The opinion in support of the decision being entered today
was not written for publication
and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte MICHIHIKO OCHIAI, TAIITI OKADA,
OSAMI AKI, AKIRA MORIMOTO,
KENJI KAWAKITA and YOSHIHIRO MATSUSHITA

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Appeal 2006-1443
Reexamination 90/005,200
Patent 5,583,216
Technology Center 1600

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Appeal 2006-1465
Reexamination Control 90/004,950
Patent 5,583,216
Technology Center 1600

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Oral Argument: 26 June 2006
Decided: 31 July 2006

Before: McKELVEY, *Senior Administrative Patent Judge*, and HANLON and DELMENDO, *Administrative Patent Judges*.

McKELVEY, *Senior Administrative Patent Judge*.

DECISION ON APPEAL UNDER 35 U.S.C. § 306

A. Introduction

The appeal is from a decision of the Examiner rejecting claims 1-5 of U.S. Patent 5,583,216 (Ochiai '216) in consolidated Reexamination Proceedings 90/004,950 and 90/005,200.

Claims 1-5 are the only claims in the patent.

The rejection is based on double patenting.

The real party in interest is Takeda Pharmaceutical Company Limited, which we are told was formerly Takeda Chemical Industries, Ltd.

Reexamination was requested by E. Thomas Wheelock, Esq., of the firm of Morrison & Foerster LLP (Palo Alto, CA).

Oral argument took place on 26 June 2006.

A transcript (Tr-) of oral argument has been made part of the record.

For reasons that follow, the decision of the Examiner rejecting claims 1-5 based on double patenting is *affirmed*.

B. The "new evidence appendix"

Following docketing of the appeal, the board requested that Appellants file a new evidence appendix comprising documents having exhibit numbers beginning with Exhibit 1001.

The Board appreciates Appellants' compliance with the request.

We have considered the following record in resolving the appeal:

(1) The specification, including the claims, of the patent under reexamination—Ochiai '216.

(2) The appeal brief filed 2 September 2005.

(3) The Examiner's answer entered 16 November 2005.

(4) The new evidence appendix filed 20 June 2006, except as noted below, but only to the extent that particular and specific portions of the documents have been called to our attention in the appeal brief or a declaration. The mere fact that a

document containing many pages has been "cited" does not mean that we have considered the entire document. Rather, we consider only that portion of the document called to our attention. *DeSilva v. DiLeonardi*, 181 F.3d 865, 866-67 (7th Cir. 1999) (court will not play archaeologist with the record); *Clintec Nutrition Co. v. Baxa Corp.*, 44 USPQ2d 1719, 1723 n.16 (N.D. Ill. 1977) (where party cites to a multi-page exhibit without citing a specific portion or page, the court will not pour over the documents to extract the relevant information).

We have not considered the following:

(1) The reply brief, which was refused entry by the Examiner. The Chief Administrative Patent Judge invited Appellants to have the appeal remanded so that the Director of Technology Center 1600 could entertain a petition to review the Examiner's refusal to enter the reply brief. Appellants declined the Chief Judge's invitation, electing instead to go forward with oral argument.

(2) Documents in the new evidence appendix which are not in English.

C. Findings of fact

The record supports the following findings of fact by at least a preponderance of the evidence.

<u>The patent under reexamination (Ochiai '216)</u>

U.S. Patent 5,583,216 (Ochiai '216) under reexamination and now on appeal issued on 10 December 1996.

Ochiai '216 is based on an application filed 8 January 1990, and claims benefit of a series of applications, the first of which was filed on 19 December 1975 (Ochiai '888).

The Ochiai '216 is based on a pre-GATT application and therefore enjoys a 17-year term.

The patent contains claims 1-5 that are reproduced in Appendix 1 of this opinion.

According to Appellants, "all claims stand or fall with *** claim 1" (Appeal Brief, filed 2 September 2005, page 6). Accordingly, we select claim 1 as representative of all of the appealed claims and confine our discussion to claim 1. 37 CFR § 41.37(c)(1)(vii) (2005).

As is apparent from Appendix 1, Ochiai '216 claim 1 is directed to a method for preparing organic "cephem" compounds having particular chemical structures.

We note that one feature of the cephem compound to be made by the process of Ochiai '216 is the presence of a —C(=NR^5)— group.

According to claim 1, the sole step in the process involves "introducing" (1) an acyl group having a first particular chemical formula "into" (2) the amino group of a "Molecule" having a second particular chemical formula.

The acyl group has a structure that includes, *e.g.*, (1) a —COOH group or (2) a —$COO^{-}{}^{+}$salt (*e.g.*, Na^+) group.

The "Molecule" mentioned in claim 1 on appeal has an amino group, *i.e.*, a chemical group having a structure which includes —NH_2.

It is known in the art that a compound with an acyl group can be made to react with a molecule having an amino group to form an "amide", *e.g.*, the reaction:

$$R—COOH + H_2N—R' \longrightarrow R—CONH—R' + H_2O.$$

The Examiner's rejection

The Examiner rejected claims 1-5 as being unpatentable based on double patenting.

