

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte BARRY LIBIN

Appeal 2008-5406
Application 10/317,633
Technology Center 1600

Decided: January 5, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims as obvious in view of prior art. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF CASE

The following claim is representative.

1. A method of treating mucositis in an immunocompromised patient, said method comprising contacting a mucositis lesion in said patient with an amount of a composition which comprises triclosan and a cationic antibacterial agent which is effective to alleviate the symptoms of mucositis.

Cited References

Cummins US 5,500,448 Mar. 19, 1996

M. Innocenti et al. (Innocenti), "Efficacy of Gelclair in Reducing Pain in Palliative Care Patients with Oral Lesions: Preliminary Finding from an Open Pilot Study," 24 JOURNAL OF PAIN AND SYMPTOM MANAGEMENT no. 5, 456-57 (Nov. 5, 2002) (Abstract Only; CHEMICAL ABSTRACT 138:297542 (2002)).

P. Weidle, "Thalidomide for Aphthous Ulcers in Patients Infected with the Human Immunodeficiency Virus," 53 AMERICAN JOURNAL OF HEALTH-SYSTEM PHARMACY 368-78 (Feb. 15, 1996) (Abstract Only; Chemical Abstract 124:278812 (2002)).

T. Arendorf et al. (Arendorf), "Benzydamine Hydrochloride (Andolex) Improves Oral Mucosal Health in the Immunocompromised Patient," 86 SOUTH AFRICAN MEDICAL JOURNAL no. 9, 1136-37 (Sep. 1996) (Abstract Only; Chemical Abstract 125:265067 (1996)).

Grounds of Rejection

1. Claims 1- 6 and 11 stand rejected under 35 U.S.C. §103(a) as being obvious over Cummins.

ISSUE

The Examiner finds that since immunocompromised patients are at high risk for secondary infections including the development of aphthous ulcers, it would have been obvious to have administered the prophylactic

treatments of the prior art to such patients, motivated by the desire to minimize discomfort caused by the development of aphthous ulcers in same. (Ans. 4-5.)

Appellant contends that there is no evidence that the causes of an aphthous ulcer and mucositis are the same or that one of ordinary skill in the art would be directed to treat mucositis with triclosan, a treatment for aphthous ulcers. (App. Br. 5.)

The issue is whether it would have been obvious to administer immunocompromised patients triclosan to treat mucositis.

FINDINGS OF FACT

1. Cummins discloses the prophylaxis of aphthous ulcers with mouthwashes or toothpastes containing triclosan and cetylpyridinium chloride (Abstract, Example 2, Claim 1, and col. 2, ll. 23 and 24). (Ans. 4.)
2. Cummins differs from the instant claims as it does not specify the treatment of mucositis in immunocompromised patients. (Ans. 4.)
3. The Examiner finds that since such patients are at high risk for secondary infections including the development of aphthous ulcers, it would have been obvious to have administered the prophylactic treatments for aphthous ulcers of the prior art to such patients, motivated by the desire to minimize discomfort caused by the development of aphthous ulcers in same. (Ans. 4.)
4. Mucositis has no known microbial or viral vector that has been implicated as the causative agent. (Spec. 1: 5-16.)

PRINCIPLES OF LAW

The Supreme Court has emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). However, an invention “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 1741. “Often, it will be necessary . . . to look to interrelated teachings of multiple [references] . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed[.]” *Id.* at 1740-41. “[T]his analysis should be made explicit” (*id.* at 1741), and it “can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” (*id.*).

ANALYSIS

Appellant argues that the Examiner has not established any connection with “the vector” that causes an aphthous ulcer and mucositis which would support the hypothesis that if one had knowledge that triclosan was effective for treating an aphthous ulcer, that person would be directed to use triclosan for treating mucositis. (Subst. Br. 4.) Appellant further argues that the Chemical Abstract references of record fail to disclose anything that would lead a skilled artisan to modify the Cummins teachings regarding the

treatment of aphthous ulcer and treat mucositis in an immunocompromised patient using the Cummins method. (Subst. Br. 5.)

Appellant challenges the relevancy of the documents cited to demonstrate the state of art, arguing that:

- 1) Chemical Abstract 138:297542 relates to the treatment of pain caused by oral lesions such as aphthous ulcers or mucositis, and not the underlying condition (Subst. Br. 5, first para.);
- 2) Chemical Abstract 124:278812 relates to the treatment of aphthous ulcers in patients with human immunodeficiency virus but does not "correlate the treatment of an aphthous ulcer with mucositis" (Subst. Br. 5, third para.); and
- 3) Chemical Abstract 125:265067 relates to the treatment of herpetic lesions, angular cheilitis and ulceration but does not connect an aphthous ulcer with mucositis in an immunocompromised patient. (Subst. Br. 6.)

The Examiner, however, argues that both mucositis and aphthous ulcer share the same symptoms of pain and ulceration of the mucosal membrane and both can occur in immunocompromised patients. (Ans. 5.) The Examiner does not agree there is no commonality of mechanism for the cause of aphthous ulcer and mucositis. (Ans. 5.)

We find that Appellant has the better argument. We agree with Appellant that the Examiner has not provided evidence or established any connection with "the vector" that causes an aphthous ulcer and mucositis which would support the hypothesis that if one had knowledge that triclosan was effective for treating an aphthous ulcer, that person would be directed to use triclosan for treating mucositis. We do not agree with the

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Examiner that the shared symptomology of pain for both aphthous ulcer and mucositis is sufficient to establish a connection between a treatment for aphthous ulcer using triclosan or cetylpyridinium chloride which are not pain relievers, and the treatment of mucositis.

CONCLUSION OF LAW

The Examiner has failed to establish a *prima facie* case of obviousness as the Examiner has not provided evidence that it would have been obvious to administer triclosan to immunocompromised patients in order to treat mucositis.

The obviousness rejection is reversed.

REVERSED

clj

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