

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 12

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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Ex parte MARTIN HAUER-JENSEN and  
PAIVI AHO

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Appeal No. 2001-1030  
Application No. 09/159,334

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ON BRIEF

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Before WINTERS, SCHEINER, and GREEN, Administrative Patent Judges.

GREEN, 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 1-6. Claim 1 is representative of the subject matter on appeal, and reads as follows:

1. A method for the treatment of radiation enteropathy in a patient or an animal in need of such treatment, comprising the step of:

administering a therapeutically effective dose of Orazipone in a pharmacologically acceptable form to said patient.

The examiner relies upon the following reference:

Backström et al. (Backström)                      5,292,771                      Mar. 8, 1994

Martenson, Jr., et al. (Martenson), "Olsalazine is contraindicated during pelvic radiation therapy: Results of a double-blind, randomized clinical trial," Int. J. Radiation Oncology Biol. Phys., Vol. 35, No.2, pp. 299-303 (1996)

Resbeut et al. (Resbeut), "A randomized double blind placebo controlled multicenter study of mesalazine for the prevention of acute radiation enteritis," Radiotherapy and Oncology, Vol. 44, pp. 59-63 (1997)

In addition, appellants rely on the following references:

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as being obvious over Backström. After careful review of the record and consideration of the issues before us, we reverse.

#### DISCUSSION

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as being obvious over Backström. According to the rejection, Backström teaches the synthesis of Orazipone and that it may be used in the treatment of inflammatory bowel disease. See Examiner's Answer, page 3. The term Inflammatory Bowel Diseases as used by Backström includes chronic inflammatory conditions of the of the gastrointestinal tract such as Crohn's disease and ulcerative colitis. See Backström, col. 1, lines 21-23. The rejection concludes:

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to follow the suggestions of Backstrom et al and generate a method of treating radiation enteropathy by administering a therapeutic amount of Orazipone because while Backstrom et al does not specifically state that their diketones are useful for in a method treating radiation enteropathy, a skilled practitioner in the art would have been motivated to utilize

Orazipone in treating radiation enteropathy having recognized that radiation enteropathy is encompassed by the Backstrom et al. reference. In particular, 'enteropathy' as defined in any standard medical dictionary is any disease of the intestines and the term 'bowel' as recognized in any standard medical dictionary is defined as the intestine. Hence, since Backstrom teaches that Orazipone may be administered to treat inflammatory bowel diseases and does not limit to one specific inflammatory bowel condition, but discloses that chronic inflammatory conditions of the gastrointestinal tract are also encompassed by their invention (abstract; column 1, lines 9-23) and since Applicant's independent claim 1 does not include a radiation step; (1) radiation exposure is not necessary in the treatment of radiation enteropathy which logic is consistent with Applicant's disclosure on page 5, lines 9-13 wherein Orazipone may be administered prior to, during, or subsequent to radiation therapy; and (2) a skilled practitioner in the art using any standard medical dictionary would recognize that 'enteropathy' and 'bowel disease' are interchangeable terms since the medical dictionary discloses that both terms refer to diseases of the intestines.

Examiner's Answer, pages 4-5.

Appellants contend that, contrary to the examiner's assertion, that radiation enteropathy does not fall under the umbrella of inflammatory bowel diseases, and is thus not encompassed by the Backström reference. Inflammatory bowel disease, according to appellants, refers only to Crohn's disease and ulcerative colitis, whereas radiation enteropathy results from exposure to radiation during cancer treatment, causing chronic intestinal toxicity that damages the small intestine. Appellants cite the Resbeut and Martenson references to support their position that radiation enteropathy is distinct from the chronic inflammatory bowel diseases encompassed by the Backström reference.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99

(Fed. Cir. 1988). Obviousness is determined in view of the sum of all of the relevant teachings in the art, not isolated teachings in the art. See In re Kuderna, 426 F.2d 385, 389, 165 USPQ 575, 578 (CCPA 1970); see also In re Shuman, 361 F.2d 1008, 1012, 150 USPQ 54, 57 (CCPA 1966). In assessing the teachings of the prior art references, the examiner should also consider those disclosures that may teach away from the invention. See In re Geisler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997).

Martenson studied the potential use of Olsalazine, a drug designed to deliver 5-aminosalicylate (5-ASA) to the bowel, for the prevention of radiation-induced bowel toxicity, as olsalazine is effective in the treatment of ulcerative colitis. See Martenson, page 300. The trial was terminated early because it was found that subjects randomized to 5-ASA had increased incidence of proctitis.

The investigators concluded that

[t]hese three studies are strikingly different from the experience with olsalazine in nonirradiated patients and suggest a possible adverse reaction between 5-ASA and pelvic irradiation. Our results do not suggest that the indications for use of olsalazine in inflammatory bowel disease should be modified.

Martenson, page 302.

Resbeut performed a double blind study to determine the efficacy of mesalazine (5-ASA) in the prevention of acute radiation enteritis. While noting that 5-ASA is used to treat inflammatory bowel disease, the reference concludes that it does not prevent acute radiation enteritis diarrhea. See Resbeut, page 62.

Thus, the prior art, when considered as a whole, does not support the examiner's contention that one of ordinary skill in the art would read inflammatory bowel diseases as used by the Backström reference to encompass radiation enteropathy. The Martenson and Resbeut references demonstrate that compounds that are known to be efficacious in the treatment of inflammatory bowel disease are not necessarily efficacious in the treatment of radiation enteropathy. At best, it may have been obvious to try and treat radiation enteropathy using Orazipone given the teachings of the Backström reference, but obvious to try is not the standard by which obviousness is determined. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) (noting that a determination of obviousness not only requires that the prior art would have suggested the claimed process to one of ordinary skill in the art, but also that the process would have a reasonable likelihood of success when viewed in light of the prior art).

CONCLUSION

Because, when considered in light of the prior art as a whole, the Examiner's Answer failed to set forth a prima facie case of obviousness, the rejection of claims 1-6 over the Backström reference is reversed.

REVERSED

SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
TONI R. SCHEINER	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
LORA M. GREEN	)	
Administrative Patent Judge	)	

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