

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 12

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte SYED M. SHAH, PANOLIL RAVEENDRANATH,
and MICHAEL Z. KAGAN

Appeal No. 2001-1020
Application No. 09/063,524

ON BRIEF

Before WINTERS, SCHEINER, and GRIMES, 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 1-3, 17, and 18. Claims 1 and 17 are representative and read as follows:

1. A compound which is a pharmaceutically acceptable salt of 3 β -hydroxy-5,7,9-estratriene-17-one 3-sulfate ester.
17. A pharmaceutical composition consisting essentially of 3 β -hydroxy-5,7,9-estratriene-17-one or a pharmaceutically acceptable salt of its 3-sulfate ester and a pharmaceutical carrier.

The examiner relies on the following references:

Goodman and Gilman's The Pharmacological Basis of Therapeutics (Goodman & Gilman), pp. 1420-1429 (7th ed. 1985)

Physicians' Desk Reference (PDR), pp. 2594-2596 (48th ed. 1994)

Claims 1-3, 17, and 18 stand rejected under 35 U.S.C. § 102(b) as anticipated by either the PDR or Goodman & Gilman.

We reverse.

Background

The specification discloses that “naturally occurring estrogenic compositions of substantial purity and low toxicity such as PREMARIN (conjugated equine estrogens)” are a standard treatment for hormone-related disorders including osteoporosis. Page 1. The specification also discloses that “3 β -hydroxy-5,7,9-estratriene-17-one 3-sulfate ester sodium salt is a minor component in PREMARIN.” Id. The specification discloses that 3 β -hydroxy-5,7,9-estratriene-17-one 3-sulfate ester sodium salt is present in PREMARIN at something less than one percent. See page 2, lines 8-11.

Discussion

The claims are directed to a pharmaceutically acceptable salt of 3 β -hydroxy-5,7,9-estratriene-17-one 3-sulfate ester (claims 1 and 2); the sodium salt of 3 β -hydroxy-5,7,9-estratriene-17-one 3-sulfate ester, at least 1% pure (claim 3); and pharmaceutical compositions consisting essentially of 3 β -hydroxy-5,7,9-estratriene-17-one, or a pharmaceutically acceptable salt of its 3-sulfate ester, and a pharmaceutical carrier (claims 17 and 18).

The examiner rejected all of the claims as anticipated by either the PDR or Goodman & Gilman. Her reasoning was that

[b]oth references teach Premarin and its estrogenic properties. . . . As indicated on page 1, lines 8-9 of the present specification, 3 β -hydroxy-5,7,9-estratriene-17-one 3-sulfate ester sodium salt is a component of Premarin. Therefore, the compound and composition recited by the instant claims are encompassed by the prior art composition.

Examiner's Answer, page 3. The examiner also cited Ex parte Reed, 135 USPQ 34 (POBA 1962), as establishing the rule that "a substance merely extracted from its parent material[,] even if in purer form," is unpatentable unless it possesses a utility different from the parent material and not evident from the art. See the Examiner's Answer, page 3. The examiner concluded that that test was not met in this case and "[t]herefore, the compound as claimed is not patentable."
Id.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). If a claimed composition is the same as a known composition, claim limitations setting out inherent properties will not distinguish the claim from the prior art. See In re Pearson, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974) ("[T]erms [that] merely set forth the intended use for, or a property inherent in, an otherwise old composition . . . do not differentiate the claimed composition from those known in the prior art."). However, the initial burden is on the examiner to establish that all of the limitations of the claims are

necessarily present in the prior art product. See Ex parte Skinner, 2 USPQ2d 1788, 1789 (Bd. Pat. App. Int. 1986) (“[T]he examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art” before the burden is shifted to Applicants to disprove the inherency.).

Here, we agree with Appellants that the examiner has not shown the claims to be anticipated by either the PDR or Goodman & Gilman. We find ourselves in agreement with the following position, stated in the Appeal Brief:

Claims 1 and 2 are compound claims, covering a single compound. . . . Neither of the references teach a single compound, but teach Premarin as a mixture of estrogenic components, and neither of the references teach anything about [the specifically claimed compound] at all. Claim 3 is a compound claim which covers [the compound] in greater than 1 percent purity, which is substantially more pure than it is in Premarin. Neither of the references discloses or teaches [the compound] in greater than one percent purity. . . . Claims 17 and 18 are pharmaceutical composition claims which cover a pharmaceutical composition containing [the compound] (or a salt of its 3-sulfate ester) as the sole active ingredient plus a pharmaceutical carrier. Neither of the references discloses a pharmaceutical composition containing [the compound] (or a salt of its sulfate ester) as the sole active ingredient in the composition. As none of the references contain all the limitations required by the claims, . . . Claims 1-3 and 17-18 are not anticipated by the PDR or Goodman and Gilman.

Page 4.

In addition, the examiner’s reliance on Ex parte Reed is misplaced. Reed does not reflect the current state of the law. It is by now well-established that the degree of purity of a compound can render it patentable over the same compound in an unpurified state, even if both materials share the same utility. See, e.g., In re Bergstrom, 427 F.2d 1394, 1401, 166 USPQ 256, 262 (CCPA

1970): “[B]y definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference, as seems to be the situation here, perforce the ‘pure’ materials are ‘new’ with respect to them” (footnote omitted, emphasis in original). See also Genentech Inc. v. Wellcome Foundation Ltd., 29 F.3d 1555, 1562, 31 USPQ2d 1161, 1166 (Fed. Cir. 1994) (claims to an enzyme preparation recited a particular specific activity; the court called the specific activity limitation “the critical distinction of those claims over the less purified materials constituting the relevant prior art.”).

Summary

The examiner has not shown the claimed compounds or compositions to be identically disclosed in the prior art. Therefore, the rejection under 35 U.S.C. § 102(b) is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Eric Grimes)	
Administrative Patent Judge)	

EG/dym

Appeal No. 2001-1020
Application No. 09/063,524

Page □PAGE □6□

Ronald W. Alice
American Home Products Corporation
Patent Law Department –2B
One Campus Drive
Parsippany NJ 07054