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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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 25

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BOSCO S. WANG, ARACELI L. LUMANGLAS,
and IAN C. HART

Appeal No. 95-3268
Application 07/521,695¹

ON BRIEF

Before WINTERS, WILLIAM F. SMITH and ROBINSON, Administrative Patent Judges.
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 5 - 32, all of the claims pending in the application. Claims 5 and 23 are illustrative of the claims on appeal and are appended to this decision.

¹ Application for patent filed May 15, 1990.

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The references relied upon by the examiner are:

Aston et al. (Aston I) EP 137,234 Apr.17, 1985

Guyton, Textbook of Medical Physiology, pub. W.B. Saunders Co., pages 919-923, (1981).

Aston (Aston II), Molecular Immunology, 24(2), pages 143-150, (1987).

Grounds of Rejection

Claims 23 - 25 stand rejected under 35 U.S.C. § 102. As evidence of anticipation, the examiner relies upon Aston (I) and Guyton.

Claims 5 - 32 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Aston (I) and Guyton.

Claims 5 - 22 and 26 - 32 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Aston (I), Guyton, and Aston (II).

We affirm the rejection of claims 23-25 under 35 U.S.C. § 102 and the rejection of claims 26, 31, and 32 under 35 U.S.C. § 103 and reverse the rejection of claims 5-22 and 27-30 under 35 U.S.C. § 103.²

² In view of our affirmance of the rejection of claims 23-25 under 35 U.S.C. § 102(b), the rejection of these claims under 35 U.S.C. § 103, over the same references, is rendered moot.

Background

The applicants' invention, as presently claimed, is described at page 2 of the specification as being directed to a method of enhancing animal growth by treating vertebrates with a combination of one or more antibodies to porcine somatotropin with porcine somatotropin. Additionally, at page 3 of the specification, applicants describe the other aspect of their invention as relating to potentiation of the activity of a somatotropin over prolonged periods of time by administering, to a vertebrate, a somatotropin in combination with one or more antibodies to said somatotropin, such that the weight of the vertebrate continues to exceed that of a vertebrate treated with the same amount of the somatotropin alone over a given period of time.

Discussion:

The rejection under 35 U.S.C. § 102(b)

Claims 23-25 stand rejected under 35 U.S.C. § 102(b) as anticipated by Aston(I) as evidenced by Guyton.

Guyton is relied upon, by the examiner, only to establish that the term "somatotropin" is synonymous with the phrase "growth hormone" (Answer, page 6), a fact conceded by appellants (principal brief, page 8). We therefore view these terms as interchangeable in our discussion of the issues in this appeal. Thus, the sole issue before us under this ground of rejection, is whether Aston (I) anticipates the subject matter of claims 23-25.

Anticipation requires the disclosure, in a single prior art reference, of each element of the claim under consideration. W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). In considering Aston (I), we note particularly Example A, which discloses the administration of a human growth hormone and antibody combination to non-human vertebrate. The observed results, over a period of three weeks, included increased weight gain in the thus treated mice as compared to the control given no growth hormone or given growth hormone without the antibody. This example would reasonably appear to meet all limitations of claim 23 and establish a prima facie case of anticipation of the claimed subject matter with regard to claims 23-25.

In rebuttal, appellants argue that the reference fails to disclose the limitations of claim 23, which require "potentiating the activity of a somatotropin over prolonged periods of time" and "such that the weight of the vertebrate [, non-human] continues to exceed that of a vertebrate [, non-human] treated with the same amount of said somatotropin alone over a given period of time." (reply brief, page 3). Where functional language is used, it is appropriate to look to the specification for guidance in determining the finite amounts which correspond to the functional language. See In re Woodruff, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); In re Herz, 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976). We find nothing in the specification which would define or limit this

cited functional claim language. Additionally, we find nothing which would reasonably suggest that the 21 day period of Example A of Aston (I) would not be regarded as a "prolonged period of time." The reference does not teach that the observed effect on weight gain ended after the 21 days, only that the test data was recorded only for that specified time period. Similarly, there is nothing in the specification which would indicate that the observed weight gain in the mice of Example A of Aston (I) treated with the growth hormone and antibody combination as compared to that of growth hormone alone, would not meet the requirement that "the weight of the vertebrate, non-human continues to exceed that of a vertebrate, non-human treated with the same amount of said somatotropin alone over a given period of time" as required by the claim 23. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown in the art does not possess the characteristic relied on. This burden is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and In re Swinehart, 439 F.2d 210, 212-213, 169 USPQ 226, 228- 229 (CCPA 1971). On the record before us, the appellants have offered no evidence which would demonstrate that the method disclosed Aston (I) would not result in the functionally defined results of

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"potentiating the activity of a somatotropin over prolonged periods of time" and "such that the weight of the vertebrate, non-human continues to exceed that of a vertebrate, non-human treated with the same amount of said somatotropin alone over a given period of time" as claimed.

We find no error in the examiner's findings that Aston (I) taken with Guyton establish a prima facie case of unpatentability of the subject matter of claims 23-25. We, therefore, affirm the rejection of claims 23-25 under 35 U.S.C. § 102(b).

The rejections under 35 U.S.C. § 103

Claims 5-22 and 27-30:

A conclusion of obviousness under 35 U.S.C. § 103 must be based upon the claimed subject matter as a whole. Accordingly, before turning to the merits of the examiner's rejection, we must first determine what subject matter is claimed.

