

UNITED STATES BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SERGIO DEL BIANCO
and GIGLIOLA SICA

Appeal No. 1996-0756
Application No. 08/027,853

ON BRIEF

Before McKELVEY, Senior Administrative Patent Judge, and
SCHAFFER and TORCZON, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

DECISION ON APPEAL

Appellants seek review under 35 U.S.C. § 134 of the final
rejection of claims 1-12 under 35 U.S.C. § 103 (Paper No. 9
(Not. App.)). We affirm.

DISCUSSION

Claims 1- 12 stand or fall together. (Paper No. 14 (App.
Br.) at 2). Claim 1 illustrates the claimed invention and is
reproduced below:

1. In a method of treating breast cancer cells
in a human patient by administering a non-steroidal
antiestrogen thereto, the improvement which
comprises administering to said patient interferon
beta prior to the antiestrogen treatment.

Interferon beta is also written "interferon- β " and "IFN- β ".

According to Appellants (Paper No. 14 at 3 to 4, emphasis in original):

The present invention is not based on the fact that a particular antiestrogen is useful in the treatment of breast cancer. It is not based on the fact that interferon- β is useful for the treatment of breast cancer. The invention is also not based on any assertion that it is unexpected to combine the separate and known antiproliferative effects of IFN- β and antiestrogen. Nevertheless, what is decidedly not obvious from the references relied on [by] the Examiner is that the use of these materials sequentially and with the IFN- β being administered first gives rise to a synergistic result.

The only point in contention is whether Appellants' results are unexpectedly synergistic. Appellants bear the burden of showing that their results are unexpected. E.g., In re Geisler, 116 F.3d 1465, 1469-70, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997). A result is synergistic if the evidence shows a combined effect greater than the sum of the separate effects. Merck & Co., Inc. v. Biocraft Laboratories Inc., 874 F. 2d 804, 808, 10 USPQ2d 1843, 1847 (Fed. Cir. 1989). Appellants rely on data described at pages 6 to 8 and illustrated at Figures 1A, 1B, and 2 of their specification to demonstrate that sequential administration of IFN- β and an antiestrogen yields a result that is unexpected.

The examiner found that unexpected results were demonstrated after six days of sequential administration of both 10 IU/ml and

100 IU/ml

concentrations of IFN-

γ followed by

tamoxifen (an

antiestrogen), but

found no synergy at an

of 1000 IU/ml, as

Appellants' Fig. 1B (right) (Paper No. 19 (Ex. Ans.) at 8).

Indeed, after six days with an IFN-γ concentration of

1000 IU/ml, there appears to be no difference between

simultaneous (circles) and sequential (triangles) treatment.

Appellants point to no other data of record to support a

finding of unexpected results. We note that after three days

(Appellants' Fig. 1A, right), the claimed sequential

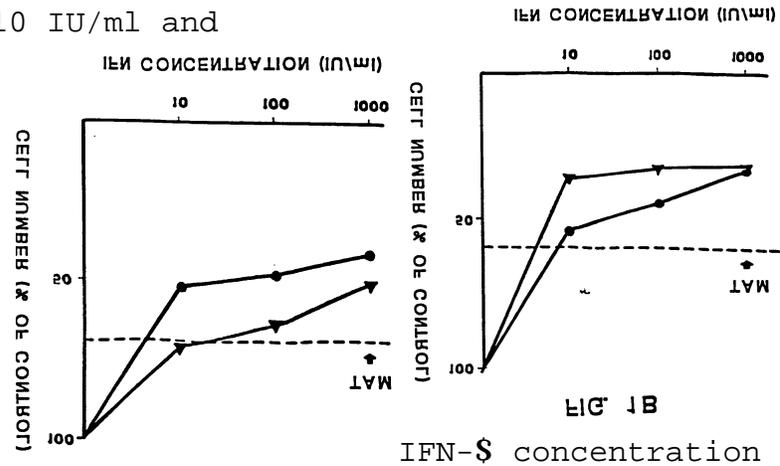
administration (triangles) is less effective than simultaneous

treatment (circles) and, using a 10 IU/ml concentration of

IFN-γ, may be less effective than tamoxifen alone (the dotted

line "TAM").

Evidence of nonobviousness must be commensurate in scope with the claims that the evidence is offered to support.



IFN-γ concentration illustrated in

E.g., In re Grasselli , 713 F. 2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). Sequential administration of IFN- α and tamoxifen at two concentrations of IFN- α appears to yield synergistic results. At other concentrations of IFN- α , sequential administration does not yield synergistic results. Appellants' claim 1 is not limited to any particular concentration of IFN- α .¹ Hence, a preponderance of evidence does not support a showing of unexpected results commensurate in scope with claim 1. The remaining claims fall with claim 1.

¹ Claim 1 is also not limited to using tamoxifen as the non-steroidal antiestrogen.

DECISION

We affirm the examiner's rejection of claims 1-12 over 35 U.S.C. § 103. The period for taking any subsequent action in connection with this appeal will be extended only under the limited circumstances provided in 37 CFR § 1.136(b).

AFFIRMED

FRED E. McKELVEY, Senior Administrative Patent Judge))
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RICHARD E. SCHAFER Administrative Patent Judge)) BOARD OF PATENT APPEALS AND INTERFERENCES
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