

**THIS OPINION WAS WRITTEN FOR PUBLICATION**

The opinion in support of the decision being entered today is binding precedent of the Interference Trial Section of the Board of Patent Appeals and Interferences. The opinion is otherwise not binding precedent. The decision was entered on 14 April 1999

Paper 57

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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HEINZ NAU and CIARAN M. REGAN,

Junior Party,  
(Application 08/446,481),

v.

SHUICHI OHUCHIDA, KAZUO KISHIMOTO,  
NARITO TATEISHI and HIROYUKI OHNO,

Senior Party  
(Application 08/681,482).

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Patent Interference No. 104,258

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Before: McKELVEY, Senior Administrative Patent Judge and  
SCHAFER, LEE and TORCZON, Administrative Patent Judges

McKELVEY, Senior Administrative Patent Judge

**ORDER DECIDING NAU MISCELLANEOUS MOTION 2**

**A. Introduction**

NAU MISCELLANEOUS MOTION 2 (Paper 51) requests that the board return OHUCHIDA REPLY 1 (Paper 48) and an accompanying

DECLARATION OF NARITO TATEISHI (Paper 49). Alternatively, Nau asks for leave to file a reply to OHUCHIDA REPLY 1.

OHUCHIDA OPPOSITION 2 (Paper 54) opposing NAU MISCELLANEOUS MOTION 2 and NAU REPLY 2 (Paper 56) have also been filed and considered.

Issues raised by NAU MISCELLANEOUS MOTION 2 are important with respect to the administration of justice before the board in interferences. Hence, we take this opportunity as a Trial Section to address those issues.

**B. Findings of fact**

Declaration of the interference

1. The interference was declared on November 30, 1998 (Paper 1) and involves a single count.

2. Nau is involved on the basis of its U.S. application filed May 22, 1995.

3. Nau has been accorded the benefit for the purpose of priority of an earlier U.S. application filed August 30, 1994.

4. Ohuchida is involved on the basis of its U.S. application filed July 23, 1996.

5. Ohuchida has been accorded the benefit for the purpose of priority an earlier U.S. application filed June 1, 1994.

6. Since Ohuchida's priority benefit date is prior to Nau's priority benefit date, Ohuchida is senior party. 37 CFR § 1.601(m).

Interfering subject matter

7. The sole count of the interference reads:

A method according to any of claims 16, 24 or 30 of the Nau application

or

a method according to claim 11 of the Ohuchida application.

8. Ohuchida claim 11 reads:

A method for treating diseases induced by reactive astrocytes, which comprises administering an effective amount of a compound of the formula (X):

[formula (X) is then set out]

or non-toxic salts thereof or acid addition salts thereof.

9. Ohuchida claim 23, which depends from Ohuchida claim 11, and has been designated as corresponding to the count, reads:

A method according to claim 11, wherein the disease is Alzheimer's disease \*\*\*.

10. Ohuchida claim 24, which depends from Ohuchida claim 11, and has been designated as corresponding to the count reads:

A method of claim 11, wherein said compound of the formula (X) is 2-propylpentanoic acid.

Early proceedings in the interference

11. Ohuchida claims the benefit of three Japanese patent applications, the earliest of which was filed on June 1, 1993 (Ohuchida Ex. 2002, second page--which is unnumbered).

12. At the time the interference was declared, Ohuchida was not accorded priority benefit of any of the three Japanese patent applications (Paper 1, page 41).

13. An early determination of Ohuchida's priority benefit date would expedite proceedings in this interference. Accordingly, an ORDER (Paper 2) was entered simultaneously with the declaration of the interference which authorized Ohuchida to file a preliminary motion before the normal times set for filing preliminary motions.

Ohuchida Preliminary Motion 1

14. Ohuchida timely filed OHUCHIDA PRELIMINARY MOTION 1 (Paper 31) in which benefit for the purpose of priority was sought for each of the three Japanese patent applications.

15. In a "FACTS" section in its preliminary motion, Ohuchida set out 21 allegations of fact.

16. According to a translation of the earliest Japanese patent application (Ohuchida Ex. 2002, page 8):

2-Propylpentanoic acid \*\*\* and non-toxic salts thereof of the present invention are useful for improvement of cerebral function, for [example] in animals including human beings, especially human beings, because they have an activity of functional improvement of astrocyte and their toxicity is very low. An object disease, for example \*\*\*, [is a] Neurodegenerative disease (e.g., Alzheimer's disease \*\*\*).

