

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ATUL D. AYER, RICHARD L.-C YIEH,
BRENDA J. POLLOCK and PATRICK S.-L WONG

Appeal No. 1996-2784
Application No. 08/069,069

ON BRIEF

Before, STONER, Chief Administrative Patent Judge and
DOWNEY and WILLIAM F. SMITH, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 6 and 7, the only claims remaining in the application. Claims 6 and 7 read as follows:

6. A method for administering an antiepileptic drug to the gastrointestinal tract of humans, wherein the method comprises:

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(a) admitting orally into the human a dosage form comprising 10 nanograms to 750 milligrams of an antiepileptic drug selected from the group consisting of valproic acid, valproic acid salts, sodium valproate, potassium valproate, calcium valproate, valpromide, valproic ester, divalproex sodium, oligomer salt of valproic acid, prodrug of valproic acid, and pharmaceutically acceptable derivatives of valproic acid; which drug possessing antiepileptic therapy is administered from a dosage form comprising a member selected from the group consisting of a sustained-release dosage form and a controlled-release dosage form; and,

(b) administering the antiepileptic drug from the dosage form over a therapeutic dose up to 750 mg over an extended period of time up to 30 hours to provide the antiepileptic therapy.

7. A method for administering an antiepileptic drug to the gastrointestinal tract of a human, wherein the method comprises:

(a) admitting orally into the human a dosage form comprising 10 nanograms to 750 milligrams of a member selected from the group consisting of one to three moles of valproic acid and one to six moles of a salt of valproic acid; an oligomer of valproic acid salt, and valproic acid containing four moles of the salt and the acid; three moles of valproic acid and calcium valproate; valproic acid and sodium valproate; valproic acid and divalproex sodium and calcium valproate and valpromide; which drug possessing antiepileptic therapy is administered from a dosage form comprising a member selected from the group consisting of a sustained-release

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dosage form and a controlled-release dosage form; and,

(b) administering the antiepileptic drug from the dosage form over a therapeutic dose up to 750 mg over an extended period of time up to 30 hours to provide the antiepileptic therapy.

The reference relied upon by the examiner is:

Theeuwes et al. (Theeuwes) 3,916,899 Nov. 04,
1975

Claims 6 and 7 stand rejected under 35 U.S.C. § 102(b) as anticipated by Theeuwes. We reverse.

Discussion

As set forth in RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984)

"Anticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention." (citation omitted). The active agent required by claims 6 and 7 is valproic acid or various derivatives thereof. The examiner's statement of the rejection as it appears at page 3

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of the examiner's answer reads:

Theeuwes '899 teaches a control release device (abstract). Oral administration is disclosed (column 12, lines 10-13). Drugs without limitation are disclosed (column 15, lines 33-35), including anticonvulsants (column 16, lines 1-2). Valproic acid is well-known in the pharmaceutical art as an anticonvulsant for the treatment of epilepsy. (Emphasis original)

The examiner has correctly determined that Theeuwes describes a method of administering a drug to a human in a sustained-release or controlled-release form. The examiner also correctly determined that the active agent which may be administered in Theeuwes can be broadly a drug and specifically an anticonvulsant. Where the examiner's case falls apart, however, is in his attempt to account for the claim requirement that the active agent is valproic acid or a derivative thereof.

In stating the rejection, the examiner only mentions that valproic acid is a known anticonvulsant. This is correct. See, e.g., the paragraph bridging pages 1-2 of the specification. However, the fact that valproic acid may be a known

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anticonvulsant does not mean that Theeuwes describes its use as the active agent in the controlled-released or sustained-released dosages of that invention. Manifestly, the examiner has not established that Theeuwes mentions valproic acid by name. Nor has the examiner begun to establish that Theeuwes describes valproic acid under the "principles of inherency." The open ended description of active agents in Theeuwes which includes drugs in general and anticonvulsants specifically does not mean

that Theeuwes describes each and every possible compound which meet those descriptions. Absent a fact-based explanation from the examiner to why Theeuwes describes the subject matter of claims 6 and 7 in their entirety, we find that the examiner has not properly established a prima facie case of anticipation.

The decision of the examiner is reversed.

REVERSED

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	BRUCE H. STONER, JR.)	
	Chief Administrative Patent Judge)	
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)	
	MARY F. DOWNEY)	BOARD OF PATENT
AND)	APPEALS
	Administrative Patent Judge)	
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	WILLIAM F. SMITH)	
	Administrative Patent Judge)	INTERFERENCES

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