

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte GEORGE F. EL KHOURY and CHRISTOPH STEIN

Appeal No. 2003-1765
Application No. 09/319,735

ON BRIEF

Before SCHEINER, MILLS and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1-3, 5-9 and 11-22, the only claims remaining in the application. Claims 1 and 8 are representative of the subject matter on appeal:

1. A method of inducing analgesia in inflamed skin or mucosal tissue, comprising topically administering to a patient in need of such treatment a topically effective amount of an opioid analgesic agent, which amount is systemically ineffective for induction of analgesia, admixed with a pharmaceutically acceptable excipient for topical administration, wherein said opioid is cyclazocone, piperidine, piperazine, pyrrolidine, morphiceptin, meperidine, trifluadom, benzeneacetamine, diacylacetamide, benzomorphan, hydromorphone, oxymorphone, levophanol, methadone, meperidine, fentanyl, codeine, hydrocodone, oxycodone, propoxyphene, buprenorphine, butorphanol, pentazocine or nalbuphine.

8. A pharmaceutical composition comprising an admixture of an opioid analgesic agent and a pharmaceutically acceptable excipient for topical administration to inflamed skin or mucosal tissue, wherein
a unit dosage amount of the admixture contains a systemically ineffective amount of the opioid analgesic agent, and

the excipient does not enhance transdermal or transmucosal transmission of the opioid analgesic agent,

with the proviso that, when the admixture is a liquid, it further comprises a component that is pharmaceutically unacceptable for parenteral administration,

wherein said opioid is cyclazocone, piperidine, piperazine, pyrrolidine, morphiceptin, meperidine, trifluadom, benzeneacetamine, diacylacetamide, benzomorphan, hydromorphone, oxymorphone, levophanol, methadone, meperidine, fentanyl, codeine, hydrocodone, oxycodone, propoxyphene, buprenorphine, butorphanol, pentazocine or nalbuphine.

The sole reference relied on by the examiner is:

MacLean

GB 2 287 404

Sep. 20, 1995

Claims 8, 9 and 11-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by MacLean, while claims 1-3, 5-9 and 11-22 stand rejected under 35 U.S.C. § 103 as unpatentable over MacLean.

We reverse these rejections. In addition, we raise an additional issue for the examiner's and appellants' consideration.

DISCUSSION

Anticipation

"[E]very limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). Moreover, "the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." In re Wilder, 429 F.2d 447, 450, 166 USPQ2d 545, 548 (CCPA 1970).

MacLean describes compositions for treating inflammatory diseases and pain, comprising combinations of substance P receptor antagonists and anti-inflammatory/analgesic compounds, some of which compounds, e.g., codeine and fentanyl, are opioid analgesics.

Claims 8, 9 and 11-14 stand rejected under 35 U.S.C. § 102(b) as anticipated by MacLean. The claims are directed to a composition comprising a mixture of an opioid

analgesic agent and a pharmaceutically acceptable excipient for topical administration.

The composition is intended for topical use, without systemic effectiveness - in keeping with this, each of the claims requires that the excipient “not enhance transdermal or transmucosal transmission of the opioid analgesic agent” (see claim 8). As explained in the specification, such excipients “are substantially nonocclusive, and generally include those which are water-soluble, such as oil-in-water emulsion bases (creams or hydrophilic ointments) and water-soluble bases such as polyethylene glycol-based vehicles and aqueous solutions gelled with various agents such as methylcellulose . . .” (specification, page 10). The examiner does not address this aspect of the claims in the statement of the rejection (except to assert that “MacLean teaches that the composition can be administered in combination with pharmaceutically acceptable carriers or diluents in a wide variety of dosage forms for oral, parenteral, or topical administration” (answer, page 4)), but nevertheless concludes that “MacLean anticipates the limitations of applicant’s composition claims” (id.).