17. Dosage amounts are described in the earliest Japanese application at page 9.

18. According to Ohuchida, Example 1 of the earliest Japanese application describes the effects of sodium valproate on astrocyte functions (Ohuchida Ex. 2002, pages 11-12).

19. Sodium valproate is the sodium salt of valproic acid. Valproic acid is another name for 2-propylpentanoic acid. See Merck Compound 10049 in The Merck Index, page 1691 (12 ed. 1996).

20. Similar effects are described in Experiment 1 of the Ohuchida U.S. application involved in the interference (pages 41-42).

21. Ohuchida reasons in its preliminary motion that it is entitled to the benefit for the purpose of priority of the Japanese patent application based on a description therein of a method using valproic acid which Ohuchida maintains is within the scope of the count.

Nau opposition to Ohuchida's preliminary motion

22. In opposing Ohuchida's preliminary motion, Nau admits or denies each of the 21 factual allegations which had been set out by Ohuchida.

23. Nau also sets out additional facts in numbered paragraphs 24 through 39.

24. On the merits, Nau argues that Ohuchida is not entitled to priority benefit because the specification of the Japanese patent application is not enabling within the meaning of the first paragraph of 35 U.S.C. § 112.

25. In particular, Nau argues that the Japanese patent applications do not describe an enabling embodiment within the scope of the count.

26. In support of its position, Nau relies on a DECLARATION OF DAVID E. PLEASURE, M.D. (Nau Ex. 1012) (Paper 44).

27. According to Dr. Pleasure, the Japanese patent applications do not provide sufficient information to allow one of ordinary skill in the art to conclude that the compounds of formula (X) can be used in the method defined by the countssee, e.g., Nau Ex. 1012, page 2).

Ohuchida's reply

28. Ohuchida filed OHUCHIDA REPLY 1 (Paper 48) to respond to Nau's opposition.

29. In its reply, Ohuchida purports to respond to the additional facts set out in paragraphs numbered 24 through 39 of Nau's opposition.

30. For the most part, however, Ohuchida does not admit or deny the additional facts set out by Nau. Rather, Ohuchida maintains that the facts "are irrelevant."

31. For example, responding to Nau's additional facts 24-26 and 33, Ohuchida states:

Nau's allegations \*\*\* with respect to "invented compounds" are irrelevant, because the count is directed to methods of therapy and use of the compounds.

32. OHUCHIDA REPLY 1 was accompanied by a DECLARATION OF NARITO TATEISHI (Paper 49).

33. In his declaration, Mr. Tateishi expresses opinions which are contrary to those expressed by Dr. Pleasant on behalf of Nau.

#### Additional observations

34. At this point in the proceedings, it will be assumed that both Dr. Pleasant and Mr. Tateishi are qualified to express the opinions set out in their respective declarations.

35. Neither Dr. Pleasant nor Mr. Tateishi have been cross-examined. Hence, credibility cannot be realistically assessed at this time.

### C. Discussion

#### 1. Ohuchida's "irrelevant" responses to Nau's additional facts

Procedures have been adopted by the Trial Section of the Interference Division of the board to make resolution of interferences just, speedy and inexpensive. 37 CFR § 1.601. One of those procedures requires that an opponent in an opposition:

shall set out \*\*\* [w]hether each fact alleged by the moving party is admitted, denied or that the opposing party is unable to admit or deny the fact alleged.

See Paragraph 26(b)(2) of the NOTICE DECLARING INTERFERENCE (Paper 1). There is a similar requirement for replies.See Paragraph 26(c)(2) of the NOTICE DECLARING INTERFERENCE (Paper 1).

An allegation that a fact set out in a motion or opposition is "irrelevant" does not comply with the noted provisions of the NOTICE DECLARING INTERFERENCE. What is required by the NOTICE DECLARING INTERFERENCE is that the fact set out be admitted, denied or that a party assert that it is unable to admit or deny the fact alleged. It is in the argument portion of a motion that a party may properly maintain that a fact is irrelevant.

