

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ANWAR A. HUSSAIN

Appeal No. 1999-1472
Application No. 08/591,767

ON BRIEF

Before WINTERS, MILLS, and GRIMES Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

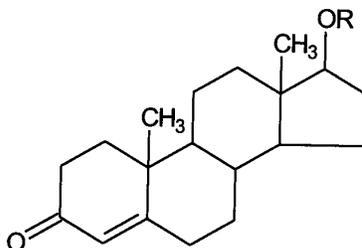
DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 15, which are all of the claims in the application.

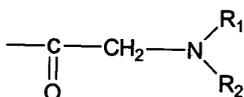
REPRESENTATIVE CLAIMS

Claims 1 and 7, which are illustrative of the subject matter on appeal, read as follows:

1. (Amended) A water-soluble testosterone analog having the following chemical structure:

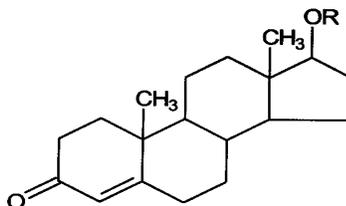


wherein R is:

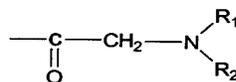


and R₁ and R₂ are lower alkyl.

7. (Twice amended) A method for increasing plasma testosterone levels comprising intranasally administering to a mammal in need of such treatment an effective amount of a testosterone analog having the following structure:



wherein R is:



and wherein R₁ and R₂ are lower alkyl.

THE PRIOR ART REFERENCE

The prior art reference relied on by the examiner is:

Hale et al. (Hale)	5,622,944	Apr. 22, 1997
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THE ISSUE

The issue presented for review is whether the examiner erred in rejecting claims 1 through 15 under 35 U.S.C. § 103(a) as unpatentable over Hale.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

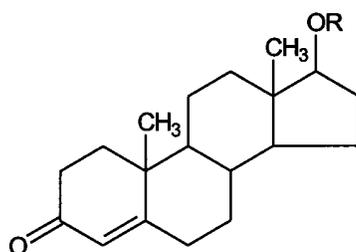
- (1) the instant specification, including all of the claims on appeal;
- (2) applicant's Appeal Brief (Paper No. 15);
- (3) the Examiner's Answer (Paper No. 16); and
- (4) the above-cited prior art reference.

On consideration of the record, including the above-listed materials, we reverse the examiner's prior art rejection.

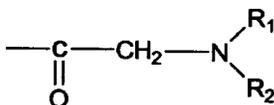
DISCUSSION

Initially, we invite attention to section (11) of the Examiner's Answer entitled "Response to Argument." There, at page 6, line 2, the examiner cites "US patent 5,61,141 [sic], col. 13, lines 25-33." This is a reference to US Patent No. 5,661,141 issued August 26, 1997 to Petrow, made of record in the advisory action mailed June 8, 1998 (Paper No. 9). Conspicuously, the examiner does not rely on Petrow in the statement of rejection under 35 U.S.C. § 103(a). As stated in In re Hoch, 428 F.2d 1341, 1342 n. 3, 166 USPQ 406, 407 n. 3 (CCPA 1970), "Where a reference is relied on to support a rejection, whether or not in a 'minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection." Here, the examiner does not rely on Petrow in setting forth the rejection under 35 U.S.C. § 103(a), and we shall not consider that reference further.

The claims on appeal call for a "testosterone analog" having the following chemical structure:



where R is:



and R₁ and R₂ are lower alkyl. It can be seen that the claims circumscribe a relatively narrow subgenus of compounds, where variables R₁ and R₂ are lower alkyl groups. Claims 1, 2, and 3 recite the testosterone analogs per se. Claims 4, 5, and 6 define an intranasal pharmaceutical composition comprising applicant's testosterone analog and a pharmaceutically acceptable carrier therefore. Finally, claims 7 through 15 recite a method for increasing plasma testosterone levels comprising intranasally administering to a mammal in need of such treatment an effective amount of the testosterone analog.

In setting forth the rejection of claims 1 through 15 under 35 U.S.C. § 103(a), the examiner refers to a genus/subgenus relationship between compounds disclosed by Hale and the testosterone analogs recited in the claims on appeal. The premise of the rejection is that (1) applicant's claims recite "a more limited genus" of testosterone analogs than the genus disclosed by Hale, and (2) it would have been obvious to a person having ordinary skill in the art "to make any of the compositions as taught by [Hale], including those of the instant claims" (Examiner's Answer, page 4, first full paragraph, emphasis added). We disagree with this line of reasoning.

The examiner appears to invoke a per se rule of obviousness, holding the claimed subject matter obvious because Hale discloses a class of testosterone prodrugs embracing the "more limited genus" of compounds recited in the appealed

claims. But that is not the law. As stated in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995), the use of per se rules flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient, but reliance on per se rules of obviousness is legally incorrect and must cease. See In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious); and In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (we decline to extract from Merck [Merck & Co. v. Biocraft Labs.], 874 F.2d 804, 806-09, 10 USPQ2d 1843, 1845-48 (Fed. Cir. 1989)] the rule that the solicitor appears to suggest-that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it).

Nor has the examiner established that the Hale patent contains guidelines or a pattern of preferences which would have led a person having ordinary skill in the art to the specific subject matter recited in claims 1 through 15. We agree with applicant and the examiner that Hale's prodrug 2.2 listed in Table 3 (column 37) appears to constitute the closest exemplified prior art compound. That prodrug, however, contains a charged chemical modifier as do most of the compounds disclosed by Hale. Simply stated, the examiner has not explained how a person having ordinary skill in the art would have been led from "here to there," i.e., from the testosterone prodrugs disclosed by Hale to the specific subgenus of testosterone analogs recited in the claims on appeal.

Further respecting claims 7 through 15, we find that Hale discloses transdermal delivery of testosterone prodrugs; that transdermal administration and intranasal

administration are distinctly different modes of administration; and that Hale does not disclose or suggest a method for increasing plasma testosterone levels by intranasally administering to a mammal in need of such treatment an effective amount of testosterone prodrugs. We enter those findings, notwithstanding the passing reference in Hale to "mucous membranes" (column 5, line 21).

For these reasons, we shall not sustain the rejection of claims 1 through 15 under 35 U.S.C. § 103(a) as unpatentable over Hale.

The examiner's decision is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Demetra J. Mills)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Eric Grimes)	
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