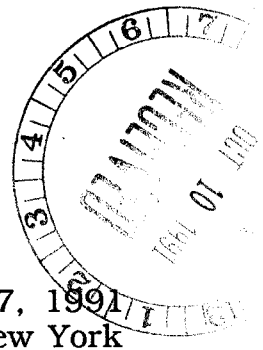


Applicant(s): Jannis G. Stavrianopoulos, et al.)
Serial No. : 07/607,347)
File Date: October 30, 1990)
Title: Composition and Kit)
Employing Chemically-)
Labelled Polynucleotide)
Probes)



Art Unit: 187 *D. Washington*
Examiner: A. Marschel *10/11/91*

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Elaine P. Brenner September 27, 1991
Elaine P. Brenner Date
Reg. No. 29,517 Commissioner of Patents and Trademarks
Washington, D.C. 20231



September 27, 1991
New York, New York

RESPONSE UNDER 37 CFR §1.115

Dear Sirs:

Please enter this response to the Office Action of March 28, 1991. This response is being timely filed with a Request for a Three-Month Extension of Time and the fee therefor. Accordingly, this response is being timely filed.

AMEND THIS APPLICATION AS FOLLOWS:

In the Specification:

Page 1 of the specification, line 1, as amended by preliminary amendment of October 30, 1990, line 2, after "1989," delete "is" and insert C1 -which issued as U.S. Pat. No. 4,994,373 on February 19, 1991, which was filed as --

Page 1 of the specification, line 1, delete "This is a continuation-in-part of applicants' pending United States patent application, serial number 461,469, filed January 21, 1983."

In the Claims:

Please amend the claims as follows:

Claim 28, Line 1, after "Claim", delete "40" and insert --27--.

Claim 30, line 1, after "Claim", delete "42" and insert --29--.

Enz-7(CIP)C2

Please Enter the Following New Claims:

Claim 33. A composition of matter which comprises a transparent or translucent non-porous system further comprising a double-stranded polynucleotide which is immobilized on a solid support wherein one of the strands is chemically labelled and capable of generating a soluble signal.

Claim 34. The composition of claim 33 wherein the solid support is contained within the transparent or translucent non-porous system.

C²
Claim 35. A method for detecting a polynucleotide sequence which comprises:

hybridizing a polynucleotide or oligonucleotide probe, which is in single-stranded form and has attached thereto a chemical label comprising a signalling moiety capable of generating a signal, to said polynucleotide sequence;

fixing said hybridized polynucleotide to a solid support which comprises or is contained within a transparent or translucent system; and

generating and detecting a signal characterized in that the transparent or translucent system is non-porous and the generated signal is a soluble signal.

Enz-7(CIP)C2

REMARKS

Reconsideration of the above-identified application is respectfully requested. The status of the claims is as follows: Claims 27-32 are pending in this application. In addition, Applicants have added new claims 33-35 based on the case as filed. Accordingly, claims 27-35 are presently under examination in this application.

Applicants would like to acknowledge that the original numbering of the instant claims was not in accordance with 37 CFR §1.126. Applicants appreciate that the Examiner has undertaken to renumber claims 40-45 as 27-32, respectively. All of the instant claims, including the dependencies of claims 28 and 30, conform to the renumbered format. Any inconvenience caused by this original oversight is sincerely regretted.

Applicants have updated the present status of the parent application, Serial No. 07/385,986 which issued as U.S. Patent No. 4,994,373 on February 19, 1991, by including the present status of the case in the instant specification. Further, Applicants have deleted the previous first line in the specification after the title which contained the reference to Serial Number 461,469, to avoid duplication with the amended language in the Preliminary Amendment and to accurately set forth the current status of the parent application which issued after the instant application was filed on October 30, 1990. Finally, Applicants appreciate the courtesy extended by the Examiner in presenting the explanation of the two digit prefix which indicates the series of a particular application in the PTO numbering system for pending applications. Applicants will endeavor to use the prefix reference in the future to more accurately specify the application in question in PTO correspondence.

Enz-7(CIP)C2

It is submitted that all of the foregoing amendments comprise subject matter which Applicants are duly entitled to claim. No new matter has been entered thereby.

Applicants have added new claims 33 and 34 to further define an embodiment of the invention which is a composition comprising a transparent or translucent system in which a polynucleotide is fixed to a solid support in double-stranded form, and in which one of the strands of the polynucleotide is chemically labelled and capable of generating a soluble signal. The transparent or translucent system either comprises or contains the solid support. New claims 33 and 34 are based upon the specification at page 10, lines 10-12, lines 17-25, and page 14, lines 26-36. Applicants thus submit that no new matter is presented hereby.

Applicants have added new claim 35 to further define the various embodiments of the invention for fixing the nucleic acid to the solid support, i.e., in single-stranded or double-stranded form. In accordance with claim 35, the invention is directed toward the detection of a polynucleotide sequence by a method in which a probe, which is chemically labelled, is hybridized to a polynucleotide sequence, and the hybridized polynucleotide is fixed to a solid support, thereby resulting in the generation of an easily detected and measurable soluble signal comprising or contained within a transparent or translucent non-porous system. Support for newly added claim 35 is set forth on page 10, lines 6-9 and page 10, lines 17-25 of the instant specification. Thus, no new matter is presented hereby.

The above claims have been added to further define the invention. Applicants submit that these claims are fully supported by the instant disclosure. Furthermore, no new matter has been introduced by any of the foregoing claims, which comprise subject matter to which Applicants are duly entitled.

Enz-7(CIP)C2

The Rejection Under 35 U.S.C. §102(b)

The Examiner has rejected claims 27-31 under 35 U.S.C. §102(b) as being anticipated by Langer et. al. In the Office Action (pages 3-4), the Examiner stated:

"Langer et. al. discloses a biotin labeled polynucleotide probe composition in the abstract. The capability of this chemically labeled probe to produce a soluble signal is via the binding of avidin coupled with an indicator enzyme as disclosed on page 6633, first column, lines 11-14. The apparatus of instant claim 31 is inherent in the hybridization assay methodology disclosed by Langer et al. The hybridization on non-porous solid supports, that are transparent or translucent, of instant claims 29-30 is disclosed by the in-situ hybridization method discussed by Langer et. al. on page 6637, second column, lines 1-8. A transparent non-porous solid support is embodied by glass slides etc. onto which chromosomes are fixed for in-situ hybridization assay.

Applicants respectfully request reconsideration of this rejection based on the following grounds.

The instant invention relates to a composition which comprises a double-stranded polynucleotide which is immobilized, in which one of the strands comprises a chemical label which is capable of generating a soluble signal comprising or contained within a transparent or translucent non-porous system. The instant invention is a departure from the prior art. According to the invention, a detectable soluble signal is generated using any one of a number of signal generating systems in any number of different formats. The soluble signal may be detected using a variety of techniques. According to the invention, chemically labelled polynucleotides or oligonucleotides are employed to detect analytes using a soluble signal.

Enz-7(CIP)C2

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