

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte JURGEN ROMISCH, ERIC-PAUL PAQUES,  
ROBERT BARTLETT and  
GERHARD DICKNEITE

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Appeal No. 1996-2216  
Application No. 08/087,058<sup>1</sup>

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ON BRIEF

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Before WILLIAM F. SMITH, SPIEGEL, and ADAMS, Administrative Patent Judges.  
SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner finally rejecting claims 7 through 9 and refusing to allow claims 1, 3 and 5 as amended subsequent to the final rejection, which are all of the claims pending in this application.<sup>2</sup> Claims 1 and 7 are illustrative and read as follows.

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<sup>1</sup> Application for patent filed July 7, 1993.

<sup>2</sup> The amendment filed January 13, 1995 (Paper No. 10) amending claims 1, 3 and 5 was entered by the examiner in the advisory action mailed February 1, 1995 (Paper No. 11).

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1. A method for the treatment of inflammatory skin disorders, intestinal disorders or purpura which method comprises administering one or more complement inhibitors from the group consisting of C1 inactivator, factor I and factor H.

7. A method as claimed in claim 1, which comprises administering 1-5000 IU/kg x day C1 inactivator, 0.005-100 mg/kg x day factor I, or 0.005-100 mg/kg x day factor H.

The references relied on by the examiner are:

|                          |           |               |
|--------------------------|-----------|---------------|
| Pelzer et al. (Pelzer)   | 4,915,945 | Apr. 10, 1990 |
| Naka et al. (Naka)       | 4,981,855 | Jan. 1, 1991  |
| Sims et al. (Sims)       | 5,135,916 | Aug. 4, 1992  |
| Glover et al. (Glover)   | 5,157,019 | Oct. 20, 1992 |
| Lezdey et al. (Lezdey)   | 5,166,134 | Nov. 24, 1992 |
| Eur. Pat. App. (EP '611) | 222 611   | May 20, 1987  |

Kitano et al. (Kitano), "New Treatment of Ulcerative Colitis with K-76," Diseases of the Colon & Rectum, Vol. 35, No. 6, pp. 560-67 (June 1992).

### ISSUE<sup>3</sup>

Claims 1, 3, 5 and 7-9 stand rejected under 35 U.S.C. § 103 as being unpatentable over EP '611, Kitano, Lezdey, Pelzer, Sims, Glover and Naka.

We REVERSE.

In reaching our decision in this appeal we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the

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<sup>3</sup> According to the examiner, the final rejection of claims 1, 3, 5 and 7-9 under 35 U.S.C. § 112, first paragraph, for lack of enablement was overcome by the amendment filed January 13, 1995 (Paper No. 10) (see the advisory action mailed February 1, 1995 (Paper No. 11)).

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appellants and the examiner. We make reference to the examiner's answer (Paper No. 14, mailed August 2, 1995) for the examiner's reasoning in support of the rejections and to the appellants' brief (Paper No. 13, filed April 13, 1995) and reply brief (Paper No. 15, filed October 2, 1995) for the appellants' arguments thereagainst.

### BACKGROUND

The claimed invention is directed to treating specific diseases, i.e., inflammatory skin disorders (e.g., pustular dermatoses, dermatitis or psoriasis), intestinal disorders (e.g., Crohn's disease or ulcerative colitis), or purpura, by administering one or more of three specific complement inhibitory agents, i.e., C1 inactivator, Factor I and Factor H.

Glover summarizes the complex interactions of the complement system, which is composed of two different pathways, the "classical" pathway and the "alternative" pathway, and which consists of a complex group of proteins in body fluids which work together with antibodies and other factors to play a role in mediating inflammation and defense against infections (col. 2, line 46 - col. 4, line 36).

