

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

Appeal No. 2004-0761
Application No. 09/794,531

ON BRIEF

Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-18 and 27-80. Claims 19-26 are also pending but have been withdrawn from consideration. Claim 1 is representative and reads as follows in the attached appendix.

The examiner relies on the following references:

Loria

WO 97/37662

Oct. 16, 1997

Berkow, Merck Manual of Diagnosis and Therapy, 16th ed., pp. 1750-1751 (1992)

Claims 1-18 and 27-80 stand rejected under 35 U.S.C. § 103.

We reverse.

Background

" Δ 5-Androstenediol (AED) is a naturally-occurring metabolite of dehydroepiandrosterone (DHEA), the most abundant product of the adrenal glands. . . . AED exists in two epimeric forms: Δ 5-androstene-3- β ,17 α -diol (α AED) and Δ 5-androstene-3- β ,17 β -diol (β AED). . . . β AED has immunostimulating properties and immune upregulating properties. α AED has been shown to induce apoptosis in transformed cells in vitro." Specification, page 2.

Discussion

Claim 1, the broadest claim on appeal, is directed to a two-step method of treating cancer (or precancer, or metastatic cancer). In the first step of the claimed method, α AED or an ether or ester derivative thereof is administered to the patient, and in a second, subsequent step, β AED or an ether or ester derivative is administered.

The examiner rejected all of the claims as obvious in view of Loria and Berkow. The examiner cited Berkow, however, only for its teaching that "aminoglutethimide and orchiectomy are useful in treating prostate cancer." Examiner's Answer, page 5. This teaching seems to be relevant only to certain dependent claims, and therefore we need not discuss Berkow further.

The examiner cited Loria's teachings that α AED inhibits tumor growth, and that the combination of α AED and β AED inhibited proliferation of breast cancer cells in vitro. See the Examiner's Answer, page 4. The examiner also noted that

Loria “teaches that β AED can enhance immune response, and [is] also useful in counteracting the untoward effects of irradiation and chemotherapy.” Id.

The examiner conceded that “Loria does not expressly teach the compounds are administered in a subsequent manner,” id., but asserted that “the optimization of therapeutic effect parameters (e.g., dosing regimens) is obvious as being within the skill of the artisan.” Id., page 5. See also page 7: “[A]djusting and optimizing the timing and administration order of the compounds would be obvious as being within the purview of the skilled artisan.”

Appellant argues that the cited references would not have suggested the claimed method of sequentially administering α AED and β AED. See the Appeal Brief, pages 8-9: “[T]he activity of the combination of α AED alone or the activity of α AED and β AED does not suggest using α AED and β AED sequentially. If anything, it suggests that α AED and β AED should be used in combination and not sequentially. Therefore, Loria does not suggest treating cancer using sequential administration of α AED and β AED. . . . Berkow does not provide any teaching or suggestion related to the administration of α AED and β AED.”

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

In considering whether a claimed invention would have been obvious at the time it was made, examiners must be careful to avoid interpreting the

references in light of the later-filed patent application. See In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999): “Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.” In the words of Judge Learned Hand, obviousness is “the creature of an imagination projected upon the future out of materials from the past.” Schaefer, Inc. v. Mohawk Cabinet Co., Inc., 276 F.2d 204, 207, 125 USPQ 318, 320 (2d Cir. 1960).

To show that a claimed invention would have been prima facie obvious, the examiner must provide evidence that the prior art would have suggested the invention as a whole to those of ordinary skill in the art. “Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.” In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000).

In this case, we agree with Appellant that the examiner has not adequately explained how the cited references would have suggested the method defined by claim 1 to a person of ordinary skill in the art reading them without the benefit of

the instant specification. In particular, the examiner has pointed to nothing in the prior art that would have led those of skill in the art to administer first α AED and then, subsequently, β AED.

The examiner pointed out that Loria teaches that the combination of α AED and β AED was effective in vitro for inhibiting the growth of breast cancer cells (Example 2). Loria also teaches, however, that the two epimers have different activities when used separately. See page 7, lines 4-13: At concentration[s] of nM or greater, the α AED significantly inhibited the growth of ZR-75-1 [breast cancer] cells. . . . As opposed to α AED, the β AED alone at 100 nM concentrations did not have any antiproliferative effect on the growth of the ZR-75-1 cells.”

The examiner cannot rely on a conclusory statement that “optimization of therapeutic effect parameters (e.g., dosing regimens) is obvious as being within the skill of the artisan,” in order to make up for deficiencies in the prior art. It is true that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). That rule, however, applies only where the variable being optimized is one that is known to affect the results of the particular process; i.e., the knowledge that the variable is result-affecting provides the motivation to optimize it. The examiner has pointed to no evidence of record showing that those of skill in the art would have been motivated to add a subsequent step of administering β AED in order to “optimize” the known process of inhibiting tumor cell growth by administering α AED.

Summary

The references cited by the examiner do not support a prima facie case of obviousness. The rejection under 35 U.S.C. § 103 is reversed.

REVERSED

Donald E. Adams)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Eric Grimes)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Lora M. Green)	
Administrative Patent Judge)	

EG/jlb

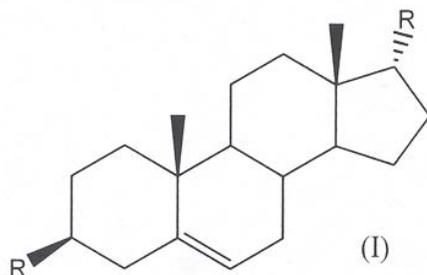
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Parker and Destefano
300 Preston Avenue
Suite 300
Charlottesville, VA 22902

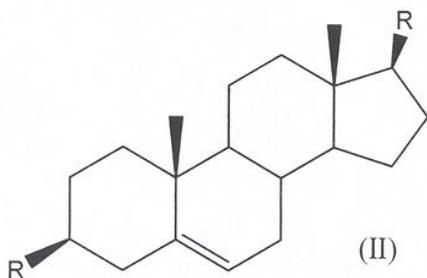
APPENDIX

1. A method of treating precancer, cancer, or metastatic cancer in a patient in need of such treatment comprising delivering to the tissues of said patient or administering to said patient a therapeutically effective amount of one or more compounds of formula (I):



wherein each R is independently selected from the group consisting of a hydroxyl, a C₁-C₃₀ ether and a C₁-C₃₀ ester; and

subsequently delivering to the tissues of said patient or administering to said patient a therapeutically effective amount of one or more compounds of formula (II):



wherein each R is independently selected from the group consisting of a hydroxyl, a C₁-C₃₀ ether and a C₁-C₃₀ ester.

