

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte JAMES A. ANGELLO

Appeal No. 2003-0736
Application No. 09/720,007

ON BRIEF

Before ADAMS, GRIMES, and GREEN, 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 1-9, all of the claims remaining. Claim 1 is representative and reads as follows:

1. A method for treating a mammal suffering from renal colic comprising administering to said mammal a pharmaceutical composition comprising an effective amount of a GABA analog.

The examiner relies on the following references:

Singh

WO 98/03167

Jan. 29, 1998

Field et al. (Field), "Gabapentin (neurontin) and S-(+)-3-isobutylgaba represent a novel class of selective antihyperalgesic agents," British Journal of Pharmacology, Vol. 121, pp. 1513-1522 (1997)

Weizel et al. (Weizel), "Use of Gabapentin in Pain Management," The Annals of Pharmacotherapy, Vol. 31, pp. 1082-1083 (1997)

Claims 1-9 stand rejected under 35 U.S.C. § 103 as obvious in view of Singh, Wetzel and Field.

We reverse.

Background

"Renal colic is commonly known as kidney stones." Specification, page 2. Kidney stones are "crystalline in structure, often with sharp edges that resemble small pieces of broken glass." Id., page 3. "The passage of these crystalline fragments is so painful that it is proverbially known as the male equivalent of 'child birth or labor.' . . . [T]he pain is so incapacitating that patients are often started on narcotic pain relievers." Id., page 2.

The specification discloses that analogs of gamma-aminobutyric acid (GABA) are known agents used in antiseizure therapy and to treat neuropathic pain. Page 1. A prior art reference also disclosed that they were useful in treating a variety of conditions, including pain, although it did not specify what forms of pain were to be treated. Id.

The specification discloses a method of alleviating the pain associated with kidney stones by "administering to a subject suffering from such pain an effective amount of a GABA analog." Page 3. Any GABA analog is appropriate,

page 4, but a preferred analog is 1-(aminomethyl)-cyclohexane acetic acid, also known as gabapentin. Page 3. The specification theorizes that

gabapentin could have a dual mechanism in the relief of acute renal colic through its interference with central and peripheral pain pathways in addition to its potential to provide ureter smooth muscle relaxation. Based on this possible dual mechanism gabapentin provides superior pain relief for renal colic relative to existing analgesics.

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Discussion

The claims are directed to a method of “treating a mammal suffering from renal colic” by administering an effective amount of a GABA analog. As the specification makes clear, the effect of the treatment is simply to relieve the pain associated with the passage of kidney stones, not to treat the renal colic per se.

The examiner rejected the claims as obvious in view of Singh, Wetzel, and Field. The examiner cited Singh and Wetzel as “teach[ing] that gabapentin and/or pregabalin can be used as a pain killer for use in a variety of pain syndromes,” although he acknowledged that “neither Singh nor Wetzel et al. highlight that pain resulting from renal colic could be effectively relieved.”

Examiner’s Answer, page 3. The examiner concluded that the claimed method would have been obvious nonetheless, because

Singh and Wetzel et al. disclose the presently claimed actives for the treatment of variety of pain disorders and Field et al. . . . teaches that gabapentin or pregabalin can be used to relieve pain without causing the side effects of morphine. From the above, the skilled artisan would have been motivated to employ either gabapentin or pregabalin for the treatment of pain associated with renal colic because the actives were known to be useful for treating

pain from a wide variety of sources and it was known that the actives did not possess the side effects of morphine.

Id., pages 3-4.

Appellant argues that the examiner has not made out a prima facie case of obviousness because, although the examiner's references teach treating pain associated with a variety of conditions, none of them teaches a treatment of renal colic. See the Appeal Brief, pages 5-8. Appellant argues that, in contrast to the conditions specifically named by Singh and Wetzel, "all of which are chronic in nature, the pain associated with renal colic is acute and sudden." Reply Brief, pages 2-3. Appellant concludes that Wetzel and Singh

would do no more than render it obvious to a skilled artisan to try to use a GABA analog for the treatment of renal colic, and that nothing in these references . . . would lead such a skilled artisan to have a reasonable expectation that the use of a GABA analog to treat the acute and sudden pain associated with renal colic would be successful.

Id. Finally, Appellant argues that Field does not remedy the deficiency of the other references, because "Field et al. adds nothing to the teachings of Wetzel et al. or Singh, but for the teaching that gabapentin is efficacious against inflammatory pain without exhibiting the side effects of morphine." Id., page 4.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). "The test for obviousness is what the combined teachings of the

references would have suggested to one of ordinary skill in the art.” In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

“Obviousness does not require absolute predictability of success.” In re O’Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). However, the prior art must provide a basis for a reasonable expectation of success. See, e.g., In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) (“[T]he expectation of success must be founded in the prior art, not in the applicant’s disclosure.”).

In this case, we agree with Appellant that the examiner’s references do not support a prima facie case of obviousness. First, as noted by Appellant, none of the examiner’s references even mentions renal colic, and therefore the references would not have suggested the specific, claimed method. See In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995) (“The test of obviousness vel non is statutory. It requires that one compare the claim’s ‘subject matter as a whole’ with the prior art ‘to which said subject matter pertains.’”); In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970) (“[E]very limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines.”). Since the cited references do not even mention renal colic, we cannot agree with the examiner that the references would have suggested a method of treating renal colic.

The examiner asserted that “[i]t is general knowledge that typical treatment of renal colic consists of the administration of morphine as a pain killer,” Examiner’s Answer, page 3, although he did not cite any evidence in the

record to support this assertion. Even assuming that the examiner is correct, however, the evidence of record does not provide the reasonable expectation of success that is necessary for a prima facie case of obviousness. The examiner's position, basically, is that pain is pain; since "the actives were known to be useful for treating pain from a wide variety of sources," Examiner's Answer, page 4, they would be expected to be useful in treating pain from any source. This position is not supported by the evidence. Wetzel, for example, states that "[i]t is unclear whether gabapentin is more effective for a specific type of pain." Page 1083.

In fact, the evidence shows that GABA analogs were expected not to be useful against some types of pain. After testing gabapentin in two rat pain models, Field concluded that gabapentin was effective in blocking hyperalgesia but was not effective against transient pain.¹ Field concluded that the data

indicate that gabapentin does not possess an antinociceptive effect in transient models of pain. The ability of gabapentin to block inflammatory- and neuropathy-induced hyperalgesia indicates that this class of compounds is effective only in sensitized pain models. Therefore, we suggest that gabapentin and (S)-(+)-3-isobutylgaba should be referred to as antihypersensitive agents rather than analgesics. As such they are not expected to abolish physiological pain but should reduce abnormal hypersensitivity induced by chronic pain.

Page 1520 (emphasis added).

Thus, we agree with Appellant that the cited references would not have provided a skilled artisan with a reasonable expectation of success. At best, the

¹ Hyperalgesia refers to "extreme sensitiveness to painful stimuli," while pain in general is referred to as "nociception." See Stedman's Medical Dictionary, pp. 732 and 1031 (attached).

references would have made the claimed method obvious to try. “An ‘obvious-to-try’ situation exists when a general disclosure may pique the scientist’s curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.” In re Eli Lilly & Co., 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). “[O]bvious to try’ is not the standard under § 103.” In re O’Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988).

Summary

The references relied on by the examiner do not specifically suggest the claimed method nor do they provide a reasonable expectation of success. We therefore reverse the rejection under 35 U.S.C. § 103.

REVERSED

Donald E. Adams)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Eric Grimes)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Lora M. Green)	
Administrative Patent Judge)	

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