

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 34

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TERRY B. STROM, XIN XIAO ZHENG and ALAN STEELE

Appeal No. 2001-0893¹
Application No. 08/968,905

ON BRIEF²

Before WILLIAM F. SMITH, SCHEINER and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 16, 18 and 34-37, which are all the claims pending in the application.

¹ We note that this appeal is related to Appeal No. 2000-0839 (Application No. 08/355,502) accordingly these two appeals were considered together.

² In accordance with 37 CFR 1.194(c), the Board decided that an oral hearing was not necessary in this appeal. Therefore, appellants' request for oral hearing is moot.

appellants' Brief⁴, and Reply Brief⁵ for the appellants' arguments in favor of patentability. We note the examiner entered and considered appellants' Reply Brief.⁶

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 3) Gerard teach "a method for treating or completely preventing septic shock in mice by administration of a therapeutic amount of IL-10..." The examiner finds (id.) that Gerard "fails to disclose a method of treating or inhibiting septic shock with a chimeric protein comprising IL-10 bonded to the Fc region of an IgG molecule." The examiner relies on Capon to make up for the deficiency in Gerard. According to the examiner (id.)

Capon teach:

chimeric proteins for directing ligand binding partners such as growth factors, hormones or effector molecules to cells bearing ligands for the ligand binding partners comprising a ligand binding partners fused to a stable plasma protein which is capable of extending the in vivo half-life of the ligand binding partner when present as a fusion with the ligand binding partner, in particular wherein such a stable plasma protein is an immunoglobulin constant domain.

Based on this evidence, the examiner finds (Answer, page 4) that "[o]ne would have been motivated to use a chimeric protein comprising IL-10 and Fc to decrease its clearance rate in vivo..."

In response, appellants argue (Brief, page 17) that "[e]ven if prima facie obviousness were established, it is rebutted by the surprising results documented in the specification" [emphasis removed]. According to appellants (id.) their results

⁴ Paper No. 28, received May 24, 1999.

⁵ Paper No. 30, received September 7, 1999.

⁶ Paper No. 32, mailed September 21, 1999.

“demonstrated not only that their IL -10/Fc chimera retains its activity – it is as effective as recombinant IL -10 (rIL -10) in in vitro and in vivo assays – but also that it conferred prolonged protection against septic shock.” With reference to page 29-30 of their specification, appellants argue (Brief, fn. 2) that when “[a]pplicants administered 4000 U of either IL -10/Fc or rIL -10 to mice 24 hours before they received a lethal dose of LPS, ... [a]ll of the animals treated with rIL -10 died, whereas 50% of the animals treated with IL -10/Fc survived....”

While the examiner states (Answer, page 9) that appellants “allege surprising results that [a]pplicants obtained prolonged protection with IL -10, however, the results, contrary to being surprising, would be what the prior art predicted,” the examiner fails to identify that portion of the prior art that “predicts” appellants’ results. We note that Capon disclose (column 15, lines 19-23) that “compositions ... in which a biologically active portion of a ligand binding partner is substituted for the variable region of an immunoglobulin chain, are believed to exhibit improved in vivo plasma half-life.” We also note that Capon contemplates (column 16, lines 48-55) preparing amino acid sequence variants of the binding partners with the objective of modifying the binding partner’s plasma half-life. Both of these disclosures, however, fail to “predict” appellants’ results wherein 50% of the animals treated with IL -10/Fc 24 hours before receiving a lethal dose of LPS survived. We are unable to find, and the examiner fails to identify the evidence supporting her statement that “the prior art predicted” appellants’ results. In other words, while Capon contemplates that the plasma half-life of a binding partner can be extended,

Capon does not provide a person of ordinary skill in the art with an expectation the binding partner's half-life could be extended 24 hours while retaining its full activity.

“When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over.” In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). “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 Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986). In maintaining a rejection in view of appellants' unexpected results “[t]he Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis.” In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968).

In our opinion, the examiner failed to provide the evidence necessary to maintain a prima facie case of obviousness in view of appellants' evidence of unexpected results. Accordingly, we reverse the rejection of claims 16, 18 and

Appeal No. 2001-0893
Application No. 08/968,905

34-37 under 35 U.S.C. § 103 as being unpatentable over Gerard in view of Capon.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
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)	
)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
Donald E. Adams)	
Administrative Patent Judge)	

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Appeal No. 2001-0893
Application No. 08/968,905

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