OHUCHIDA REPLY 1 does not comply with Paragraph 26(c)(2) of the NOTICE DECLARING INTERFERENCE. Rather, Ohuchida attempts to avoid direct admissions or denials. Ohuchida's action makes it

very difficult for the board to determine what facts are or are not dispute.

Since OHUCHIDA REPLY 1 does not comply with the NOTICE DECLARING INTERFERENCE, it will be returned. Ohuchida shall be given an opportunity to present a reply which meets the letter and spirit of the procedures designed by the Trial Section.

Parties in interferences are put on notice that, in the future, a response which maintains that an allegation of fact is irrelevant will be taken as an admission that the fact is true and correct. A party will not be able to later maintain that the fact is not correct. Compare Marshall v. Sedlock and Francisco, Inc., 83 Lab. Cas. (CCH) P33,641, 1978 U.S. Dist. LEXIS 18964 (E.D. Mich 1978) (copy attached) and Dunlop v. Quality Spring Products, Inc., 20 Fed. R. Serv. 2d (Callaghan) 561, 1975 U.S. Dist. LEXIS 12010 (W.D. Mich 1975) (copy attached) (both holding that an averment in a pleading that a fact is immaterial is insufficient to constitute a denial of the fact alleged). See also Reed v. Hickey, 2 F.R.D. 92, 1941 U.S. Dist. LEXIS 2101 (E.D. Pa. 1941) (copy attached) (holding that when an allegation of fact is neither admitted nor denied, "but proof there is demanded if material" is not a denial).

2. The Tateishi declaration

a.

It has long been the perception of most, if not all, of the administrative patent judges of this board that counsel routinely

raise new arguments and present new evidence with replies. Presentation of new arguments and evidence with replies raise several concerns which the Trial Section had hoped to eliminate through requirements in the NOTICE DECLARING INTERFERENCE.

One concern is whether a good faith effort was made in the first instance in filing a motion, including a preliminary motion. To this end, it is the practice of the Trial Section to consider a motion. If it finds that the motion fails to make out a prima facie case for relief, the motion may be denied without consideration of any opposition or reply. The Trial Section does not deem it fair to an opponent when a party "gets its licks in" for the first time at the reply stage after the opponent can no longer submit evidence and/or argument. In short, the Trial Section hopes to eliminate the unfair tactical advantage which can be gained through improper replies.

Another concern is that improper replies make the decision-making process difficult. It is time-consuming to read a motion only to discover that the issue to be resolved is joined at the reply stage. Hence, new arguments and new evidence at the reply stage generally result in inefficient administration of justice inefficient, all contrary to the philosophy set out in 37 CFR § 1.601.

The Trial Section's concern with replies is not a new development. At the time the "new" interferences rules were being considered, it was proposed to allow replies only for

certain motions. Notice of Proposed Rulemaking, Patent Interference Proceedings, 49 Fed. Reg. 3766, 3776 (col. 3), 3793 (col. 2) (Jan. 30, 1984). As a result of comments received following the notice of proposed rulemaking, it was decided to permit replies in all instances. However, the following observation can be found in the Notice of Final Rule (emphasis added):

Another comment made at the hearing suggested that a reply to an opposition to a motion should be permitted as a matter of course. Upon consideration of the comment, it has been decided to authorize the filing of replies to opposition to all motions. Presently, replies are permitted as a matter of course only for oppositions to motions under 37 CFR 1.231 [1984]. Section 1.638(b), as changed, would permit the reply in every instance. The PTO over the years has received complaints concerning the inability of a party to file replies. The change being made in § 1.638(b) will be reviewed sometime in the future to determine whether authorizing replies is helpful to the Board and/or whether undue delay in resolving interference occurs because replies are filed. Moreover, the PTO will make a judgment on whether "new issues" are being raised as a matter of course in replies. It can thus be seen that the change in authorizing replies may be considered experimental and could be changed in the future if found to be counter-productive or

inconsistent with the objective of resolving  
interferences in a relatively prompt manner

Notice of Final Rule, Patent Interference Proceedings, 49 Fed. Reg. 48416, 48442 (col. 3) (Dec. 12, 1984). The Trial Section has gone out of its way to eliminate the raising of new arguments in replies. See Paragraph 31 of the NOTICE DECLARING INTERFERENCE. If the interference bars wishes to retain its option of being able to file replies, then it should make every effort to avoid raising improper new arguments and presenting improper new evidence with replies. Quite frankly, if the efforts of the Trial Section are not successful, we see the next step as a proposal to amend the rules to permit a reply only with leave of an administrative patent judge.

b.