We understand a "first" double patenting rejection to be bottomed on the claims of each of

(1) Ochiai U.S. Patent 4,298,606 ('606) (Ex. 1036) or

(2) Ochiai U.S. Patent 4,098,888 ('888) (Ex. 1037) or

(3) Ochiai U.S. Patent 4,203,899 ('899) (Ex. 1038)

"in view of "

(a) Chauvette (Ex 1039),

(b) Gottstein (Ex. 1040),

(c) Cocker (Ex. 1041),

(d) Fieser (Ex. 1042) and

(e) Dolfini (Ex 1043).

Examiner's Answer entered 16 November 2005, page 3.

A "second" double patenting rejection is bottomed on the claims of either

(1) Ochiai '888 (Ex. 1037) or

(2) Ochiai '606 (Ex. 1036).

Examiner's Answer, page 16.

Ochiai '606

Ochiai '606 issued on 3 November 1981 and accordingly has expired.

Ochiai '606 is based on an application filed 28 August 1979 and claims benefit of at least an application filed 19 December 1975 (Ochiai '888).

Claim 1 of Ochiai '606 is directed, *inter alia*, to cephem compounds having a particular formula (Ochiai, col. 38, line 67 through col. 39, line 24). *See* the (a) member of the Markush group of claim 1.

The process of claim 1 on appeal can be used to make some of the cephems covered by claim 1 of Ochiai '606, including cephems with a —C(=NR^5)— group.

The method of claim 1 on appeal can be used to make the cephems of claim 1 of Ochiai '606 at least when:

(1) R^8 of Ochiai '216 claim 1 is hydrogen (—H);

(2) —CH(R^2)— of Ochiai '606 is —C(=NR^5)— and R^5 is hydroxyl (—OH);

(3) R^3 of both claim 1 on appeal and Ochiai '606 is hydrogen or methoxy (— OCH_3); and

(4) R^4 of both claim 1 on appeal and Ochiai '606 is hydrogen (—H) or acetoxy.

Ochiai '606 claim 15 (1) is narrower than Ochiai '606 claim 1 and (2) is also directed to cephem compounds which can be produced by the process of claim 1 on appeal at least when:

(1) R^9 of claim 15 of Ochiai '606 is amino (—NH_2);

(2) R^5 of claim 15 of Ochiai '606 and claim 1 on appeal are hydroxyl;

(3) R^{11} of claim 15 of Ochiai '606 and R^3 of claim 1 on appeal are hydrogen or methoxy; and

(4) R^4 of claim 15 of Ochiai '606 and claim 1 on appeal are hydrogen.

A process described in Ochiai '606 for making the cephems of claims 1 and 15 of Ochiai '606 is reacting compound VI (col. 1, line 36) with compound V (col. 1, line 46). *See also* (1) col. 2, lines 26-29 and (2) col. 6, line 55 through col. 7, line 62.

Compound VI of Ochiai '606 is the "Molecule" with the amino group of claim 1 on appeal.

Compound V is the compound with the acyl group of claim 1 on appeal.

The process described in Ochiai '606 for making cephems is the process of claim 1 on appeal.

Ochiai '888

In view of the rationale for our affirmance, we find it unnecessary to make detailed findings with respect to what is claimed and described in Ochiai '888.

Ochiai '888 has expired.

Ochiai '899

In view of the rationale for our affirmance, we find it unnecessary to make detailed findings with respect to what is claimed and described in Ochiai '899.

Ochiai '899 has expired.

Other prior art cited by the Examiner

The Examiner cited prior art in support of one of the double patent rejections on appeal.

In view of the rationale for affirmance, we find it unnecessary to discuss the cited prior art.

Wuest Declaration

Appellants rely on declaration testimony of Dr. James D. Wuest (Ex 1001).

The Wuest declaration was filed on or about 2 September 2005.

Dr. Wuest has a Ph.D. in organic chemistry.

In Dr. Wuest's opinion none of the prior art cited by the Examiner describes or suggests introducing an acyl group into an amino group of a "Molecule" as called for by claim 1 on appeal.

As noted earlier, we do not find it necessary to discuss or rely on the prior art cited by the Examiner.

Accordingly, we have no occasion to assess the weight to be given Dr. Wuest's opinions with respect to that prior art.

Dr. Wuest seems to be of the opinion that, prior to considering the Ochiai specifications, a person having ordinary skill in the art would not have had a reasonable expectation that the process of Ochiai '216 claim 1 would be successful.

As explained in Paragraph 15 of his declaration, Dr. Wuest suggests that one skilled in the art would have expected that "self-condensation" would occur.

What is "self-condensation"?

What Dr. Wuest suggests is that a person having ordinary skill in the art might at first blush believe that the compound with acyl group of Ochiai '216 claim 1 would react with itself and not the "Molecule" of claim 1. Why? Because (1) the compound has both an acyl group (e.g., —COOH) and an amino group (e.g., —NH_2) and, (2) as noted above and known in the art, acyl groups react with amino groups to form amide groups, in this case a group with the formula —CONH—.

