

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal
and (2) is not binding precedent of the Board. Paper No. 75

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MASAAKI YAMADA, YASUJI FURUTANI, MITSUE NOTAKE
and JUNITI YAMAGISHI

Junior Party,¹

v.

BHARAT B. AGGARWAL

Senior Party.²

Patent Interference No. 103,605

FINAL HEARING: July 7, 1999

Before CAROFF and METZ and LORIN, Administrative Patent Judges.

CAROFF, Administrative Patent Judge.

¹ Application 08/084,445, filed 07/01/93, now U.S. Patent No. 5,288,852, granted 02/22/94. Accorded benefit of serial nos. 07/089,134, filed 08/25/87, now abandoned; and 06/708,846, filed 03/05/85, now abandoned. Japanese applications 59-172307, filed 8/17/84; 59-82653, filed 4/23/84; and 59-43617, filed 3/6/84. Assigned to Dainippon Pharmaceutical Co., Ltd., Osaka, Japan.

² Application 08/375,052, filed 01/18/95. Accorded the benefit of U.S. Application 08/191,751, filed 02/03/94, now abandoned; 07/915,038, filed 07/15/92, now abandoned; 06/677,454, filed 12/03/84, now abandoned; and 06/628,059, filed 07/05/84, now abandoned. Assigned to Genentech, Inc..

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FINAL DECISION UNDER 37 CFR § 1.658

This interference involves an application of the junior party, Aggarwal, and a patent of the senior party, Yamada et al. (Yamada)³.

According to the record before us, the involved Aggarwal application is assigned to Genentech, Inc.; and the involved Yamada patent is assigned to Dainippon Pharmaceutical Co., Ltd.

The subject matter involved in this interference relates to a polypeptide having human tumor necrosis factor activity, and which is more particularly defined by the following count, the only count in this interference:

Count 1

1. A polypeptide having human tumor necrosis factor activity and being selected from the group consisting of

(a) the polypeptide having the amino acid sequence of the following formula, and

(b) a polypeptide having an amino acid sequence resulting from the addition of one or two amino acid residues from the precursor portion of said polypeptide (a) to the N-terminus of the following formula:

³ We note that Yamada was accorded senior party status in the Decision on Motions (Paper No. 43, page 6) of Oct. 21, 1998.

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The claims of the parties which correspond to this count are:

Aggarwal: Claims 41-43

Yamada: Claims 1, 2 and 4

Aggarwal has agreed to forgo its right as junior party to put on a case for prior inventorship with respect to the invention defined by the count of this interference (see Paper No. 49). Accordingly, a judgment against Aggarwal as to the subject matter of the count will be entered in short order.⁴

Before issuing judgment against Aggarwal, we are asked to decide whether Yamada claims 1 and 4 are unpatentable under 35 U.S.C. § 102(a) or 35 U.S.C. § 103⁵.

Both parties have presented a record, submitted exhibits, filed briefs and appeared, through counsel, at final hearing⁶.

⁴ The final judgment in this interference, *infra*, will indicate that Aggarwal is not entitled to any claims which correspond to the count.

⁵ This patentability question is the only issue raised in the parties' briefs and, therefore, the only issue before us for decision. The issue was originally raised in a preliminary motion filed by Aggarwal (Paper No. 22); and consideration of the motion was deferred to final hearing in the Decision on Motions of Oct. 21, 1998 (Paper No. 43).

⁶ The Aggarwal record, exhibits, brief and reply brief will be respectively referred to, as appropriate, by the abbreviations "AR", "AX", "AB" and "ARB" followed by a pertinent page or

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No issue of interference-in-fact has been raised in this proceeding.

OPINION

The sole issue before us⁷ is whether Yamada claims 1 and 4 are unpatentable under 35 U.S.C. § 102(a) or 35 U.S.C. § 103 in view of either Aggarwal et al. (AX-2) or Pennica et al. (AX-3).

