

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- (2) is not binding precedent of the Board.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. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte KEIJI TAMURA

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Appeal No. 1996-0111  
Application No. 08/041,428

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HEARD: May 18, 2000

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Before WINTERS, ROBINSON, and ADAMS, Administrative Patent Judges.  
ROBINSON, Administrative Patent Judge.

**DECISION ON APPEAL**

This is a decision on appeal from the examiner's final rejection of claims 1-26, which are all of the claims pending in this case. Independent claims 1 and 25 are illustrative of the subject matter on appeal and read as follows:

1. A method for controlling the health of a group of animals and maintaining the group of animals in a condition of optimum health to maximize the productivity of the animals in the group, comprising the steps of

(a) quantitatively determining the normal upper limit for the  $\alpha_1$ -acid glycoprotein value in a selected body fluid for normal healthy animals of the kind in the group;

(b) measuring the  $\alpha_1$ -acid glycoprotein values in said selected body fluid of the animals in the group;

(c) comparing the measured  $\alpha_1$ -acid glycoprotein values obtained in step (b) to the normal upper limit determined in step (a);

(d) identifying the animals in the group with  $\alpha_1$ -acid glycoprotein values that exceed said normal upper limit;

(e) using the information obtained in step (d) to assess the relative health of the animals in the group; and

(f) based upon the assessment of step (e), taking the action required to promote and maintain the optimum health of the animals in the group, thereby maximizing the productivity of the animals in the group.

25. A method for maintaining a herd of animals assembled from different sources in a condition of optimum health and homeostatic balance, said herd being composed of one type of animals selected from the group consisting of veal calves, pigs and cattle, wherein said herd is maintained in a condition of optimum health and homeostatic balance by measuring the  $\alpha_1$ -acid glycoprotein values in a selected body fluid of the animals, comparing the measured  $\alpha_1$ -acid glycoprotein values to a normal upper limit for  $\alpha_1$ -acid glycoprotein for the selected body fluid in the type of animals in the herd, identifying individual animals with  $\alpha_1$ -acid glycoprotein values that exceed said normal upper limit, using the measured  $\alpha_1$ -acid glycoprotein values to assess the relative health and homeostatic balance of the herd, and taking the action required to promote and maintain the health and homeostasis balance of the herd.

The references relied upon by the examiner are:

Ruhenstroth-Bauer et al. (Ruhenstroth-Bauer)	4,215,109	July 29, 1980
Shell et al. (Shell)	4,492,753	Jan. 8, 1985
Fudenberg	4,801,533	Jan. 31, 1989

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Toyama et al. (Toyama)

EP 0 199 196

Oct. 29, 1985

Belpaire et al. (Belpaire), "α<sub>1</sub>-Acid Glycoprotein and Serum Binding of Drugs in Healthy and Diseased Dogs," J. Vet. Pharmacol. Therap., vol. 10, pp. 43-48 (1987).

Tamura et al. (Tamura I), "Isolation, Characterization, and Quantitative Measurement of Serum α<sub>1</sub>-Acid Glycoprotein in Cattle," Japanese J. Vet. Sci., vol. 51(5), pp. 987-994 (1989).

Tamura et al. (Tamura II), "Measurement and Significance of Proteins in Cow's Milk," Japanese J. of Vet. Sci., vol. 110, page 279 (1990).

Itoh et al. (Itoh), "Serum α<sub>1</sub>-Acid Glycoprotein in Cattle with Inflammatory Disease and that after Operation," Japanese J. Vet. Sci., vol. 52(6), pp. 1293-1296 (1990).

#### **GROUND OF REJECTION**

Claims 1-26 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Fudenberg, Toyama, Shell, Ruhstroth-Bauer, and Belpaire.

Claims 25-26 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Tamura I, Tamura II, and Itoh.

#### **Background**

At pages 1 and 7 of the Specification, applicant describes the invention as relating to a method which provides an effective, accurate and objective method for measuring the α<sub>1</sub>-acid glycoprotein (AGP) levels in the body fluids of different types of animals as an objective indication of the relative health and/or homeostatic balance of individual animals or a group of animals to provide a basis for effective animal management.

### **Discussion**

#### **The rejections under 35 U.S.C. § 103**

In considering the issues raised by this appeal, we have considered the Examiner's Answer, the Supplemental Answer, the references relied on by the examiner, Appellant's Brief and Reply Brief, the declarations of Dr. Brown and Dr. Coffey, as well as the record as a whole.

