

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte JOSE R. URIBE

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Appeal No. 1995-3021  
Application 07/949,347

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH, and LORIN, 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 1 through 9, all the claims pending in the application. Claims 1 and 6 are representative of the subject matter on appeal and read as follows.

1. A method for systematically treating and relieving pain which comprises orally administering to a patient in need of treatment, a composition consisting of 1000 mg. of acetyl salicylic acid or acetaminophen, admixed with 7.5 to 20 mg. of codeine as a centrally active agent.

6. A therapeutic composition, in unit dosage form, for the systematic treatment and relief of pain, said composition consisting of about 1000 mg of a peripheral acting agent comprising

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acetyl salicylic acid, acetaminophen or a combination of 10 to 80% of acetyl salicylic acid and 20 to 90% of acetaminophen, and from 7.5 to 20 mg of codeine as a centrally active agent.

The references relied upon by the examiner are:

Hertz et al. (Hertz), Chemical Abstracts, "Analgesic effect of acetaminophen-codeine combination in mice," Vol. 103, p. 59, abstract 64783K (1985).

Windholz et al. (Windholz), The Merck Index, "An Encyclopedia of Chemicals, Drugs, and Biologicals," Tenth Edition pp. 7, 15 and 350, abstracts 39, 98 and 2423 (1983).

A reference relied upon by this merits panel is:

Hertz et al. (Hertz), "Analgesic Effect of Acetaminophen-Codeine Combination in Mice," Drug Development Research, Vol. 6, pp. 55-60 (1985).

Claims 1, 2, 4 through 6, 8 and 9 stand rejected under 35 U.S.C. § 103 on the basis of The Merck Index. Claims 1, 3, 6 and 7 stand rejected under 35 U.S.C. § 103 on the basis of the Chemical Abstracts citation. We reverse.

## DISCUSSION

### 1. Background

As set forth in the background portion of the specification, analgesic compositions were known prior to the present invention which involved codeine as the central acting agent and either acetaminophen or acetyl salicylic acid or a combination of these two agents as the peripherally acting agent. Appellant indicates that the "most universal combinations come in two forms of either 30 or 60 mg of codeine with 300 mg acetaminophen or 325 of acetyl salicylic acid." Appellant indicates that there is a tradeoff in determining the amount of codeine to be included in such a composition. Smaller amounts of codeine are less effective as an analgesic

while larger amounts of codeine result in severer side effects. Appellant also acknowledged in this portion of the specification that compositions were available containing 300 mg of acetaminophen or acetyl salicylic acid and lower amounts of codeine such as 7.5 mg or 15 mg. These compositions are stated to have been used for children or patients with small body weight.

The claimed invention differs from the acknowledged prior art in that the present unit dosage form must contain 1,000 mg of acetyl salicylic acid or acetaminophen or a combination of the two in which 10 to 80% of the combination may be acetyl salicylic acid and 20 to 90% may be acetaminophen. Importantly, the claimed unit dosage forms contain 7.5 to 20 mg of codeine. Appellant asserts at page 3, lines 6-15 of the specification that the claimed compositions having a relatively lower amount of codeine are still an effective analgesic. In support of this assertion, appellant relies upon what is termed a "certification" from Dr. Wayne Pasanen. A copy of the certification is attached to the "Reply of Appellant To Supplemental Examiner's Answer" filed April 23, 1998 (Paper No. 24). Dr. Pasanen indicates that he has been collaborating with appellant in a clinical study involving the present invention since 1985. The study included a "Treatment A" wherein 300 mg of acetaminophen with 30 mg of codeine was used and a "Treatment B" wherein a treatment involving 1,000 mg of acetaminophen with 15 mg of codeine. Dr. Pasanen states in paragraph 4 that he has "examined and made comments on the protocol of the study, and I believe that it is a well controlled investigation, with methodology that is quite relevant to clinical practice." In relevant part, Dr. Pasanen states in paragraph 5:

The results [of the clinical study] are surprising and useful. In addition to the benefit of lowering the consumption of the Centrally Acting Agent, the efficacy-to-adverse-reactions ratio is not just maintained, but substantially improved by the innovative combination. In fact, this ratio is sixty six percent (66%) higher for Treatment B than for Treatment A.