In light of the comments made in subpart "a" above, the presentation of the Tateishi declaration with Ohuchida's reply, as opposed to with the preliminary motion, gave us pause. However, what appears at first blush to be an unfair advantage gained by Ohuchida, upon mature reflection, turns out not to be the case. Nevertheless, Nau has been placed in an untenable position, but not because Ohuchida filed new arguments and new evidence with its reply. Rather, it is the circumstances of this case which place Nau behind the eight ball.

c.

We start our analysis with the interference as declared. The examiner held that the specification of the involved Ohuchida application describes the invention of Ohuchida claim 11 in the manner required by the first paragraph of 35 U.S.C. § 112. If the examiner had felt otherwise, Ohuchida claim 11 would have been rejected ex parte and the Ohuchida and Nau files would not have been forwarded to the board for declaration of an interference.

Ohuchida was not accorded the benefit for the purpose of priority of its Japanese patent applications at the time the interference was declared. Hence, Ohuchida had to file a preliminary motion for priority benefit. 37 CFR § 1.633(f). The party moving for benefit bears the burden of proof. 37 CFR § 1.637(a). See also Kubota v. Shibuya, 999 F.2d 517, 27 USPQ2d 1418 (Fed. Cir. 1993) (agreeing with the Commissioner that the moving party had burden of proof on motions filed prior to amendment of Rule 637(a); 58 Fed. Reg. 49432, 49434 (Sept. 23, 1993)).

In this case, however, the specification of the involved Ohuchida application and the specification of the Japanese patent application appear to be similar--at least where it counts. Given the examiner's treatment of the involved Ohuchida U.S. application, it does not logically follow that Ohuchida would be expected to imagine and respond to all possible arguments which

might be made by Nau in an opposition. Rather, in this case, the issue of non-compliance with the first paragraph of 35 U.S.C. § 112 surfaces--properly--for the first time upon the filing of Nau's opposition. The issue of non-compliance is joined--again properly--when Ohuchida filed its reply. Thus, despite the burden of proof provisions of 37 CFR § 1.637(a), this is a case where a benefit application contains a statement of utility which appears sufficient on its face. An issue of its insufficiency arises only after an opposition is filed.

In view of the circumstances of this case, it might be said that a de facto shift in the burden of proof to Nau has occurred even though the de jure burden of proof remains on Ohuchida. Ohuchida had a reasonable expectation that the PTO would find its Japanese application sufficient given the examiner's treatment of its involved U.S. application. On the other hand, Nau had no input during the ex parte prosecution of the Ohuchida application prior to the interference. We simply do not know whether the examiner would have rejected Ohuchida's claims for failure to comply with the first paragraph of 35 U.S.C. § 112 had the examiner had the benefit of the Pleasant declaration.

For the reasons given, we cannot say that Ohuchida's presentation of what might be regarded as "new" argument in, and "new" evidence with, its reply in this case was improper. Rather, Ohuchida's new argument and new evidence appear to be a legitimate response to a proper first instance attack on the

sufficiency of the specifications of its Japanese patent applications made by Nau in a legitimate opposition to Ohuchida's preliminary motion. Thus, this is a rare case where the general rule against raising new arguments and presenting new evidence in a reply does not work.

The proper course of action in this case is to put the parties back to the time when Nau filed its opposition. Ohuchida, if it be so advised, may cross-examine Dr. Pleasant. If after cross-examination, Ohuchida persists in its effort to obtain benefit for the purpose of priority of its Japanese applications, it may file a reply (with or without the Tateishi declaration). If Ohuchida files a reply and relies on the Tateishi declaration, Nau may cross-examine and file a further reply. In this manner, Nau will have the last word with respect to what might be its de facto burden of establishing the insufficiency of the specifications of the Japanese patent applications.

#### **D. Order**

Upon consideration of NAU MISCELLANEOUS MOTION 2 (Paper 51), and for the reasons given, it is

ORDERED that the motion is granted to the extent that the Ohuchida reply and the Tateishi declaration shall be returned to Ohuchida without prejudice to further proceedings consistent with the terms of this order.