Dr. Wuest illustrates his concern in the chemical reaction set out in Paragraph 15 of his declaration where it is suggested that the Compound of Ochiai '216 might become involved in self-condensation more or less according to the chemical equation:

$$n\ H_2N—R—COOH \longrightarrow H_2N—(R—CONH)_{n-1}—R—COOH$$

Dr. Wuest does not satisfactorily explain why one skilled in the art would have expected the "hindered" amine group attached to an aromatic-like group on the compound also having the acyl would have been expected to be more reactive than the primary amine group attached to the molecule.

Dr. Wuest expressed other reasons why, absent the Ochiai specifications, one skilled in the art would not have expected the Ochiai '216 claim 1 process to be successful.

However, Dr. Wuest acknowledges that one skilled in the art would have been able to carry out the process of claim 1 of Ochiai '216 as described in the specification of Ochiai '216. Wuest declaration, Paragraph 43.

In fact, Dr. Wuest goes on to tell us that based on "references" published between 1989 and 1997 one skilled in the art would have been able to carry out the process of Ochiai '216 claim 1 as described by Ochiai '216 notwithstanding any concerns expressed in the prior art. Wuest declaration, Paragraph 44.

Dr. Wuest testified that "there are various possible alternative pathways for making the cephem compound of claim 1 of the '216 patent." Wuest declaration, Ex. 1001, Paragraph 50.

Dr. Wuest starts his analysis by noting that "There Are Other Potential Routes for Making the Final Product of Claim 1 Of the '216 Patent". Wuest declaration, Ex. 1001, page 22.

We take Dr. Wuest's testimony to be that, as of the date he signed his declaration in 1999, one skilled in the art would have understood that there "are various possible alternative pathways for making the cephem compound of claim 1 of the '216 patent." Wuest declaration, Ex. 1001, Paragraph 50.

The Morin document contains numerous pages and is an example of a large document submitted by Appellants where only a few pages are mentioned in the Wuest declaration. Consistent with our previous observation, we have considered only the pages mentioned.

With reference to page 21 of Morin *et al.*, Chemistry and Biology of β-Lactam Antibiotics (1982) (Ex. 1010), we think that Dr. Wuest is trying to tell us that compounds similar to the starting materials in the process of Ochiai '216 claim 1 are shown as Compounds 65 and 66.

According to Dr. Wuest, a displacement reaction is said to be shown on page 87 of Morin. Wuest declaration, Ex. 1001, page 23 and Ex. 1010, page 87.

Dr. Wuest goes on to testify that "[a]lthough the Morin reference does not specifically disclose coupling of an amino-substitute thiazolyl compound to penicillin sulfoxide, given the examples taught in the Ochiai specification, I would expect that this reaction could be carried out." Wuest declaration, Ex. 1001, page 23.

The Examiner's assessment of the Wuest declaration testimony

The Examiner was not impressed with Dr. Wuest's declaration testimony and declined to give the testimony much, if any, weight.

Among other things, the Examiner found that the testimony was "speculative" and had never been performed. Examiner's answer, page 8; Tr-8:16-18. The Examiner further found that the process suggested by Dr. Wuest was not described by Ochiai. The Examiner still further found that the process suggested by Dr. Wuest relies on a compound not shown to have been known earlier than the 1982 date of Morin.

Usami declaration

Appellants also rely on a declaration of Mr. Hirofumi Usami filed on or about 2 September 2005. Ex. 1035.

Mr. Usami is employed in the intellectual property department of the real party in interest--Takeda. Usami declaration, Paragraph 3.

Through Mr. Usami's testimony, we are told about what appears to have been a somewhat long and involved prosecution of the numerous Ochiai applications.

According to Mr. Usami, part of the reason for the long prosecution is that Takeda was unable to promptly obtain claims to cover competitors' later developed compounds within the scope of Ochiai's generic claims "because of the refusal of the Examiner to allow generic claims and the long appeal pendency at the Board *** that was the norm in the 1980's ***." Usami declaration, Paragraph 20.

Mr. Usami undertakes an explanation of why "process of making" claims like those in claim 1 of Ochiai '216 were not presented early in the Ochiai patent application filing strategy. Usami declaration, Paragraph 25.

According to Mr. Usami, (1) process of making claims "were not valuable in terms of protection of pharmaceutical compounds" and (2) "claims of this type were not considered patentable under the case law of the United States ***." Usami declaration, Paragraph 25.

The "were not valuable" portion of Mr. Usami's testimony is apparently based on his view that the § 271(g) protection now available was not then available in the United States as Mr. Usami believes it was in Europe.

Since 1989, § 271(g) protection has been available in the United States; a person infringes a patented process if the product made by the process is made abroad and the product is imported into the United States during the life of the process patent.

