varians, wherein the bacteriocin "has agar well incubation test activity against . . . Listeria monocytogenes." Claims 36, 38 and 40, which depend directly or indirectly from claim 23, are product by process claims.

Similarly, independent product claim 42 is directed to a "cell-free Micrococcus varians culture-medium-supernatant composition comprising a bacteriocin which has agar well incubation inhibition test activity against bacterial strains including Listeria monocytogenes." Claim 45, the only other independent claim, is directed to a bacteriocin having a sequence identical to the bacteriocin isolated from deposited strains CNCM I-1586 and CNCM I-1587, or one differing by "from 1 to 4 amino acids."

The specification identifies two strains of Micrococcus varians that produce a bacteriocin capable of inhibiting Listeria monocytogenes in agar well inhibition tests, and also outlines a straightforward protocol for determining whether other strains of Micrococcus varians do as well (specification, pages 7-8). One skilled in the art, having "in-hand" the knowledge that some strains of Micrococcus varians produce a bacteriocin capable of inhibiting Listeria monocytogenes, need only subject a given strain of Micrococcus varians to an agar well inhibition test to determine whether it could be used to practice the invention. It may be, as the examiner argues, that "activity must be determined empirically and cannot be predicted a priori" (Answer, page 7), but the fact that some experimentation would be required, and some of the experimentation would produce negative results, is not enough to establish that the experimentation would be undue. Nor is it the function of the claims to specifically exclude possibly inoperative embodiments. Nothing in the examiner's analysis establishes that the number of inoperative embodiments would be significant enough to force one of ordinary skill in the art to experiment unduly in order to practice the claimed invention. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984).

Finally, the examiner's rationale does not begin to come to grips with those

product claims limited to a bacteriocin comprising an amino acid sequence identical to the sequence of the bacteriocin produced by Micrococcus varians strains CNCM I-1586 and CNCM I-1587 (e.g., claim 45).

In our judgment, the reasons cited in support of the examiner's rejection are insufficient to support the examiner's conclusion that "[t]he specification does not enable any person skilled in the art . . . to practice the invention commensurate in scope with [the] claims" (Answer, page 5). Accordingly, the rejection of the claims under the first paragraph of 35 U.S.C. § 112 is reversed.

REVERSED

William F. Smith Administrative Patent Judge	)
Toni R. Scheiner Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

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