## 2. Merck Index

The Merck Index only describes what most reasonable people would have admitted to have been known at the time of the present invention, i.e., acetaminophen, acetyl salicylic acid and codeine were each known to be useful as analgesics. The Merck Index does not describe or provide any dosing information for any of these compounds either individually or in combination. While one might very well be “motivated” to optimize amounts of these three agents, the question is why would one of ordinary skill in the art find it obvious to use the precise amounts required by the claims on appeal? The evidence relied upon by the examiner, The Merck Index, provides no information on dosing. Viewing the examiner's rejection in the factual vacuum in which it exists, The Merck Index simply does not allow one to get from here to there. Viewing The Merck Index by itself, one is only left to surmise and conjecture as to possible effective combinations of the three known analgesics.

The admitted prior art in the background portion of the specification is more relevant in determining the patentability of the claims on appeal than The Merck Index. At least the background information describes the amounts of acetaminophen, acetyl salicylic acid and codeine used in previous unit dosage forms of these known analgesic agents. However, as pointed out above, the unit doses required by the claims on appeal differ from those admitted to

have been known in the prior art. The examiner has not presented a fact based analysis as to why it would have been obvious to one of ordinary skill in the art to change the relative proportions of these three known analgesic agents in the prior art compositions in order to arrive at the claimed subject matter. Absent such a fact based explanation, we do not find that the examiner has properly sustained his initial burden of establishing a prima facie case of obviousness.

Even if we were to find that the examiner had established a prima facie case of obviousness, the rejection could not be sustained. As mentioned above, appellant relies upon the certification of Dr. Pasanen as objective evidence of obviousness. As set forth in In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986):

If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

Here, the only statement we have from the examiner in regard to Dr. Pasanen's certification appears at page 6 of the Supplemental Examiner's Answer (Paper No. 25, May 18, 1998) where the examiner indicates that the certification of Dr. Pasanen had been considered but "is not deemed persuasive since the certification does not disclose the dosage range of codeine set forth in applicant's claim 1." It is not clear what the examiner means from this statement. Again, what is needed is a fact based explanation why the rebuttal evidence relied upon by appellant is not entitled to sufficient weight so as to outweigh the evidence of obviousness relied upon by the examiner, here, The Merck Index.

The examiner's consideration of the evidence in this matter constitutes legal error.

The rejection over The Merck Index is reversed.

### 3. Chemical Abstracts

In short, the rejection based upon the Chemical Abstracts citation suffers from the same defect as the rejection based upon The Merck Index. While the Chemical Abstracts citation does state that the combined use of acetaminophen and codeine resulted in an analgesic affect which was 1.8-6.6 times greater than when each drug was given alone, the point remains that the Chemical Abstracts citation does not describe the amount of active agents used. Without knowing the amounts of acetaminophen and codeine used in that study, it is not apparent how the examiner can properly assert that the claimed invention would have been obvious from a consideration of that reference.

The rejection over Chemical Abstracts is reversed.

### OTHER ISSUES

As explained, the examiner and appellant confined their consideration of Chemical Abstracts citation to the abstract. Neither the examiner nor appellant appear to have obtained and evaluated the full text document. It is not apparent why the examiner and appellant would spend their resources debating the patentability of claims in a factual vacuum of an abstract when the full text document is readily available.

Be that as it may, we have obtained a copy of the full text document. Upon return of the application, the examiner should carefully consider the document and determine whether it

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adversely affects the patentability of the claims on appeal. It so, the examiner should issue an appropriate Office action setting forth such a rejection.

The decision of the examiner is reversed.

REVERSED

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
William F. Smith	)	BOARD OF PATENT
Administrative Patent Judge	)	APPEALS AND
	)	INTERFERENCES
	)	
	)	
Hubert C. Lorin	)	
Administrative Patent Judge	)	

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Richard Y. Laughlin  
RIBIS, GRAHAM & CURTIN  
4 Headquarters Plaza  
P. O. Box 1991  
Morristown, NJ 07962-1991