While he does not say so in so many words, we believe Mr. Usami's "were not considered patentable" portion of his testimony is based on cases like *In re Larsen*, 292 F.2d 531, 130 USPQ 209 (CCPA 1961) and its progeny.

Mr. Usami recognizes that a case decided shortly after *Larsen* left open the possibility that appropriate evidence in a particular case might provide a means for overcoming *In re Larson* rejections of method claims, but says that he has no recollection of having seen the case. The case is *In re Ross*, 305 F.2d 878, 134 USPQ 320 (CCPA 1962).

We understand that Mr. Usami is telling us that post *Larsen* it was not worth pursuing "method of making" claims until § 271(g) protection became available in 1989.

Accordingly, if we are to believe Mr. Usami, and if we correctly understand what he is trying to tell us, it was not until 1990, when the application which matured into

Ochiai '216 was filed, that it was worth Takeda's time and effort to file "method of making" claims for some of the cephem compounds of the claims of Ochiai '606.

Mr. Usami does not tell us why the cephems of method claims of Ochiai '216 are not exactly co-extensive with the cephems of Ochiai '606 and we perceive no reason why they could not have been exactly co-extensive.

Other findings as necessary appear in the Discussion portion of this opinion.

D. Discussion

1.

Double patenting is designed to prevent an unjustified extension of patent rights beyond the term of a patent. Since double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis is on the claims of the patents involved in the analysis, in this case Ochiai '216 and Ochiai '606. As applied to the facts of this case, the appeal boils down to the following issue:

> Having taken out a full-term cephem compound patent (Ochiai '606), are Appellants also entitled to take out yet another full-term patent to a method of making some of those cephem compounds where (1) the claimed method for making the cephem compounds is described in the cephem compound patent and (2) there is no credible alternative method for making the cephems which does not involve an infringement of the method patent?

We think not.

Our appellate reviewing court and the Patent and Trademark Office have recognized at least two categories of double patenting.

A first form of double patenting is where a second patent claims the same invention as a first patent. The second patent is said to be precluded based on double patenting bottomed on the statutory language in 35 U.S.C. § 101 which states that "a patent" may be issued for certain inventions.

A second form of double patenting is where a second patent claims a different invention from a first patent, but the invention claimed in the second patent would have been obvious based on the invention claimed in the first patent—with or without considering additional relevant prior art.

We believe there may be a tendency to try to "pigeon hole" every double patenting situation into one of these two recognized categories of double patenting. However, we decline to hold that every double patenting must fit precisely into one of the two categories. In our view, the focus should be on whether a second patent unjustly extends the patent rights of a first patent. Each case, of course, must be decided on its facts.

2.

As applied to the facts of this case, we think that a decision of the Supreme Court provides support for the decision of the Examiner to reject claims 1-5 on appeal based on double patenting. *Mosler Safe & Lock Co. v. Mosler, Bahmann & Co.*, 127 U.S. 354, 8 S.Ct. 1148 (1888).

In *Mosler*, a patent was obtained for an article, viz., "[a]n angle-bar for safe frames." U.S. Patent 281,640 issued 17 July 1883 based on an application filed

27 December 1881. A second patent was obtained for a "process of bending angle-irons." U.S. Patent 283,136, issued 14 August 1883 based on an application filed 11 December 1882. As in the case, before us, the method patent was applied for after the article patent was applied for. The Supreme Court recognized that the method claims and the article claims "might have been all included in one application had the patentee chosen to so present them." 127 U.S. at 359, 8 S.Ct. at 1150. The Supreme Court found that "the claim for the process in No. 283,136 is merely for the process or method *** involved in making the article covered by claims 1 and 2 of No. 281,640. In other words, claims 1 and 2 of No. 281,640 are each for an article produced by a described method or process, and the claim of No. 283,136 is for such a method or process of producing such article." 127 U.S. at 361, 8 S.Ct. at 1151-52. The Supreme Court reasoned that "the inventor cannot afterwards, on an independent application, secure a patent for the method or process of cutting away the metal and then bending it so as to produce the identical article covered by the previous patent, which article was described in that patent as produced by the method or process sought to be covered by taking out the second patent."

Ochiai '216 covers the method described in Ochiai '606 for making at least some of the cephems claimed in Ochiai '606. Appellants have not shown that they presented the method claims of Ochiai '216 in the application that matured into Ochiai '606. Rather, Appellants waited until 15 years into the prosecution of the family of Ochiai applications to first present the method claims on appeal. In this sense, Ochiai's experience is similar to Mosler's experience, although the time difference between presentation of article and method claims in Mosler's case is considerably shorter.

When Appellants received Ochiai '216, they acquired the right to prevent others from making (1) the cephems falling within the scope of claims 1-5 of Ochiai '216 and (2) some of the cephems claimed in Ochiai '606.

After 1989, and as a result of enactment and codification of 35 U.S.C. § 271(g), Appellants also acquired the right to exclude others from making or using some of the cephems of now expired Ochiai '606 if those cephems were made abroad using the method claimed in Ochiai '216.