### OPINION

To establish a prima facie case of obviousness, there must be both some suggestion or motivation to modify the references or combine reference teachings and a reasonable expectation of success. Furthermore, the prior art must teach or suggest all

the claim limitations. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Here, none of the applied prior art references disclose treating any one of the specified diseases by administering any one of the specified complement inhibitors. Those references that treat one of the specified diseases, i.e., Kitano treats ulcerative colitis and Naka treats psoriasis, do so with a different agent, i.e., K-76 and a 3-aminopyrazolo[3,4-d]pyrimidine derivative, respectively (Kitano, page 560; Naka, col. 1, lines 6-28). The examiner has not explained what would have motivated one of ordinary skill in the art to substitute C1 inactivator, Factor I and/or Factor H for the K-76 of Kitano, especially since Kitano discloses that K-76 inhibits C5 and Factor I (page 560, col. 1, para. 1). Naka discloses its 3-aminopyrazolo[3,4-d]pyrimidine derivatives inhibit type III allergic reactions (col. 4, lines 33-36). The examiner has failed to establish a nexus between C1 inactivator, Factor I or Factor H and a type III allergic reaction. Thus, the examiner has failed to establish what would have motivated one of ordinary skill in the art to substitute C1 inactivator, Factor I and/or Factor H for the 3-aminopyrazolo[3,4-d]pyrimidine derivative of Naka. Similarly, those references that administer one of the specified complement inhibitors treat different diseases, i.e., EP '611 treats an autoimmune disease with Factor I and/or H (abstract) and Lezdey treats allergic rhinitis with a serine protease inhibitor and/or an acute phase reactant, e.g., C1 inhibitor (col. 2,

line 46 - col. 3, line 32). Again, the examiner has failed to establish a pathophysiological nexus between these diseases and inflammatory skin disorders, intestinal disorders or purpura which would provide a motivation to treat a different disease with the therapeutics of EP '611 and/or Lezdey with a reasonable expectation of success. While the examiner states that "[o]ne of the symptoms of SLE (i.e., systemic lupus erythematosus) is a necrotizing, inflammatory skin disorder" (answer, page 4), the examiner did not point out, and we do not find were, EP '611 discloses a necrotizing, inflammatory skin disorder to be a specific symptom of SLE.

The remaining references, Pelzer, Glover and Sims, do not overcome the deficiencies of the Kitano, Naka, EP '611 or Lezdey. Pelzer describes a process for purifying C1 inactivator, which C1 inactivator inactivates C1 esterase in the complement system, "controls" blood clotting enzymes, and is the medicant of choice for hereditary angioedema (col. 1, lines 7-23). Sims prevents platelet and endothelial cell activation and cytolysis by complement proteins by administration of an 18 kDa C5b-9 inhibitory protein that is expressed on erythrocyte membranes (abstract). Glover discloses serine protease inhibitor peptides adapted to provide enhanced selectivity and/or potency for a target protease, including proteases involved in blood clotting and clot degradation and in complement activation (col. 4, lines 53-67).

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The examiner has not established that all inflammatory conditions have the same etiology and, therefore, are amenable to the same therapeutics. Furthermore, as argued by appellants, "complement inhibitors exert their effects at different points along the complement cascade. Hence, complement activation in a particular disease may bypass the point at which a proposed inhibitor may exert its effects" (reply brief, page 7). Thus, the examiner has not established that the action of one known complement inhibitor is reasonably predictive of the action of any other known complement inhibitor absent a knowledge of where the complement inhibitors exert their effects in the complement cascade. Finally, the examiner has neither acknowledged nor addressed appellants' separate patentability arguments drawn to the specified dosages recited in claims 7 and 8 (brief, pages 14-15), although the examiner acknowledges that "Appellant's brief includes a statement that claims 1, 3, 5 and 7-9 do not stand or fall together and provides reasons [therefore] ... " (answer, page 2). This is clear legal error.

Based on the foregoing, we find the examiner has not carried her burden of establishing a prima facie case of obviousness.

#### CONCLUSION

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To summarize, the decision of the examiner to reject claims 1, 3, 5 and 7-9 under 35 U.S.C. § 103 as being unpatentable over EP '611, Kitano, Lezdey, Pelzer, Sims, Glover and Naka is reversed.

REVERSED

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|-----------------------------|---|-----------------|
| WILLIAM F. SMITH            | ) |                 |
| Administrative Patent Judge | ) |                 |
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|                             | ) | BOARD OF PATENT |
| CAROL A. SPIEGEL            | ) | APPEALS         |
| Administrative Patent Judge | ) | AND             |
|                             | ) | INTERFERENCES   |
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| DONALD E. ADAMS             | ) |                 |
| Administrative Patent Judge | ) |                 |

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