



## BANBURY CENTER HIGHLIGHTS

### PATENTING OF LIFE FORMS

October 18-21, 1981

Organized by:

Norton Zinder, Rockefeller University;  
Neil Reimers, Stanford University;  
David Plant, Fish & Neave, New York

*Like many Banbury Center meetings, Patenting of Life Forms was particularly significant because it brought together a diverse group of experts. In this meeting, patent attorneys familiar with patents in the physical sciences and leading experts in the still fledging field of recombinant DNA reviewed and discussed the U.S. Supreme Court decision that opened the gate to the development of the biotechnology industry.*

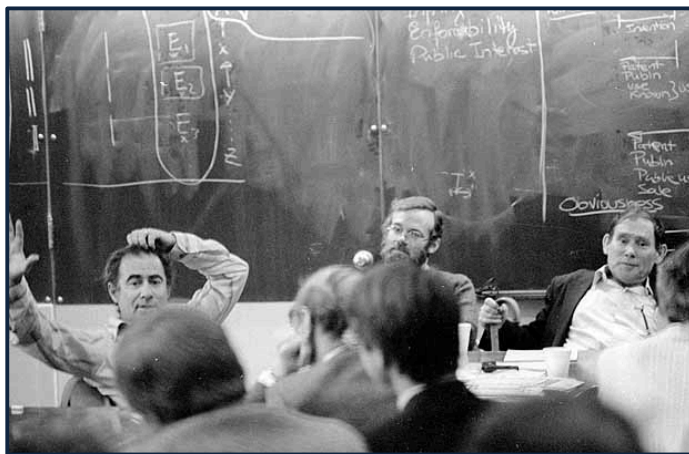
In June 1980, the US Supreme Court ruled in the case of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) to settle the following:

Title 35 U.S.C. 101 provides for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter." Respondent filed a patent application relating to his invention of a human-made, genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria. A patent examiner's rejection of the patent application's claims for the new bacteria was affirmed by the Patent Office Board of Appeals on the ground that living things are not patentable subject matter under 101. The Court of Customs and Patent Appeals reversed, concluding that the fact that micro-organisms are alive is without legal significance for purposes of the patent law.

The Court affirmed that Chakrabarty's bacterium was patentable. This was, needless to say, a controversial decision and it was greatly to the merits of Zinder, Reimers, Plant and Victor McElheny (as director of the Banbury Center) that they were able to convene this meeting only 15 months after the Supreme Court pronounced its verdict.

It was a landmark decision not so much for the particulars of the case as for opening up the idea that patents in biology were as much worth pursuing as those in electronics or chemistry. The ramifications of the consequences are with us today.

The papers presented in the meeting were published as *Patenting of Life Forms*, #10 of the Banbury Report series.



Norton Zinder, Ron Davies, Sydney Brenner



## PATENTING OF LIFE FORMS: Meeting Report

The manipulation of the genetic chemical, DNA, for scientific study of how it governs the operations of normal and abnormal cells, seems unable to proceed without intense controversy. The very birth of a convincing double-helical model of the structure of DNA in 1953, emerging dramatically in such a way as to capture the attention of brilliant workers, intensified struggles between old and new approaches to biological science, even as it opened enormous new fields of research.

In the early 1970's, scientists involved in studying DNA themselves unleashed an increasingly passionate public debate on what then seemed to be possibilities of risks to humans from work on recombinant DNA. This debate brought molecular biology to the brink of regulations that might have stifled research of vast potential value, for such purposes as the elucidation of human cancer induction, in its cradle. But by its very intensity, and extensiveness, the debate sharpened popular consciousness of the practical potential of such research in fundamental biology and genetics.

In a few years, attention shifted, once again with drama, to attempts to speed the commercial application of the new biology, in the development of new food-plant varieties, the management of diseases in commercially important animals, microbe-assisted manufacture of pharmaceuticals, or even in reducing the internal energy tax that must be paid by such energy industries as oil refining.

The dark colors of earlier debate on risks and the roseate glow of anticipated commercial benefits both spread over the 1980 decision of the United States Supreme Court that microorganisms themselves, created by genetic manipulation techniques, could be patented along with processes for making or using such microorganisms.

The decision that the genetically engineered organism itself would be patentable is likely to have its greatest immediate effect in making the life of patent lawyers somewhat less complicated. The organism itself can be used in disputes over whether a patent has been infringed. Enforcement of patents of genetically engineered microorganisms should be simpler.