3.

Appellants bottom their argument for reversal on the proposition that the process claimed in Ochiai '216 is an "independent and distinct" invention from the cephems of Ochiai '606.

In what is generally recognized as a double patenting case, the Supreme Court in *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 199, 14 S.Ct. 310, 315 (1894) made the following observation:

> The result of the foregoing and other authorities is [1] that no patent can issue for an invention actually covered by a former patent, especially to the same patentee, *although the terms of the claims differ*; [2] that the second patent, although containing a broader claim, more generical [today we would say "generic"] in its character than the specific claims, contained in the prior patent, is also void; but [3] that where the second patent covers matter described in the prior patent, essentially distinct and separate from the invention covered thereby, and claims made

thereunder, its validity may be sustained." (Emphasis and numbers in brackets added).

One of the "foregoing and other authorities" referred to by the Miller court is *Mosler Safe & Lock Co. v. Mosler, Bahmann & Co.*, 127 U.S. 354, 8 S.Ct. 1148 (1888). According to the Miller court, in *Mosler* "it was held that, a patent having issued for a product as made by a certain process, a later patent could not be granted for the process which results in the same product." 151 U.S. at 197, 14 S.Ct. at 315.

4.

Appellants present two arguments, using the rubric "independent and distinct", in an attempt to fit their case for reversal into the "distinct and separate" category mentioned in *Miller*.

Appellants' first "independent and distinct" argument is based in part on a restriction requirement made in a different Ochiai application by former Examiner Nicholas Rizzo. At the same time, Appellants candidly acknowledge that "[n]o claim is made for the statutory shield of 35 U.S.C. § 121 ***." *See* the last three lines on page 12 of the Appeal Brief.

Appellants' second "independent and distinct" argument is based in part on their opinion that there are methods other than the method of Ochiai '216 for making the cephems of expired Ochiai '606.

5.

Appellants' first argument is bottomed on a restriction requirement made by former Examiner Nicholas Rizzo.

According to Appellants, Examiner Rizzo made a restriction requirement between claims said to cover an acylation process and claims said to cover a displacement process. We have found a document in the record discussing a restriction requirement between acylation and displacement processes. *See* Exhibit 1046. However, Exhibit 1046 is confusing to say the least. Exhibit 1046 consists of five pages. The first page discusses claims 6-10 and 15-18, is dated 28 May 1991 and appears to be part of application 07/462,492. The second page discusses claims 1-21, is dated 6 December 1976 and appears to be part of application 07/642,356. Page 3 discusses a restriction requirement between different compounds and appears to be part of application 07/642,356. The fourth page returns to application 07/462,492 and is the page discussing a restriction between an acylation process and a displacement process. The fifth page seems to be part of the file of application 07/462,492. In sum, it would appear that the second and third pages should not have been included in the exhibit.

It appears that Examiner Rizzo made a restriction requirement between claims 6-10 (Group A) calling for what is characterized as an acylation process and claims 15-18 (Group B) calling for what is characterized as a displacement process. The language of claims 6-10 and 15-18 has not been placed before us and therefore we are unable to determine the precise metes and bounds of those claims or of the subject matter involved in the Rizzo restriction. Our appellate reviewing court has observed that "§ 121 only applies to a restriction requirement that is documented by the PTO in enough clarity

and detail to show consonance. The restriction requirement documentation must identify the scope of the distinct inventions that the PTO has restricted ***." *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382, 68 USPQ2d 1865, 1872 (Fed. Cir. 2003). While we are not dealing with a § 121 situation here, Appellants having expressly declined to place any reliance on § 121, we believe the Federal Circuit's *Geneva* observations are applicable here where Appellants in part bottom their case based on what they characterize as a restriction requirement albeit a restriction requirement in a related, but different, case. Having failed to favor us with a copy of the claims said to have been restricted by Examiner Rizzo, we are unable to determine the precise nature of that restriction requirement or the weight, if any, to be given to the Rizzo restriction requirement.

In our view, the Rizzo restriction requirement does not give much aid and comfort to Appellants. They have not sufficiently established what the restriction requirement was actually about, and in particular what the displacement process was all about. In short, Appellants' restriction proofs are not bottomed on sufficient and credible evidence.

6.

Appellants have an alternate theory. According to Appellants, we should find that there are two 'independent and distinct" processes that can be used to make the cephems of Ochiai '606.

Appellants' theory is based on the declaration testimony of Dr. Wuest. As noted earlier, the Examiner was not impressed with Dr. Wuest's testimony.

According to Appellants, the Examiner has to believe Dr. Wuest's testimony because there is no opposing evidence. Wrong! The Examiner is entitled to assess

testimony and there is no requirement of law that an examiner must have counter-testimony or evidence to discredit declaration testimony. *See*, *e.g.*, *Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997) (fact-finder need not credit unsupported assertions of an expert witness). At oral argument, Appellants acknowledge that one reason the Examiner declined to credit Dr. Wuest was that the alternate process Dr. Wuest has suggested has not been shown to have been "actually been carried out ***." Tr-8:16-18. Appellants go on to say "[b]ut the [E]xaminer never provided any references to dispute the credibility of the expert opinion of Dr. Wuest on this point." Tr-8:20-22. In point of fact, however, Appellants do not, and cannot, deny the correctness of the Examiner's observation that the Wuest alternative process has not been shown to have been carried out.

