

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte ROBERT E. GARFIELD and KRISTOF CHWALISZ

Appeal No. 2001-0982
Application No. 08/310,950

ON BRIEF

Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

ADAMS, 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 1-23, which are all the claims pending in the application.

Claims 1 and 16 are illustrative of the subject matter on appeal and are reproduced below:

1. A method of treatment selected from the group consisting of (a) preventing or treating atherosclerotic vascular disease in a mammal; b) hormone replacement therapy in a peri- or post-menopausal female mammal; and c) treating hypertension in a mammal, which comprises administering to the afflicted mammal an amount of prostacyclin or prostacyclin analog in combination with one or more of an estrogen and a progestin, in amounts effective to ameliorate or prevent the appearance of the symptoms thereof, wherein said amounts are synergistically effective and the amounts of prostacyclin, prostacyclin analog, estrogen or progesterone are individually ineffective or marginally effective.

16. A pharmaceutical composition comprising an admixture of (a) prostacyclin or prostacyclin analog and at least one of (c) an estrogen and (d) a progestin, wherein the amounts of (a) and (c) and/or (d) are synergistically effective and are individually ineffective or marginally effective.

According to appellants' dependent claims the prostacyclin or prostacyclin analog may be iloprost (see e.g., claim 7), the progestin may be progesterone (see e.g., claim 10), and the estrogen may be an estradiol (see e.g., claim 12). As set forth in appellants' specification (pages 9-10) the method aspect of the invention involves administering a prostacyclin or a prostacyclin analog in a amount bioequivalent to 0.1-10 ng/kg/min of prostacyclin intravenously, and one or both of a progestin and an estrogen in an amount of estrogen bioequivalent to approximately 2 mg per day of estradiol and an amount of progestin bioequivalent to 50-300 mg of injected progesterone. Furthermore, the specification states (page 10), "[a] synergistic effect is achieved when a progestational and/or estrogenic agent is administered concurrently with the prostacyclin or prostacyclin analog."

The references relied upon by the examiner are:

Adams et al. (Adams), "Effects of Estrogens and Progestins on Atherosclerosis in Primates," in Sex steroids and the cardiovascular system, Schering Foundation Workshop 5, pp. 161-175 (P. Ramwell et al., eds., Springer Verlag) (1992)

Braun et al. (Braun), "Antiatherosclerotic Properties of Oral Cicaprost in Hypercholesterolemic Rabbits," Prostaglandins in the Cardiovascular System, pp 282-288 (1992)

GROUND OF REJECTION

Claims 1-23 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

Claims 1-23 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite since they are not limited to the elected species.¹

Claims 1-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Adams in view of Braun.

We reverse.

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, bridging sentence, pages 3-4), appellants' "claims are beyond the limited specification since they do not claim the amounts of active agents which will yield the synergistic effect."

However, as appellants' explain (Reply Brief, page 1), the claims are limited to "synergistically effective amounts". In addition, appellants emphasize (Reply Brief, page 4), "[t]he specification clearly indicates that the invention can provide a synergistic effect; see page 10, lines 25-30." Furthermore, appellants argue (Reply Brief, page 1), "[d]etermining synergistically effective amounts of the individual components of the composition other than those explicitly

¹ It appears through an inadvertent error the examiner did not restate this ground of rejection under § 10 of the Answer. Nevertheless, the examiner clearly maintained this ground of rejection at page 5 of the Answer ("Therefore the rejection is proper under 35 USC 112 [sic], second paragraph since the claims are indefinite.").

disclosed in the specification would require no more than routine experimentation in view of the extensive teachings of the specification and level of skill in the art.

In this regard, we remind the examiner whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

On this record, the examiner provides no analysis consistent with holding in Wands. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement. The burden of proof does not shift to appellant until the examiner first meets his burden.

In re Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370.

Accordingly, we reverse the rejection of claims 1-23 under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH:

According to the examiner (Paper No. 17, page 2), the claims “are indefinite as to the medical disorder to be treated. The claims are not limited to the elected species which [sic] was examined, i.e., hormone replacement therapy.”

However, as appellants point out (Reply Brief, page 2²), “such limitation is premature, since the [e]xaminer would be compelled to continue examination of the full scope of the claims once the § 103 rejection is withdrawn.” We agree. See MPEP § 803.02. Accordingly, we reverse the rejection of claims 1-23 under 35 U.S.C. § 112, second paragraph as indefinite since they are not limited to the elected species.

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 4), Adams “teach the beneficial effects of hormone replacement therapy in the treatment of atherosclerosis” and Braun “teach Prostacyclin is benificail [sic] in the treatment of atherosclerosis.” Based on this evidence and with reference to In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), the examiner concludes “it would have been prima facie obvious under 35 U.S.C. [§] 103 to administer a composition of iloprost/progesterone/estradiol jointly as a method of HRT

² For administrative convenience we refer to the pages of the Reply Brief as if they were numbered consecutively from the first page through the last page (page 4).

[hormone replacement therapy].” We note, however, the examiner’s failure to identify the amount of prostacyclin or other hormone taught by Adams or Braun. In addition, we note that according to the examiner the results taught by Adams and Braun demonstrate that the individual use of the hormones was “beneficial,” contrary to the requirements of the claimed invention wherein “the amounts of prostacyclin, prostacyclin analog, estrogen or progesterone are individually ineffective or marginally effective.”

In addition, we note appellants’ argument (Reply Brief, page 4) that notwithstanding the examiner’s conclusion “there was no expectation that the use of the combination of a prostacyclin with a progestin and/or an estrogen for treatment of hypertension, hormone replacement therapy and/or atherosclerosis would be that the combination of compounds would have a synergistic effect.” While we recognize that synergism, in and of itself, is not conclusive of unobviousness³, on this record the examiner failed to provide evidence suggesting that something more than an additive effect would be obtained through the combination of Adams with Braun. In this regard, we note the examiner’s reliance (Answer, page 5), “on the rejection made in the final office action as set forth above.” As set forth in the Final Office Action, the examiner finds (Paper No. 17, page 2), “[t]he motivation is obvious to combine the agents to achieve an additive effect.” Stated differently, the examiner has provided no evidence, on this record, to suggest that a synergistic effect would have been expected.

³ See In re Huellmantel, 324 F.2d 998, 1003, 139 USPQ 496, 500 (1963) (synergism might be expected.).

Based on the evidence before us, it is our opinion that the examiner failed to meet his burden⁴ of providing the evidence necessary to establish a prima facie case of obviousness. Accordingly, we reverse the rejection of claims 1-23 under 35 U.S.C. § 103 as being unpatentable over Adams in view of Braun.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
)
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) BOARD OF PATENT
Donald E. Adams)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Lora M. Green)
Administrative Patent Judge)

⁴ The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

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