We read claims 5-22 and 27-30 to require, in relevant part, the administration of a somatotropin and one or more monoclonal antibodies obtained from the deposited hybridomas designated as PS-7.6 (ATCC HB 10416), PS-3.12 (ATCC HB 10415) and PS-8.3 (ATCC HB 10417); no more and no less. The examiner has offered no evidence or put forth no facts relating to the use of these specified monoclonal antibodies. 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). The examiner's rejection of these claims is fatally defective since they do not properly account for and establish the obviousness of the subject matter as a whole. 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). We conclude that, with regard to claims 5-22 and 27-30, the examiner has failed to establish a prima facie case of obviousness. We, therefore, reverse the rejection of claims 5-22 and 27-30 under 35 U.S.C. § 103.

Claims 26, 31 and 32:

Claims 26, 31, and 32 stand rejected under 35 U.S.C. § 103 as being obvious over Aston (I) in view of Guyton and as obvious over Aston (I) in view of Guyton and Aston (II). We elect to treat these two grounds of rejection together, since the rejection over Aston (I) and Guyton is subsumed by the rejection over Aston (I), Guyton, and Aston (II).

As noted above, it is the initial burden of the patent examiner to establish that claims presented in an application for patent are unpatentable. In re Oetiker, supra. On the record before us, we agree that Aston (I) generically discloses the potentiating of the hormonal activity of growth hormones by administering, to non-human vertebrate, a growth hormone with at least one antibody which binds to that hormone in order to obtain an increase in cumulative weight gain in the vertebrate. In addition, Aston (II), which discloses porcine somatotropin as a growth hormone, would have suggested to those of

ordinary skill in this art to substitute porcine somatotropin and its antibodies for the growth hormone and antibodies of Aston (I). Where, as here, a prima facie case of obviousness has been established, the burden of going forward shifts to the appellants. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984), In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147, (CCPA 1976).

The appellants have offered no arguments or evidence to indicate that one of ordinary skill in this art would have expected any difference in results in the methodology of Aston (I) if porcine somatotropin were substituted for the human growth hormone specifically disclosed.

In rebuttal, appellants' urge (principal brief, pages 20 and 21) that Aston (I) does not teach:

the novel concept that administration of an antibody to a somatotropin together with that somatotropin potentiates the activity of the somatotropin over prolonged periods of time, such that the weight of the vertebrate continues to exceed that of a vertebrate treated with the same amount of the somatotropin alone.

However, as we pointed out in our consideration of the rejection of claims 23-25 under 35 U.S.C. § 102(b), supra, this functional language is not defined in the specification and does not serve to distinguish the claimed subject matter from the disclosure of Aston (I).

To the extent that appellants have attempted to compare the claimed method with that of Aston (I) (principal brief, pages 9-16 and 21-22), we note that there are no side-by-

side comparisons. In comparing the evidence of the specification with the evidence presented in *Aston* (I), appellants attempt to compare results where the test animals differ, the regimens of administration differ, and where the dosages differ. We find that we agree with the examiner's determination (Answer, pages 14-15) that appellants have provided no relevant evidence which establishes the alleged unexpected results. It is well settled that the burden of establishing the significance of data in the record, with respect to unexpected results or for other purposes, rests with appellants, which burden is not carried by mere arguments of counsel. See generally *In re Geisler*, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997); *In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1689-90 (Fed. Cir. 1996); *In re Merck & Co., Inc.*, 800 F.2d 1091, 1099, 231 USPQ 375, 381 (Fed. Cir. 1986).

To the extent that appellants may allege criticality with regard to the number of days of administration, the dosage amounts, percentage weight gain, number of injections, or appellants' 56 day study, we note simply that there are no claim limitations directed to these parameters and therefore they do not serve to distinguish the claimed subject matter from the disclosure of the cited references.

On the record before us, we find that the examiner has established a prima facie case of unpatentability of the claimed method. Appellants have failed to overcome the prima facie case against patentability, either by arguments or evidence. Therefore, the

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rejection of claims 26, 31, and 32 under 35 U.S.C. § 103 is affirmed.

SUMMARY

To summarize, the decision of the examiner to reject claims 23-25 under 35 U.S.C. § 102 is affirmed. The decision of the examiner to reject claims 26, 31 and 32, under 35 U.S.C. § 103 is affirmed. The decision of the examiner to reject claims 5-22 and 27-30 is reversed.

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

AFFIRMED-IN-PART

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
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DOUGLAS W. ROBINSON)	
Administrative Patent Judge)	

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AMERICAN CYANAMID COMPANY
PATENT LAW DEPARTMENT
ONE CYANAMID PLAZA
WAYNE, NJ 07470-8426

APPENDIX

5. A method for potentiating the activity of pST which comprises administering to a vertebrate, non-human an effective growth enhancing amount of pST and an effective pST-potentiating amount of one or more monoclonal antibodies which specifically bind pST or an antigenic equivalent of pST, wherein the monoclonal antibodies are selected from the group consisting of monoclonal antibodies designated PS-7.6 (ATCC HB 10416), PS-3.12 (ATCC HB 10415) and PS-8.3 (ATCC HB 10417).

23. A method for potentiating the activity of a somatotropin over prolonged periods of time which comprises administering to a vertebrate, non-human an effective growth enhancing amount of a somatotropin and an effective somatotropin-potentiating amount of one or more antibodies which specifically bind said somatotropin or an antigenic equivalent of said somatotropin, such that the weight of the vertebrate non-human continues to exceed that of a vertebrate, non-human treated with the same amount of said somatotropin alone over a given period of time.