Dr. Wuest characterized the proposed "alternative pathways" as "Potential Routes" and "possible" alternatives. As indicated earlier, Dr. Wuest does not indicate that any scientist made any attempt to carry out his suggested alternative. While Dr. Wuest refers to a Morin text, the most he can say is that "I would expect that this reaction [meaning the Ochiai reaction] could be carried out." Wuest declaration, Ex. 1010, page 23. Why? Painting with a broad brush, Dr. Wuest refers to the examples in Ochiai specifications, but does not refer to any particular example or why the content of the examples provides a basis for his "I would expect" opinion. Moreover, as developed during oral argument, counsel for Appellants conceded that Dr. Wuest made no analysis of the advantages and disadvantages of his proposed reaction scheme vis-à-vis the reaction schemes actually described in the Ochiai specifications. Tr-24:13-22. There is no discussion by Dr. Wuest as to why one skilled in the art would go out of the

way to use his "potential" or "possible" reaction schemes when there is a detailed and straightforward reaction scheme described in the Ochiai specifications. Appellants have not shown us that the Wuest alternative processes may be described in the family of Ochiai applications. On this record, it would appear that the Wuest alternative method is a post-litigation afterthought, particularly given the 1982 date of Morin when compared to the 1975 filing date of the first Ochiai application. We cannot say that the Examiner did not have a sufficient basis for finding that the Wuest testimony was "speculative" and we do not think it is our role in this case to second-guess the Examiner's assessment of the Wuest testimony. The Examiner works in the art area day to day; we do not.

When pressed at oral argument, counsel for Appellants maintained that Ochiai '606 describes at least two methods for making the cephems of claim 1 of Ochiai '606. Tr-6:18 *et seq*. A first method is reacting compound VI with compound V. Ochiai '606, col. 2, lines 26-29 and col. 6, line 55 through col. 7, line 62. A second method is reacting compound IX with a "nucleophilic" compound. Ochiai '606, col. 2, lines 33-35 and col. 8, line 32 through col. 9, line 24. A third method, not discussed at oral argument, may be reducing compound VII. Ochiai '606, col. 2, lines 30-32 and col. 7, line 63 through col. 8, line 31.

Each of the three methods described in Ochiai '606 involves the use of the process of claim 1 of Ochiai '216.

The first method involves reacting an acyl containing compound with an amine "Molecule" as described in our findings.

The second method involves using Ochiai '606 compound IX (top of col. 2). R^6 of compound IX can be various organic moieties, including acyloxy, such as

acetyloxy. Ochiai '606, col. 8, lines 34-35. The process of claim 1 on appeal can be used to make Compound IX when R^4 of claim 1 on appeal is a residue of a nucleophilic compound. For example, R^4 can be —W—R where W is oxygen and R is acyl. One example of an —W—R group is acyloxy, e.g., acetyloxy. Ochiai 216, col. 6, lines 30 and 39. The method of claim 1 of Ochiai '216 can be used to make some of the compounds falling within the scope of Ochiai '606 compound IX.

The third method involves use of Ochiai '606 compound VII (col. 1, line 60). Some of the compounds falling within the scope of Ochiai '606 compound VII are made by reacting a compound having an acyl group with a "Molecule" in accordance with claim 1 of Ochiai '216.

What surfaces from the discussion above is that regardless of whether one skilled in the art practices the first, second or third method described in Ochiai '606, that person uses the process of claim 1 of Ochiai '216 to make at least some of the Ochiai '606 compounds. The Ochiai '216 method is used to make compounds via the first method. The process is also used to make starting materials for practicing the second or third method. We have a case where all the described methods for making some of the '606 cephems in one fashion or another involve the use of the process of claim 1 of Ochiai '216. Having rejected Dr. Wuest's speculative method, no credible method for making the cephems of Ochiai '606, other than those described in Ochiai '606, has been placed before us. This is not a case where a credible alternative method for making the Ochiai '606 compounds has been established. Appellants have not established that there are credible separate "independent and distinct" methods for making some of the cephems claimed in Ochiai '606.

7.

At oral argument, Appellants indicated that "the final product of the [Ochiai] '216 process is substantially coextensive with the two final product patents that are the subject of the double patenting rejection." Tr-17:19 through 18:4. One of the "two final product patents" is Ochiai '606. Nevertheless, we recognize that the process of Ochiai '216 cannot be used to make all of the cephems within the scope of claims 1 and 15 of Ochiai '606. In other words, the scope of the cephems that can be made using the process of claims 1-5 of Ochiai '216 is narrower than the scope of the cephems covered by Ochiai '606, although the scope of the cephems made by claim 15 of Ochiai '606 is very close. However, to the extent that the process of Ochiai '216 is used to make only some of the cephems within the scope of the Ochiai '606 claims, Appellants ultimately conceded at oral argument that the public is not entitled to use that process to make "some of the cephems" of Ochiai '606. Tr-19:19 through 20:10. In effect, the claims of Ochiai '216 operate to extend the patent rights conferred by now expired Ochiai '606 at least to the extent that the Ochiai '606 and Ochiai '216 claims are co-extensive.

