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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Stavrianopoulos et al.

Serial No.: 08/486,070

Filed: June 7, 1995

#### For: ARRAYS AND SYSTEMS COMPRISING ARRAYS FOR GENETIC ANALYSES AND OTHER APPLICATIONS

Group Art Unit: 1631

Ex'r: Ardin H. Marschel, Ph.D.

60 Executive Boulevard Farmingdale, NY 11735-4716

Mail Stop Non-Fee Amendment Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

## DECLARATION OF DR. DOLLIE M. W. KIRTIKAR UNDER 37 C.F.R. §1.132

I, Dollie M. W. Kirtikar, hereby declare as follows:

### **BACKGROUND**

En= 7/0//02)

1. I am presently Senior Scientist for Enzo Biochem, Inc., 60 Executive Boulevard, Farmingdale, New York 11735-4716, having held that position since 1997. Prior to my present position, I was Research Scientist for Enzo, having been first hired in February 1979. During the early 1990s, I held other positions within Enzo or its subsidiaries, including Production Manager and Supervisor of QA/QC. My professional experience is listed on my curriculum vitae attached as Exhibit 1.

2. In terms of my education, I received my Bachelor of Science (B.Sc.) with honors from the University of Bombay, Bombay, India in 1952, graduating with a major in microbiology and a minor in chemistry. In 1957, I received a Master of Science (M.Sc.) from the Seth C.S. Medical College, University of Bombay. In 1967, I was awarded a Doctor of Philosophy (Ph.D) from the University of Kansas. My doctoral thesis was titled "Phenotypic Transformation."

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3. From 1969 to 1971, I received a visiting fellowship from the Nucleic Acid Research Foundation of Netherlands, under which I carried out research on enzymes and factors involved in DNA transcription in the Biochemistry Department, University of Netherlands, Croningen, Netherlands. From 1971 to 1977, I was a research associate in the Biochemistry Department, Case Western Reserve University School of Medicine, Cleveland, Ohio. At Case Western, I conducted research on enzymes involved in DNA repair following treatment with cancer-causing physical and chemical agents. From 1977 to 1978, I was a research associate in the Radiology Department, Stanford University Medical Center, Stanford, California, where I conducted research on DNArepair deficient bacteria. My education and research experience are listed on my CV (Exhibit 1).

4. During my education and research spanning the years 1961 to 1978, I held a number of teaching positions which are listed on my CV (Exhibit 1).

5. I am the author of several scientific publications and the inventor named on several U.S. and foreign patents and patent applications. My scientific publications are listed on my CV (Exhibit 1). Representative issued U.S. patents are listed on my CV (Exhibit 1). I am also a co-inventor on the above-identified U.S. Patent Application Serial No. 08/486,070, filed on June 7, 1995 (hereinafter "the '070 application"). I am familiar with the specification for the '070 application that was filed on June 7, 1995. I have also read the Declaration of Dr. Jannis G. Stavrianopoulos, who is one of my co-inventors on the '070 application.<sup>1</sup> I have additionally read the Office Action mailed on July 2, 2003.

6. As a co-inventor, I am making this Declaration on behalf of and at the request of the assignee.

Enz-7(D)(C3)



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<sup>&</sup>lt;sup>1</sup> I understand that Dr. Stavrianopoulos's Declarati n was submitted to the Unit d States Patent and Trademark Office in Applicants' June 17, 2002 Supplemental Amendment T [Their] April 10, 2002 Amendment Under 37 C.F.R. §1.116.

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### EXPERIMENTS UNDERLYING THE '070 APPLICATION

7. In connection with the present invention, my co-inventors and I discovered that nucleic acids could be fixed to non-porous solid supports and remain available for hybridization and detection. In our research and experiments that led to the present invention and the filing of the first application in January 1983, my co-inventors and I investigated different support materials, shapes, surfaces and treatments with respect to fixing nucleic acids to supports in hybridizable form. In at least two separate instances, we constructed an array of different nucleic acids fixed or immobilized to two different kinds of solid supports. Among the different solid supports I investigated prior to 1983 are those listed below in chronological order (most recent at the bottom). Copies of pages from my laboratory notebook are also included herewith as Exhibits 2-9.

SUPPORT/SURFACE	TITLE OF LABORATORY NOTEBOOK PAGE(S)	<u>EXHIBIT NO</u> .
[flat] microscope slides with	Detection of glucosylated DNA with	2
slots	fluorescent Con-A on slides	
(preprinted slides) <sup>2</sup>	(microscope slides with slots)	
	Con-A binding to glucosylated DNA treated	3
glass tubes	glass tubes Binding of DNA to glass	
glass tubes	Concentration curve for DNA binding to	4
	activated glass tubes	
	(Con A binding to DNA on the glass surface)	
plastic wells	DNA binding to activated surfaces plastic	5
	wells treated with epoxy-glue	
plastic plates	Activated plastic plates Detection of	6
	glycosylated DNA by con A alkaline	
	phosphatase	
glass tubes	DNA binding to activated glass surface	7
glass fiber filters	Preparation of glass fibre filter	8
glass tubes/slides	Preparation of Silanized glass	9

 $<sup>^2</sup>$  My laboratory notebook refers to "microscope slides with slots." In common parlance, "slots" may suggest rectangular channels, troughs or indentations. In the context of my experiments, h wever, "slots" refers t the flat circles that are preprinted onto flat microscope slides. It is known in th art that 'slots' is a synonym for the circles on preprinted slides, also known as cytology slides.

Enz-7(P)(C3)



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8. Since the focus of our investigations was attachment of nucleic acids to ostensibly inert materials, such as glass and plastic, I focused upon surface treatments for glass and plastic that would permit such binding. Because the shape of these materials is irrelevant to their surface chemistry, I used a variety of differently shaped supports to carry out these experiments, including microscope slides, glass fibers, test tubes, microtitre plates and wells.

### FLAT MICROSCOPE SLIDES WERE USED IN OUR EXPERIMENTS

9. As indicated above and as shown in my laboratory notebook pages (Exhibits 2 and 9), on at least two separate occasions I fixed nucleic acids to flat microscope slides.

### ARRAYS OF DIFFERENT NUCLEIC ACIDS WERE CONSTRUCTED ON SEPARATE OCCASIONS WITH DIFFERENT SOLID SUPPORTS

10. As shown in my laboratory notebook pages (Exhibits 2 and 8), I constructed two nucleic acid arrays<sup>3</sup>, one using preprinted microscope slides and the other using glass fiber filters. See the second page of both Exhibits 2 and 8.

A. In the first array (Exhibit 2, second page), T4 and  $\lambda$  DNA were spotted on twelve locations on the same flat microscope glass slide. The flat microscope slide was a preprinted glass slide, also called a cytology slide.

B. In the second array (Exhibit 8, second page), T4 and  $\lambda$  DNA were each spotted three times on the same glass fiber filter. In fact, two such arrays in the form of glass fiber filters were taped to my original laboratory notebook page

<sup>&</sup>lt;sup>3</sup> This is true under a restrictive definition of "nucleic acid array" as meaning a plurality of various nucleic acids arranged on a solid support. Under the plain definition – a plurality of (various or identical) nucleic acids arranged on a solid support – more of my experiments could be charact rized as involving construction of nucleic acid arrays.



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