#### **Claims 1-26:**

The examiner has cited references establishing a correlation between increased levels of "  $\alpha_1$ -acid glycoprotein in the body fluids of humans (Fudenberg, Toyama, and Shell), rats (Ruhstroth-Bauer) and dogs (Belpaire) and the presence in the animals of certain disease or inflammatory conditions as compared to healthy animals. (Answer, pages 5-6). While acknowledging that none of the references disclose "using these correlations as a basis for managing farm animals or experimental animals" (Answer, page 6), the examiner concludes that (Answer, pages 6-7):

it would have been obvious to one of ordinary skill to use the widely available knowledge that increased "  $\alpha_1$ -AGP levels are indicative of disease or inflammation to assess the health status of groups of animals and to take whatever action is necessary in order to diagnose the suspected condition and subsequently to treat the condition in order to save the diseased animal or to separate the affected animals from the healthy ones in order to prevent contagion.

If we step back for a moment and view the prior art relied upon by the examiner in the absence of applicant's disclosure and claims, we find, as acknowledged by the examiner, that there is nothing in the prior art which would reasonably suggest to one of ordinary skill in this art to take the information provided by the references regarding the presence of elevated levels of " <sub>1</sub>-AGP in diseased animals and use it in a diagnostic method for evaluating the relative health within a group of animals and used this information in animal management as presently claimed.

As stated by appellants (Principal Brief, page 10):

The animal management methods described in the pending claims require a series of specifically stated steps for controlling and maintaining a population of animals in a condition of optimum health to maximize productivity and insure commercial marketability, for evaluating the health profile of animal groups and for maintaining the quality of products at an acceptable level. Neither the cited references themselves nor the knowledge generally available to those skilled in the art at the time [sic, of] the present invention was made contains any suggestion whatever of the animal management methods described in Appellant's claims.

It is the initial burden of the patent examiner to establish that claims presented in an application for patent are unpatentable. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In order to meet the burden of establishing a prima facie case of unpatentability of the claimed subject matter the examiner must establish that there is a reason, based on the prior art, or knowledge generally available in the art, as to why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 n.24, 227 USPQ

657, 667 n.24 (Fed. Cir. 1985). On the record before us, the examiner has failed to provide any factual evidence which would have suggested the use of the correlation of the levels of " <sub>1</sub> -AGP in animals to certain specific disease conditions in diagnostic methods for determining the presence of a disease condition in a group of animals, the use of such diagnostic methodology in a method of controlling the health of a group of animals, or maintaining the group of animals in a condition of optimum health as claimed. Thus, we find that as to this rejection the examiner has failed to establish a prima facie case of obviousness within the meaning of 35 U.S.C. § 103.

Where, as here, the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). Therefore, the rejection of claims 1-26 under 35 U.S.C. § 103 as unpatentable over Fudenberg, Toyama, or Shell taken in view of Ruhestroth-Bauer and Belpaire is reversed.

**Claims 25-26:**

In considering the issues raised by the rejection of claims 25-26 under 35 U.S.C. § 103 as unpatentable over Tamura I, Tamura II and Itoh, we must first review the examiner's holding that the subject matter of claims 25-26 is not entitled to the effective filing date of the parent application and that therefore Tamura I, Tamura II and Itoh constitute prior art with regard to these claims.

It is the examiner's position that the terminology and concept encompassed by the claim limitation of "homeostasis" was not disclosed in the parent application and that therefore claims 25-26 are not entitled to the benefit of the filing date of the parent applications under the provisions of 35 U.S.C. § 120. (Answer, page 11).

Citing the Declaration of Dr. Brown as supporting evidence, appellant argues that "the term 'optimum health', found by the Examiner to be supported by the original parent case . . . encompasses 'homeostasis' as that term is commonly used and understood in the art" and further that "the term 'homeostasis', which was used in combination with 'optimum health' for emphasis rather than to designate a new and different concept, might be fairly deduced from the original disclosure by one skilled in the animal management art." (Principal Brief, page 17-18)

However, as our appellate court stated in Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

It is the disclosures of the applications that count. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. (Citation omitted).

Having reviewed the disclosure of the parent applications, we find no description within the meaning of 35 U.S.C. § 112, first paragraph, of the concept of homeostasis or homeostatic balance. Further, the use of the terminology "homeostasis" and "optimum health" at pages 2-3 of the present specification suggests that they are more reasonably intended to refer to alternative aspects of health rather than, as urged by appellant, a situation where homeostasis is merely encompassed within the concept of optimum health. Therefore, we find no error in the examiner's determination that claims 25-26 are entitled to the filing date of the current application as the effective filing date. Thus, we agree with the examiner that Tamura I, Tamura II, and Itoh constitute prior art as to these claims.