Yamada claim 4 is a dependent claim, and its patentability is not separately argued from that of claim 1. Accordingly, claim 4 stands or falls with claim 1, and we will limit our consideration to claim 1, which reads as follows⁸:

⁶(...continued)
exhibit number. Similar abbreviations will be used when referring to the record, exhibits and brief of Yamada (YR, YX, YB).

⁷ Aggarwal also argues that Yamada's involved U.S. application fails to provide sufficient written description support for Yamada claim 1. Although no statutory basis for this position is expressly cited by Aggarwal, it is couched in terms reflecting the provisions of 35 U.S.C. § 112. However, the issue of whether the Yamada U.S. application is in compliance with the requirements of 35 U.S.C. § 112 is not before us since the issue has not been raised in a proper or timely manner. In this regard, Aggarwal's sole preliminary motion (Paper No. 22) fails to clearly and precisely state that this issue, in particular, is a basis upon which relief is requested as required by 37 CFR § 1.637(a). Rather, the motion (pages 1; 26) focuses exclusively upon 35 U.S.C. § 102 and 35 U.S.C. § 103 as the ultimate statutory basis for a finding of unpatentability.

⁸ We note here that the first portion of the count happens to
(continued...)

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1. A polypeptide having human tumor necrosis factor activity and being selected from the group consisting of

(a) the polypeptide having the amino acid sequence of the following formula, and

(b) a polypeptide having an amino acid sequence resulting from the addition of one or two amino acid residues from the precursor portion of said polypeptide (a) to the N-terminus of the following formula:

Ser Ser Ser Arg

Thr Pro Ser Asp Lys Pro Val Ala His Val
Val Ala Asn Pro Gln Ala Glu Gly Gln Leu
Gln Trp Leu Asn Arg Arg Ala Asn Ala Leu
Leu Ala Asn Gly Val Glu Leu Arg Asp Asn
Gln Leu Val Val Pro Ser Glu Gly Leu Tyr
Leu Ile Tyr Ser Gln Val Leu Phe Lys Gly
Gln Gly Cys Pro Ser Thr His Val Leu Leu
Thr His Thr Ile Ser Arg Ile Ala Val Ser
Tyr Gln Thr Lys Val Asn Leu Leu Ser Ala
Ile Lys Ser Pro Cys Gln Arg Glu Thr Pro
Glu Gly Ala Glu Ala Lys Pro Trp Tyr Glu
Pro Ile Tyr Leu Gly Gly Val Phe Gln Leu
Glu Lys Gly Asp Arg Leu Ser Ala Glu Ile
Asn Arg Pro Asp Tyr Leu Asp Phe Ala Glu
Ser Gly Gln Val Tyr Phe Gly Ile Ile Ala
Leu.

(underlining added for emphasis)

Significantly, Yamada acknowledges (YB-3) that if it is found that Yamada's three Japanese priority applications⁹ do not provide a sufficient written description of the subject matter of claims 1 and 4, then "the Pennica et al. and Aggarwal et al.

⁸(...continued)
be identical to Yamada claim 1.

⁹ The three Yamada Japanese priority applications are 43,617/84 (AX-7); 82,653/84 (AX-8); and 172,307/84 (AX-9). These three applications will be respectively referred to hereinafter as J1, J2 and J3.

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publications are effective as references and defeat the patentability of these claims." Accordingly, the basic underlying issue to be decided is whether the aforementioned Japanese applications provide sufficient written description support for the subject matter defined by Yamada claims 1 and 4 within the ambit of 35 U.S.C. § 112 and, more particularly, whether those applications provide sufficient support for the limitation in part(b) of claim 1 which has been underlined, *supra*, for emphasis. See Ex parte Kitamura, 9 USPQ2d 1787, 1792 (Bd. Pat. App. & Int. 1988); Kawai v. Metlesics, 480 F.2d 880, 884-86, 178 USPQ 158, 162-63 (CCPA 1973).