Given the rationale upon which double patenting is based, we see no reason why a process claim and the expired compound have to be co-extensive in scope to sustain a rejection for double patenting. Just as one described species or several species may anticipate a genus in an anticipation analysis under 35 U.S.C. § 102(b) even if other described species do not anticipate, we see no reason why double patenting should not apply, under the facts of this case, where a process claim operates to preclude making of some compounds of an expired compound patent. It should suffice to justify double patenting that some or all of the compound claims of an expired compound patent

continue to be monopolized by virtue of patent rights in a narrow method patent. In *In re Vogel*, 422 F.2d 438, 442, 164 USPQ 619, 622 (CCPA 1970), the former CCPA noted that issuance of a second patent to a process of treating meat would extend the time of monopoly as to a process of treating pork claimed in a first patent. Here, to the extent the Ochiai '216 patent extends the monopoly as to the compounds which can be made by that process which are the same as the compounds covered by claim 1 of Ochiai '606, the monopoly of Ochiai '606 is also extended, particularly as to products made abroad by the process and subsequently imported into the United States. Tr-20:11 through 21:1.

Double patenting should not turn on "creative" method claim drafting. Rather, the focus should be on an analysis of whether all or some of a patentee's patent rights are being unjustly extended. For example, in this very case it is not apparent, and Mr. Usami did not explain, why Ochiai '216 method claims were not drafted to include making all of the cephems of Ochiai '606 claims 1 and 15. Appellants conceded at oral argument, as they had to, that product and process claims could have been presented in a single application. Tr-11:7-10. See also Tr-25:6 through 26:1. In our opinion, what might be characterized as Appellants' creative and conveniently timed claim drafting should not be a back door "around" double patenting.

8.

Appellants presented the declaration testimony of Mr. Hirofumi Usami (Ex 1035) to explain why the Ochiai '216 process claims were first presented in 1990 in the application that matured into Ochiai '216. Ochiai '216 is based on several continuations, continuations-in-part and divisions of an Ochiai application filed in 1975, *viz.*, Ochiai '888. As noted in our findings, Mr. Usami states that process claims were not earlier

presented because (1) process protection was said not to be valuable until 1989 when § 271(g) was enacted and (2) process claims were not patentable in the United States. Appellants seem to be saying that because they could not have benefited from process claims pre-1989, they were under no obligation to present process claims.

It may be fairly debatable whether any weight should be assigned to Mr. Usami's testimony. How relevant is it to any issue before us? To the extent that double patenting ought to be based in whole or in part on equitable, as opposed to wholly legal, considerations, we would find that Mr. Usami's declaration amounts to an "excuse" but not a "justification" for the delay in presenting the process claims on appeal. Appellants' delay in seeking process protection has extended in part the 1998 expiration date of Ochiai '606 until 2013, all because Takeda did not diligently pursuant its right to a process patent.

It is true that § 271(g) made process claims more valuable. Tr-25:6-13. However, Congress has long authorized inventors to apply for patents on processes. 35 U.S.C. § 101. Moreover, the law encourages individuals to diligently seek to protect their "rights" and not delay to the prejudice of others. The "others" in this case is the public.

It is also true that *In re Larsen* and some of its progeny could have been viewed as discouraging inventors to seek certain process claims. Tr-10:2-5. Included among the progeny is *In re Durden*, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985). Tr-10:3. Notwithstanding the 1985 *Durden* decision, Edwin P. Pleuddemann and his assignee Dow Corning Corporation, applied for a process patent on 14 October 1986, as a division of a product patent filed on 29 November 1985. Unlike Ochiai and Takeda,

Plueddemann and Dow Corning Corporation successfully sought to vindicate what they felt was their right to a process patent notwithstanding *Larsen* and *Durden* and did so prior to enactment of § 271(g). *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990). Moreover, in this very case, we note that Appellants, like Pleuddemann, successfully overcame a so-called *Durden* rejection. *In re Ochiai*, *supra*.

9.

Appellants cited and rely on *In re Cady*, 77 F.2d 106, 25 USPQ 345 (CCPA 1935). According to Appellants, the 1952 Patent Act and subsequent PTO pronouncements codified the holdings of *Cady*. A first holding was that if a restriction requirement is made, the PTO cannot use double patenting. The holding is codified in 35 U.S.C. § 121. Here there was no restriction. A second holding is said to be that if there are two methods of a making a product, the methods might be regarded as independent and distinct from each other and the product. The pre-271(g) *Cady* holding and any PTO codification of that holding is not applicable to the facts of this case. Appellants have failed to establish that there two "independent and distinct" methods for making the cephems of Ochiai '606 which do not involve the use of the Ochiai '216 process.