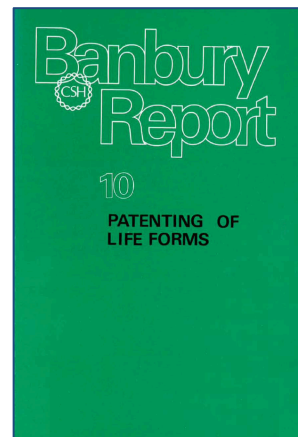
But such practical utility of a court decision does not explain the extraordinary public interest that surrounded the decision that a microorganism developed by Ananda Chakrabarty, then of General Electric Company and now of the University of Illinois, should obtain a patent from the U.S. Patent and Trade-mark Office. For many, the decision took on a wider, largely emotional significance. To an imperfectly informed public, the decision seemed to say that "life," whatever that term might mean, could be patented, and thus,

that some kind of permission had been granted for genetic manipulations that people had become accustomed-if largely by science fiction-to consider menacing.



*Neil Reimers, Matt Scharff, Bill Udry*

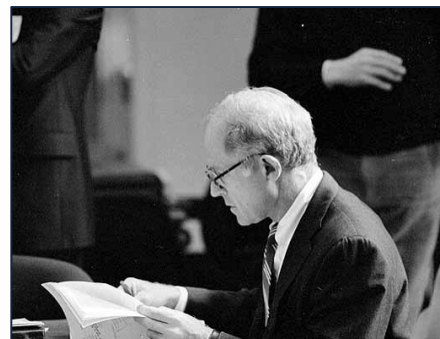
For scientists, the decision also was a shock. The notion that fundamental biological discoveries could be turned into intellectual property through the patent system forced many biologists to consider what the rapid elaboration of such property would do to the organization of the university laboratories. For many biologists, the situation was new and apparently challenging to cherished beliefs and practices. It seemed of little help to reflect that chemists had been wrestling with similar problems for a century, and physicists for almost as long. Even for patent attorneys, the practical helpfulness and technical





narrowness of the 1980 Chakrabarty decision was overshadowed by unease about the vast unexplored legal territory represented by the forest of work on DNA. So, in the summer of 1980, there seemed to be a strong need for a meeting between biologists and patent lawyers, at which the two groups could explore the disparate traditions of advanced genetics and patent law.

The hope was that the lawyers and scientists would each come away understanding the other's environment and culture a little better. The idea came up in conversations among Phillip Sharp, an alumnus of Cold Spring Harbor Laboratory, now at the Massachusetts Institute of Technology, and Joseph Sambrook and J.D. Watson, both of Cold Spring Harbor Laboratory. I received the assignment of trying to organize a meeting that would take the Banbury Center from its dominant focus on environmental health risk assessment into a broader realm of the social implications of advances in molecular biology.



*David Plant*

Over the next few months, we were fortunate in recruiting three organizers of very different backgrounds who could recruit in turn the participants needed to carry the meeting beyond the reutterance of pious generalities. With the help of David W. Plant of the patent law firm of Fish and Neave, Niels J. Reimers of the technology licensing office at Stanford University, and Norton D. Zinder of Rockefeller University, we were able to aim at a meeting that could explore the practical impact of the Chakrabarty decision on both biological science and patent law.

Of particular assistance in keeping the feel of the meeting firmly planted on the ground was the participation of Judge Giles Rich of the U.S. Court of Customs and Patent Appeals (since reorganized into the U.S. Court of Appeals for the Federal Circuit). Before going on the bench in 1956 by appointment of President Eisenhower, Judge Rich had helped in the drafting of the 1952 revisions of the U.S. Patent Code. He wrote the lower court opinion in the Chakrabarty case that was upheld by the Supreme Court. Judge Rich enlivened the sessions of the conference with penetrating questions.

We also were aided by the participation of Alvin Tanenholtz, the chief examiner in the Patent and Trademark Office in the biotechnology field, and of Alan MacPherson, former chief counsel of National Semiconductor Corporation, who gave us a lively and very detailed review of a branch of the electronics industry whose use of patents is very different from that of the pharmaceutical industry.