Appellants argue that “the examiner appears to be overlooking the fact that applicants’ claims require that the amount of active agent administered be ‘systemically ineffective for induction of analgesia’” (Brief, page 3). In our view, this issue is not relevant to these composition claims. MacLean broadly describes compositions comprising opioid analgesics and “carriers and diluents” suitable for topical use. The admonition in claim 8 that “a unit dosage,” i.e., the amount applied, contains a systemically ineffective amount of the opioid analgesic, is tantamount to a statement of intended use, rather than a physical limitation serving to distinguish over MacLean’s composition. Nevertheless, as discussed above, claim 8 explicitly requires an excipient that “does not enhance transdermal or transmucosal transmission of the opioid

analgesic agent.” While MacLean states that topical administration should be accomplished “in accordance with standard pharmaceutical practice” (MacLean, page 4, lines 5-8), the examiner has not established that standard practice for topical administration dictates excipients that do not enhance transdermal or transmucosal transmission.

As discussed above, the examiner has the initial burden of coming forward with evidence tending to disprove novelty; conclusory statements are insufficient to discharge the burden of establishing a prima facie case of anticipation. Inasmuch as the examiner has not provided evidence establishing that MacLean describes a composition which meets all of the limitations of the claims, the rejection of claims 8, 9 and 11-14 under 35 U.S.C. § 102(b) is reversed.

Obviousness

Claims 1-3, 5-9 and 11-22, directed to methods of inducing topical analgesia without also producing a systemic effect,¹ stand rejected under 35 U.S.C. § 103 as unpatentable over MacLean. However, the statement of the rejection amounts to an assertion that the subject matter of these claims is anticipated by MacLean, inasmuch as the examiner concludes that “the amounts disclosed in MacLean must read on Appellant’s claimed amounts” “because MacLean teaches successful topical administration of the same drugs, for the same purpose” (Answer, page 5), and moreover, “it would have been obvious to one of ordinary skill in the art that [MacLean’s] amounts of the opioid agent are below [] systemic amounts” (id.). In an apparent reference to the reasoning in In re Best, 562 F.2d 1252, 195 USPQ 430

¹ Except for claim 15, which is directed to a composition.

(CCPA 1977), the examiner maintains that “the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences” (Answer, page 5).

As set forth in In re Best, 562 F.2d at 1255, 195 USPQ at 433-44:

Where . . . the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, on ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO’s inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Nevertheless, the examiner’s rejection would shift the burden of proof to appellant merely on the basis of a general statement that it is possible to administer antiinflammatory/analgesics “topically when treating inflammatory conditions of the skin . . . by way of creams, jellies, gels, pastes, ointments and the like, in accordance with standard pharmaceutical practice” (MacLean, page 4). The examiner has made no attempt to establish what “standard pharmaceutical practice” entails with respect to topical application of analgesics. On this record, it is unreasonable to shift the burden to appellant to establish that MacLean administers a topically effective, but systemically ineffective, amount of opioid analgesic. Accordingly, the examiner’s rejection of claims 1-3, 5-9 and 11-22 over MacLean is reversed.

OTHER ISSUE

We note that appellants have disclaimed the terminal portion of the statutory term of any patent granted on the present application which would extend beyond the term of U.S. Patent No. 5,589,480 (see paper no. 16 of the present application).

However, claim 15 of the present application appears to be identical in scope with claim

16 of the patent. Inasmuch as statutory double patenting cannot be obviated by a terminal disclaimer, it is not clear why claim 15 has not been canceled or subjected to a double patenting rejection under 35 U.S.C. § 101.

REVERSED

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Toni R. Scheiner)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
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Demetra J. Mills)	APPEALS AND
Administrative Patent Judge)	
)	INTERFERENCES
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)	
Lora M. Green)	
Administrative Patent Judge)	

Appeal No. 2003-1765
Application No. 09/319,735

Page 7

Millen, White, Zelano & Branigan
2200 Clarendon Blvd., Suite 1400
Arlington, VA 22201