

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte C. GARRISON FATHMAN*

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Appeal 2007-4156  
Application 10/263,937  
Technology Center 1600

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Decided: December 11, 2007

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Before DONALD E. ADAMS, DEMETRA J. MILLS, and  
LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 7, and 8, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a method for treating autoimmune disease in a patient. Claim 1 is illustrative:

1. A method for treating autoimmune disease in a patient, the method comprising:

introducing into said patient a dendritic cell that localizes at the site of autoimmune lesions, wherein said dendritic cell is genetically modified to express an IL-4 encoding genetic sequence;

wherein said dendritic cell localizes at said site of autoimmune lesion and produces said IL-4, thereby treating said autoimmune disease.

The Examiner relies on the following prior art references to show unpatentability:

Feili-Hariri et al. "Immunotherapy of NOD Mice With Bone Marrow-Derived Dentritic Cells" 48 Diabetes 2300-2308 (December, 1999) (hereafter Feili-Hariri).

Cameron et al. "Biolistic Medicated Interleukin 4 Gene Transfer Prevents the Onset of Type 1 Diabetes" 11 Human Gene Therapy 1647-1656 (August 10, 2000) (hereafter Cameron).

The rejection as presented by the Examiner is as follows:

Claims 1, 7, and 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Feili-Hariri and Cameron.

We reverse.

## DISCUSSION

Claim 1 is drawn to a method for treating autoimmune disease in a patient. The method comprises the single step of introducing, into a patient, a dendritic cell that localizes at the site of autoimmune lesions. Claim 1 places two limitations on the dendritic cell:

a. the dendritic cell is genetically modified to express an IL-4 encoding genetic sequence; and

b. the dendritic cell localizes at the site of autoimmune lesion and produces IL-4, thereby treating the autoimmune disease. Claims 7 and 8 depend directly from claim 1.

The Examiner finds that Feili-Hariri teaches a method for treating autoimmune disease (insulin dependent diabetes mellitus) in a patient (Answer 3). The Examiner finds that Feili-Hariri's method comprises the step of introducing, into a patient, a dendritic cell that localizes at the site of autoimmune lesions (the pancreas) (*id.*). The Examiner recognizes, however, that Feili-Hariri does not teach a dendritic cell that expresses an IL-4 encoding genetic sequence (*id.*). In this regard, we note that Feili-Hariri's dendritic cells were not genetically modified, but instead were pulsed with antigen (Feili-Hariri 2300: abstract). The Examiner relies on Cameron to make up for this deficiency in Feili-Hariri.

The Examiner finds that Cameron "teaches the use of gene transfer to the skin of a diabetic patient for the expression of IL-4 as a treatment for diabetes" (*id.*). Cameron, however, does not teach a genetically modified dendritic cell. Instead, Cameron teaches the use of a gene gun to administer biolistic inoculations into abdominal skin (Cameron 1648: col. 2, ll. 43-46).

Based on this evidence the Examiner concludes that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to perform a method for treating an autoimmune, disease insulin dependent diabetes mellitus, in a patient (Answer 4). According to the Examiner, such a method would comprising the step of introducing, into a patient, a dendritic cell that is genetically modified to express an IL-4 encoding genetic sequence, wherein the dendritic cell will

localize to the site of the autoimmune lesion, express IL-4, and thereby treat the autoimmune disease (*id.*).

In response, Appellant asserts that because both Feili-Hariri and Cameron fail to teach a genetically modified dendritic cell, neither reference alone or in combination teach or suggest the claimed invention (Br. 5). The Examiner does not dispute Appellant's argument that neither reference teaches a genetically modified dendritic cell, instead the Examiner asserts that "neither the method of Feili-Hariri et al. nor the method of Cameron et al. was 100% effective, thus, the combination of methods addressing the disease from different directions would be expected to provide improved efficacy" (Answer 6). Assuming *arguendo* that the Examiner's position had merit, the Examiner fails to explain how this combination of methodologies leads to Appellant's claimed invention, or more generally to a dendritic cell that is genetically modified. Following the Examiner's logic, a person of ordinary skill in the art would have been led to administer dendritic cells according to Feili-Hariri's method and administer IL-4 by bolistic injection according to Cameron's method.

Contrary to the Examiner's intimation, the mere recognition that "[t]he genetic modification of cells has been routine in the art for some 20+ years" (Answer 5) does not mean that a person of ordinary skill in the art would willy-nilly modify any cell with any gene to treat a disease. As Cameron points out "[t]he recent ill-fated attempt at adenovirus-based gene therapy has prompted researchers to better understand the nature of gene therapy vectors and to develop safer approaches . . ." (Cameron 1654: col. 2, ll. 48-51). The approach taken by Cameron was not to genetically modify a

dendritic cell, but instead to administer IL-4 by biolistic gene delivery (Cameron 1648: col. 2, ll. 43-46).

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, 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.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007). In determining whether a reason exists to combine prior art references a court may “consider the inferences and creative steps a person of ordinary skill in the art would employ.” *Id.* However, for the foregoing reasons, the inferences and creative steps derived from the prior art on this record fail to lead a person of ordinary skill in the art to Appellants’ claimed invention

On this record, the Examiner has failed to identify a viable reason why a person of ordinary skill would have been led to combine the teachings of Feili-Hariri and Cameron in the manner set forth in Appellant’s claimed invention. In this regard, Feili-Hariri teaches that the “treatment of NOD mice with DC [(dendritic cell)] alone has the potential to be immunotherapy for diabetes in these mice” (Feili-Hariri 2307: col. 2, ll. 20-22). Therefore, what is it that leads a person of ordinary skill in the art to modify Feili-Hariri’s dendritic cell with an IL-4 encoding genetic sequence?

Cameron fails to provide a satisfactory answer to this question. Instead, Cameron expresses the need for caution in the use of gene therapy applications, and instead anticipates that the use of biolistic gene delivery in

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combination with stabilized cytokine gene expression will “find generalized application in the prevention of T1D and other autoimmune disorders” (Cameron 1654: col. 2, ll. 48-54). The Examiner fairs no better in answering the question, choosing to engage in supposition (Answer 6-8), rather than providing a fact-based reasoned analysis of the evidence on this record that support his rationale.

On reflection, we find that the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, we reverse the rejection of claim 1, 7, and 8 under 35 U.S.C. § 103(a) as unpatentable over the combination of Feili-Hariri and Cameron.

## CONCLUSION

In summary, we reverse the rejection of record.

## REVERSED

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