Aggarwal, as the moving party, bears the burden of persuasion. See Behr v. Talbott, 27 USPQ 2d 1401, 1405 (Bd. Pat. App. & Int. 1992); and 37 CFR § 1.637(a). After a thorough review of the entire record in light of the opposing positions taken by the parties in their briefs, we agree with Aggarwal that Yamada's Japanese priority applications (J1-J3) do not provide sufficient descriptive support, within the context of the first paragraph of 35 U.S.C. § 112, for the subject matter defined by the Yamada claims in dispute. Although there is great force of logic in Yamada's position, we conclude that Aggarwal's position better conforms with the facts and pertinent case law on the

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subject. While we are in substantial agreement with Aggarwal's

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position, as thoroughly expressed in Aggarwal's well-reasoned brief and reply brief, we offer the following remarks for emphasis.

Initially, we shall briefly address three preliminary matters which are in dispute: 1. the scope of part(b) of Yamada claim 1; 2. the qualifications of Yamada's declarant, Dr. Matsushima, as an expert witness; and 3. the propriety of combining teachings from separate priority documents.

With respect to the scope of part(b) of Yamada claim 1, Yamada argues for a narrow interpretation limited to two specific polypeptides where the amino acid residues added to the 155 amino acid mature human TNF polypeptide are only "Arg" or "Val-Arg."¹⁰ (YB-4, 15-20). On the other hand, Aggarwal argues for a much broader interpretation where the one or two amino acid residues added to the mature hTNF can be any one or two amino acids from the precursor portion. (ARB 3-8, 16-17). While both interpretations are plausible, we subscribe to Aggarwal's interpretation since, in our opinion, it represents the broadest reasonable construction of the claim language in dispute for the reasons given by Aggarwal. In so construing the claim, we are

¹⁰ Hereinafter, the 155 amino acid mature human TNF polypeptide will be referred to in abbreviated form as "mature hTNF."

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not bound by any statements made in the examiner's Initial Memorandum (AR-00144).

As for the qualifications of Dr. Matsushima, we find that Dr. Matsushima is qualified as an expert witness for the reasons given by Yamada (YB 14-15).¹¹ Indeed, Aggarwal's case for unpatentability appears to depend, in part, on testimony elicited from Dr. Matsushima. (AB 16-24, 26-27, 43-45, 51-54, 56). Therefore, it appears somewhat incongruous, to say the least, for Aggarwal to insist that Matsushima's testimony is not entitled to any weight.

Continuing, we additionally find that it would be improper to combine teachings from separate priority documents, in determining whether the description requirement of 35 U.S.C. § 112 has been met, for the reasons given by Aggarwal (ARB-19). In particular, we are unaware of any legal precedent for doing so, and Yamada has not cited any. Moreover, the pertinent sections of the patent statute, 35 U.S.C. § 119(a) and 35 U.S.C. § 119(c), both appear to require that a claimed invention must be described in a single earlier-filed application, i.e., either

¹¹ By analogy to our role as the trier of fact, it is within our discretion to admit the testimony of an expert. Kumho Tire Co. v. Carmichael, ___ U.S. ___, 131 F.3d 1433, 50 USPQ2d 1177 (1999).

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in "an application" or in "a subsequent regularly filed application", in order to be accorded the benefit of the filing date of that earlier application. In other words, there is no basis whatsoever in the statute for combining the disclosures of separate priority documents when determining whether any of those documents provide a sufficient description of an invention to satisfy the first paragraph requirements of 35 U.S.C. § 112.

Even if we were to view all of the foregoing factors in a light most favorable to Yamada¹², we agree with Aggarwal that none of Yamada's Japanese priority applications, taken singly or in combination, provide sufficient disclosure of the subject matter defined in part(b) of Yamada claim 1 to satisfy the description requirement of 35 U.S.C. § 112, first paragraph.

While we are in substantial agreement with Aggarwal's position, as reflected in Aggarwal's brief (AB 32-60) and reply brief (ARB 16-32), we view the following factors as being determinative.

