

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte

JOERG ROSENBERG, GUNTHER BERNDL, JOERG NEUMANN,
and JOERG BREITENBACH

Appeal 2008-3642
Application 10/343,019
Technology Center 1600

Decided: September 8, 2008

Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a process for treating oral mycoses. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

“Itraconazol[e] … is known as an effective active ingredient for oral, parenteral and topical[al] treatment of various types of my[c]oses” (Spec. 1). “However, since itraconazole is almost insoluble in water (less than 1 µg/ml), bioavailability is a major problem. Many attempts have been made to improve the bioavailability of …insoluble drug compounds. Among them, solid dispersions of drug and hydrophilic polymers have been suggested to enhance the solubility of the drug” (*id.*).

The Specification discloses “formulations and dosage forms for application in the oral cavity for the treatment of my[c]oses, especially my[c]oses of the oral cavity” (*id.* at 2).

DISCUSSION

1. CLAIMS

Claims 1-8 are on appeal. Claim 9 is also pending but has been withdrawn from consideration by the Examiner (Appeal Br. 2).

Claims 1 and 2 are representative and read as follows:

Claim 1: A process for treatment of oral mycoses, said process comprising

positioning in an oral cavity a solid dosage form comprising itraconazole molecularly dispersed in a pharmaceutically acceptable matrix, which is obtained by a melt-extrusion process to deliver an effective amount of itraconazole directly to the oral cavity.

Claim 2: The process of claim 1, wherein the dosage form is in the form of a lozenge.

2. OBVIOUSNESS I

Claims 1 and 3-6 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Baert.¹ The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner relies on Baert as disclosing “a solid dispersion comprising itraconazole [sic] and a polymer (matrix) used in treatment of fungal infection (mycoses),” with a dosage form that is “preferably a tablet” (Answer 3). The Examiner also relies on Baert as disclosing “pharmaceutical dosage forms for oral administration such as tablets and capsules” and that other dosage forms are contemplated (*id.* at 4). The Examiner reasons that the above cited teaching of Baert “encompasses any dosage form” and thus suggests the limitation of delivering “an effective amount of itraconazole directly to the oral cavity” (*id.*).

The Examiner finds that Baert “does not specifically teach a method of treating oral mycoses,” but that it “teaches a method of treating fungal (mycoses) infections in general” (*id.*), and that the teaching of treating mycoses generally would have provided motivation to treat oral mycoses specifically with a reasonable expectation of success (*id.*).

We conclude that the Examiner has set forth a *prima facie* case that claim 1 would have been obvious to the ordinary artisan. Baert discloses “novel pharmaceutical compositions of itraconazole which can be administered to a mammal suffering from a fungal infection . . . compris[ing] particles obtainable by melt-extruding a mixture comprising itraconazole and an appropriate water-soluble polymer” (Baert, abstract).

¹ Baert et al., WO 97/44014, Nov. 27, 1997.

Baert also suggests that the novel compositions provide improved bioavailability of itraconazole (*id.* at 1) and discloses that “[i]traconazole ...is a broadspectrum antifungal compound developed for oral, parenteral and topical use” (*id.*).

We agree with the Examiner that it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to arrive at the invention of claim 1 based on the teaching of Baert. Given the disclosure in Baert that itraconazole is a broad spectrum antifungal compound that can be administered both orally and topically, one of skill in the art would have understood that mycoses, including oral mycoses, could be treated topically by direct placement of the disclosed itraconazole formulation.

Appellants argue that Baert “relates exclusively to the systemic administration of itraconazole” and that Baert teaches away from the present invention because it repeatedly stresses “the importance of swallowing their dosage form, and go to great lengths to facilitate the swallowing of the dosage form” (Appeal Br. 5). Appellants also argue that “[a]t the time the present invention was made delivery of itraconazole directly to the oral cavity had not been contemplated, and so a skilled artisan had no way to know how to deliver an effective amount of itraconazole directly to the oral cavity” (*id.* at 7).

We are not persuaded by this argument. It is true that Baert does not expressly suggest the treatment of oral mycoses by positioning a dosage form of itraconazole in the oral cavity, but the prior art need not expressly suggest an invention in order to have made it obvious. “[T]he ‘motivation-suggestion-teaching’ test asks not merely what the references disclose, but

whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). *See also KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (The obviousness analysis “can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006) (The “suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense.”).

While Baert does not specifically disclose the treatment of oral mycoses directly, Baert discloses that its dosage form has improved bioavailability and that itraconazole is known for the topical treatment of mycoses. Given the disclosure that itraconazole is known to be safe for oral administration and that mycoses can be treated topically with itraconazole, one of skill in the art, faced with the problem of oral mycoses, would have been predictably led to the solution of directly delivering itraconazole to oral mycoses using a dosage form made using known tabletting methods, leading to the method of claim 1.

3. OBVIOUSNESS II

Claims 2, 7, and 8 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Baert and Ansel.² The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner relies on Baert as discussed above, but finds that Baert “does not teach a dosage form of a lozenge, or a tablet for buccal, sublingual, gingival, or palatinal application” (Answer 5). The Examiner finds that Ansel discloses that “tablet types include buccal and sublingual tablets” (Answer 5). The Examiner also relies on Ansel as disclosing that “lozenges are solid dosage forms containing a medicinal agent and are also intended for the oral cavity” (*id.*).

The Examiner concludes that it “would have been obvious to a person of ordinary skill in the art at the time the invention was made to interchange between tablet types because Baert et al. teaches the composition in a tablet form and Ansel et al. teaches various tablet forms are within the purview of a skilled artisan” (*id.*). The Examiner reasons that motivation to combine the reference is provided by Ansel’s teaching that “buccal and sublingual tablets ‘enable the oral absorption of drugs that are destroyed by the gastric juice and/or are poorly absorbed from the gastrointestinal tract’” and that “lozenges ‘are intended to be slowly dissolved in the oral cavity’ for localized or systematic effects” (*id.* at 5, citing Ansel 202).

We agree with the Examiner’s reasoning and conclusion.

Appellants argue that “a person of ordinary skill in the art had no apparent reason to treat oral mycoses by applying in an oral cavity a solid

² Ansel et al., “Pharmaceutical Dosage Forms and Drug Delivery Systems,” 202-203 (7th ed., Lippincott, Williams & Wilkins, 1999).

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dosage form comprising itraconazole molecularly dispersed in a pharmaceutically acceptable matrix, which is obtained by a melt-extrusion process,” and thus “there was no apparent reason for the skilled person to adopt the buccal or sublingual tablets of Ansel et al., even though these forms were known” (Appeal Br. 9).

We are not persuaded by this argument for the reasons set forth above.

SUMMARY

The Examiner’s rejections are supported by a preponderance of the evidence of record. We therefore affirm the rejection of claims 1-8 under 35 U.S.C. § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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