In sitting forth the basis of the rejection of claims 25-26 the examiner cites Tamura I as teaching (Answer, page 11):

purification of bovine " <sub>1</sub> -AGP and raising antisera for use in a single radial immunodiffusion assay. Tamura further discloses elevated serum " <sub>1</sub> -AGP in animals with various conditions, e.g., see p[age] 933: "The amount of circulating " <sub>1</sub> -AG<sup>1</sup> also seems to correlate with the extent of the disease ... Therefore, quantitative measurement of serum " <sub>1</sub> -AG in cattle may be a useful aid in monitoring the course of various diseases ... Furthermore, increases in " <sub>1</sub> -AG without apparent diseases may indicate sub-clinical pathological conditions."

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<sup>1</sup> The designation "AG", as used in Tamura I, Tamura II, and Itoh, represents " -1-acid glycoprotein. See Tamura I at page 987, line 1 of the Abstract.

Similarly, the examiner cites Tamura II as teaching alterations in " $\alpha_1$ -AGP in diseased cattle following treatment with antibiotics and upon reappearance of the disease condition.

(Answer, page 12). The examiner states that Itoh discloses (Answer, page 12):

changes in " $\alpha_1$ -AGP in cattle with inflammatory diseases and after surgical operations and also discloses that effective treatment of inflammatory diseases with antibiotics was correlated with return of the " $\alpha_1$ -AGP level to normal.

The examiner concludes that (id.):

it would have been obvious to one of ordinary skill in the art to measure and monitor " $\alpha_1$ -AGP in the body fluids of animals including cattle in order to assess the animals' health as taught by Tamura (1) or Tamura (2) or Itoh because each reference teaches both methods for measurement and the value of monitoring the " $\alpha_1$ -AGP in body fluid samples in animals such as cattle.

Appellant's only argument as to whether Tamura I, Tamura II, and Itoh are sufficient to establish a prima facie case of obviousness is that (Principal Brief, page 19): these publications arguably give some general guidance and may suggest exploration of the claimed animal management method. However, their teachings are not sufficiently specific to lead one of ordinary skill in the art to the claimed method. Simply because a method is arguably "obvious to try" does not make an invention obvious.

We do not agree that Tamura I, Tamura II and Itoh merely provide general guidance which might suggest exploration of the claimed animal management method. The references each describe the identification of diseased animals, the treatment and monitoring of the animals as the disease condition is treated by monitoring the " $\alpha_1$ -AGP

levels in the animal. Of particular relevance is that portion of Tamura I at page 992, column 2, first full paragraph which states:

the serum levels of . . . mucoproteins in cattle with hepatic abscess were much higher than those of healthy controls, and pointed out that the measurements of these serum markers were useful for determination of the prognosis of cattle with inflammatory diseases and also for monitoring the effectiveness of therapy.

Tamura I also suggests at page 993, column 1, second full paragraph that the evaluation of serum  $\alpha_1$ -AG levels may provide a useful markers for the screening for various abnormality. Similarly, Tamura II in the last paragraph of the translation would reasonably appear to describe the determination of the level of  $\alpha_1$ -AGP in normal healthy cattle's milk, compares this with the level of  $\alpha_1$ -AGP in cattle with mastitis, monitors the decrease to normal levels of this elevated level of  $\alpha_1$ -AGP after treatment with antibiotics, notes that the elevated levels reappeared upon reappearance of mastitis and concludes that "it is significant to measure AGP . . . in milk in order to track or observe the mastitis treatment."

Itoh also states (page 1296, column 1, last paragraph):

Those results suggest that serum  $\alpha_1$ -AG level in recovered cases was not increased, while it was high in unrecovered cases. As an indicators for the diagnosis of inflammatory disease, the assay of serum  $\alpha_1$ -AG seemed to be very useful for evaluation of an appropriate treatment and of condition of postoperative course in cattle.

Thus, these references reasonably appear to describe a process for monitoring or managing a group of animals, including cattle, where the normal levels of  $\alpha_1$ -AGP of healthy animals is determined, the AGP levels are monitored in diseased animals, and this

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serum marker is used as an diagnostic tool for evaluating the health of animals within the group in order to permit the treatment of the animals identified as having a diseased condition. On this record, the examiner's reasoning, supported by the facts and evidence presented, are sufficient to establish a prima facie case of unpatentability as to the claimed subject matter.

Having weighed appellant's arguments and evidence against the evidence in favor of unpatentability, we agree with the examiner's determination that Tamura I, Tamura II and Itoh are sufficient to establish a prima facie case of unpatentability as to the claimed subject matter which is not overcome by either arguments or convincing evidence. We, therefore, affirm the rejection of claims 25-26 under 35 U.S.C. § 103.

### **Summary**

The rejection of claims 1-26 under 35 U.S.C. § 103 over the combination of Fudenberg, Toyama, Shell, Ruhenstroth-Bauer, and Belpaire is reversed. The

rejection of claims 25-26 under 35 U.S.C. § 103 over the combination of Tamura I, Tamura II, and Itoh is affirmed.

No period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

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**AFFIRMED-IN-PART**

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