First of all, it is significant that both Vehar and

¹² In other words, in reaching our conclusions we accept, arguendo, Yamada's narrow interpretation of the scope of part (b) of Yamada claim 1, and that the disclosures in J1-J3 can be viewed in combination, while also giving due weight to the testimony of both Dr. Matsushima and Dr. Vehar as expert witnesses.

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Matsushima suggest that the J1-J3 disclosures encompass a large number of possible amino acid additions to mature hTNF. For instance, Dr. Vehar testified that the number of possible addition products suggested in Yamada's Japanese priority applications is greater than 1,000 (AR-00006, 00059-60, 00114-115). Dr. Matsushima's testimony suggests that the number of possible addition products within the ambit of the combined J1-J3 disclosures is 78 (YR 00038-39, 00044-45, 00052-53). Yamada specifically acknowledges that the effective teaching of the three priority applications is that mature hTNF can be modified by addition of from one to 78 amino acids from the precursor portion, representing a group of 78 possible embodiments (YB-27).

More significantly, as aptly pointed out by Aggarwal (AB 43-44), there is no specific disclosure in the Yamada priority applications of at least the two amino acid adduct which is particularly recited in part(b) of Yamada claim 1. Moreover, none of those applications provide any direction, i.e., "blazemarks", to guide a skilled artisan to select the two amino acid adduct, in particular, from among at least 78 adducts subsumed within the genus generally defined in those applications. Yamada has simply failed to show otherwise. In the absence of such blazemarks, merely describing a relatively

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large genus of adducts is not sufficient to satisfy the written description requirement as to a particular species or sub-genus; even if a skilled artisan could contemplate and "write out" the individual structures of each member of the genus.

Thus, in accordance with pertinent case law, we conclude that Yamada's three Japanese priority applications, whether taken singly or in combination, fail to reasonably convey to persons skilled in the art that, as of the filing dates thereof, Yamada had possession of, i.e., had invented, a polypeptide having an amino acid sequence resulting from the addition of two amino acid residues from the precursor portion to the N-terminus of mature hTNF, as specifically recited in Yamada claim 1. See The Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1566, 43 USPQ 2d 1398, 1404 (Fed. Cir. 1997); Fujikawa v. Wattanasin, 93 F.3d 1551, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996); Forssmann v. Matsuo, 23 USPQ2d 1548, 1550 (Bd. Pat. App. & Int. 1992); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Consistent with the foregoing, it has been held that "one cannot describe what one has not conceived." See Fiers v. Sugano, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Also, see Amgen, Inc. v. Chugai Pharmaceutical Co.

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927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991), cert. denied, 112 S.Ct. 169. Further, conception of a genus is not generally sufficient to establish conception of every species or subgenus within the scope of the genus. Tucker v. Natta, 171 USPQ 494, 498 (Bd. Pat. App. & Int. 1971); Davidson v. Carpenter, 123 USPQ 171, 173 (Bd. Pat. App. & Int. 1959). In this light, viewing Yamada's prior applications in terms of a "conception" approach, we are even more convinced that they fail to reasonably convey to persons skilled in the art that, as of the filing dates thereof, Yamada had possession of, i.e., had specifically conceived of, the two amino acid adduct defined in part(b) of Yamada claim 1.

For all of the foregoing reasons, we hold that Yamada claims 1 and 4 are unpatentable under either 35 U.S.C. § 102(a) or 35 U.S.C. § 103.

JUDGMENT

In view of the foregoing, judgment as to the subject matter of the sole count in issue is hereby awarded to Yamada et al., the senior party patentee.

Accordingly, Yamada et al. are entitled to their patent claim 2 corresponding to the count but, in view of our holding, supra, are not entitled to their patent claims 1 and 4

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corresponding to the count. Junior party Aggarwal is not entitled to a patent containing its claims 41-43 which correspond to the count.

MARC L. CAROFF)	
Administrative Patent Judge)	
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ANDREW H. METZ)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
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