10.

Appellants have discussed *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). We are not at all sure what *Schneller* has to do with the issues on appeal. We agree with Appellants that *Schneller* is not controlling. Accordingly, further discussion concerning *Schneller* would not be productive.

11.

Appellants make a point in the Appeal Brief, and at oral argument, that the Examiner has "combined" several Ochiai patents to make the double patenting rejecting. Tr-15:12-17.

We do not think the Examiner combined several Ochiai patents to make the rejection. However, given the rationale upon which we have affirmed, we find it unnecessary in this case to resolve any issue of whether two or more patents owned by a patentee may be "combined" to support a double patenting rejection of another patent owned by the patentee. We leave that issue for another day.

E. ORDER

Upon consideration of the record indicated above and for the reasons given, it is

ORDERED that the decision of the Examiner rejecting claims 1-5 is affirmed.

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a) (2005).

AFFIRMED.

FRED E. McKELVEY, *Senior Administrative Patent Judge*

ADRIENE LEPIANE HANLON
Administrative Patent Judge

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Administrative Patent Judge

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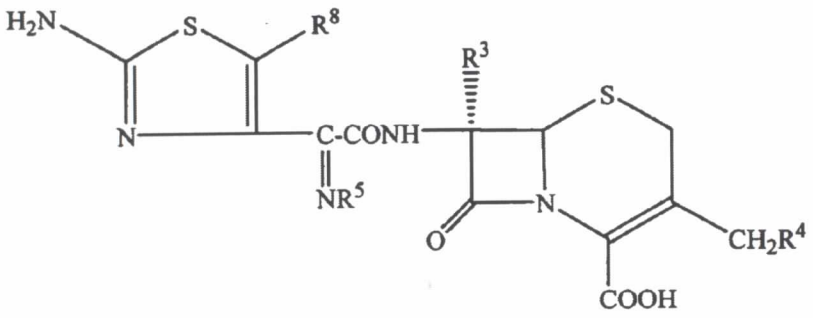
CLAIMS APPENDIX

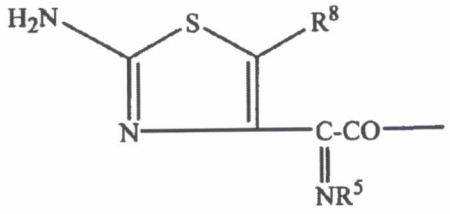
APPENDIX A: THE CLAIMS

[37 C.F.R. § 41.37(c)(1)(viii)]

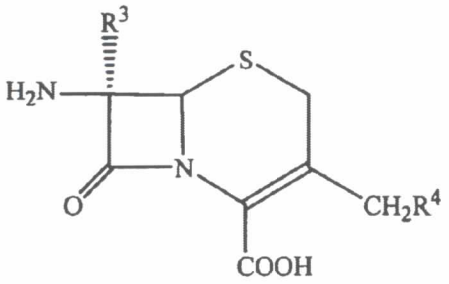
1. A process for preparing a cephem compound of the formula:



wherein R^3 is hydrogen or methoxy, R^4 is hydrogen or a residue of a nucleophilic compound, R^5 is hydroxyl or a protected hydroxyl, and R^8 is hydrogen or a halogen, or a pharmaceutically acceptable salt or ester thereof, which comprises introducing an acyl group of the formula:



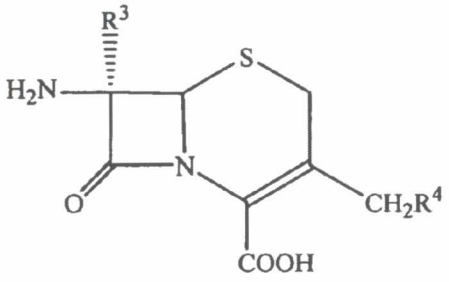
wherein R^5 and R^8 are as defined above into the amino group of the molecule of the formula:



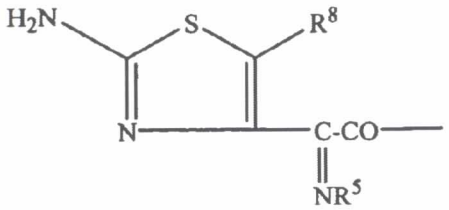
wherein R^3 and R^4 are as defined above or a salt or ester thereof.

2. A process of claim 1 wherein R^3 and R^8 are hydrogen.

3. A process according to claim 1, wherein the introduction is performed by reacting a compound of the formula:



or a salt or ester thereof, with a compound of the formula:



wherein R^1 is an amino group, or a salt or reactive derivative thereof.

4. A process of claim 3 wherein the amino group as R^1 is amino.

5. A process of claim 3 wherein the amino group as R^1 is protected amino, and subsequent to said introduction the protective group is removed.