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December 11, 1991

VIA TELEFACSIMILE (011-61-3-654-4906)
John Slattery
Davies and Collison
1 Little Collison Street
Melbourne, Victoria 3000
AUSTRALIA

Re: SHANNON et al. - U.S.S.N. 07/478,000
REGULATION OF EXPRESSION OF GM-CSF GENE
Our Reference: SHANNON 1
Your Reference: 3642 EJH/JMS/EC

Dear John:

We have now received a final rejection of the above-identified application. The deadline for filing a notice of appeal or a continuation application is March 2, 1992, but is retroactively extendible for up to three months with the payment of extension fees at the time of response.

We are permitted to file an amendment to put the case in better condition for allowance or appeal, but the Examiner will not enter the amendment if it raises new issues. Moreover, the amendment does not save the application from abandonment unless it results in allowance. See 35 U.S.C. 116 and MPEP 714.12, 714.13. The Examiner may insist that reasons be given why the amendments were necessary and were not earlier presented. 35 U.S.C. §116(b). For procedural reasons, it is generally preferable to file such an amendment a month earlier than the aforementioned deadline.

Declarations and exhibits also may be submitted after final rejection. However, unless they are submitted for the purpose of overcoming a new ground of rejection, the Examiner may insist that a showing of good cause be made. See MPEP 716; but compare 37 C.F.R. 1.195.

Filing a continuation application allows us to amend the claims as a matter of right, and to freely submit new declarations or exhibits in support of patentability. In general, appeal should be taken only when you have a fully developed claim set and a complete evidentiary record in support of patentability.

The Examiner asserts that no screening process is seen in the instant application and therefore objects to the specification.

The application presently contains the following categories of claims:

Claims 1-5, a method for controlling expression of GM-CSF;
Claims 6-7, methods of diagnosis of diseases associated with expression of GM-CSF;
Claim 8, a method for identifying an agent for regulating the binding of nuclear proteins to the GM-CSF promoter; and
Claims 9 and 11-14, directed to the regulatory agents per se.

In considering the rejection, please bear in mind that these groups may require separate treatment. For example, the Examiner says, "The instant specification discloses only three [two?] substances that were tested for effecting the binding of nuclear proteins with the promoter region of a GM-CSF or other cytokine. This is not enough of a showing to support a claim which could embrace any protein or any agent". The relevance of this argument to the screening method claim is dubious. Demonstration of a identification of three different suitable substances seems ample proof of the generic efficacy of the screening method, absent evidence to the contrary. The argument is more apropos to the composition claims, which perhaps could be limited to NF-GMa, NF-GMb, and their derivatives and homologues with the desired activity. This would also resolve the indefiniteness rejection of claims 9 and 14.

The indefiniteness rejection of claims 1-5 can be cured by reciting in claim 1 that the binding is regulated by exposing the promoter region of the GM-CSF gene in said cells to a regulatory molecule according to claim 9.

I have pointed out the highlights of the office action, but you should nonetheless review it in detail. I await your comments and instructions.

Best regards.

By: _____
Iver P. Cooper

IPC/amm
Enclosure
shannon1.frj