Evidence of the strong interest in the meeting was provided by the fact that no less than 15 industrial companies agreed to cosponsor it: Baxter-Travenol Laboratories, Inc., Chevron Research Company, The Dow Chemical Company, E.I. duPont de Nemours and Company Inc., Exxon Research and Engineering Company, Hoffmann-LaRoche Inc., Johnson and Johnson, Eli Lilly and Company, Merck Sharp and Dohme Research Laboratories, Monsanto Company, National Distillers and Chemical Corporation, Pfizer Inc., Schering-Plough Corporation, Smith Kline and French Laboratories and The Upjohn Company. It is a pleasure to thank them all for their splendid help toward both the conference and the



*Norton Zinder, Mark Ptashne, Sydney Brenner*



publication of this report, and for sending strong representatives to the conference.

A number of the companies contributing to the conference on Patenting of Life Forms had been long-time contributors to Cold Spring Harbor Laboratory, or recent contributors to other Banbury conferences, but others assisted us for the first time. The conference represented an important step forward in intellectual as well as financial support from industry to Cold Spring Harbor Laboratory and its Banbury Center.



*Axel Ullrich*

Lawyers attending the meeting were able to gain some idea of the extraordinary richness and complexity of the work in the exploding field of molecular biology. The scientists were able to see somewhat better why the emergent technologies of recombinant DNA seem absorbable in the tradition of patent law. Both sides realized that the true impact of the Chakrabarty decision will become apparent only gradually, as the result of a slow, case-by-case building of a body of patents, and decisions in suits over those patents. It may be that participants in the Banbury meeting of 18 to 21 October 1981 will wish to reassemble in future to assess what has happened by them.

Such an intellectual enterprise as the Patenting conference and this report of its proceedings is impossible without the cooperation of scores of people. I wish to thank not only the organizers but each of the participants, including those who went on to provide us with detailed manuscripts. As in each Banbury Report, it is my pleasure to thank my administrative assistant, Beatrice Toliver, and the Banbury editor, Lynda Moran, for their devoted work at every stage of the conference and its report. I wish also to thank J.D. Watson, Director of Cold Spring Harbor Laboratory, for his continuing refusal to be checked by difficulties. This is the central quality for success in entrepreneurial enterprises like Cold Spring Harbor Laboratory or its Banbury Center.

*Victor K. McElheny*  
*Cambridge, Massachusetts, May 1982*





## **PATENTING OF LIFE FORMS: Program**

### **Session 1: Scientific Issues**

J. Hicks, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York

*The life cycle of the common microbial hosts, with emphasis on yeast, the most complex.*

M. Scharff, Albert Einstein College of Medicine, Bronx, New York

*Monoclonal antibodies. What defines a permanent cell line, differentiating what is novel or unique; what parameters distinguish one hybridoma from another?*

C.M. Croce, Wistar Institute of Anatomy and Biology, Philadelphia, Pennsylvania

*Monoclonal antibody systems with potential for diagnosis of pancreatic and other forms of cancer.*

H. Heyneker, Genentech, Inc., South San Francisco, California

*Vector systems and expressions in E. coli.*

A. Ullrich, Genentech, Inc., San Francisco, California

*Gene transfer - Moving a human gene to a mouse genome.*

S. Brenner, Cambridge University Medical School, Cambridge, United Kingdom

*Recombinants that are the same but different.*

### **Session 2: Open Forum on Scientific Issues**

Chairperson: N.D. Zinder, Rockefeller University, New York, New York

Discussants: N.H. Carey, Celltech, Slough, United Kingdom

P.A. Sharp, Massachusetts Institute of Technology, Cambridge, Massachusetts

J. Davies, Biogen, SA, Geneva, Switzerland

J. Sambrook, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York

### **Session 3: Legal Issues**

D.W. Plant, Fish & Neave, New York, New York

*Primer on law on patents and other intellectual property.*

B.I. Rowland, Townsend and Townsend, Palo Alto, California

*Should the fruits of genetic engineering be patentable?*

V. Vossius, Vossius, Vossius, Tauchner, Heunemann, Rauh, Munich, Germany

*Discussion of items I and II as they relate to European and German patent law.*

T.D. Kiley, Genentech, Inc., South San Francisco, California

*Assuming patentability, what property rights should accrue to workers in this field?*

J.W. Schlicher, Genentech, Inc., South San Francisco, California

*The extent to which antitrust and patent misuse law limits the manner in which patents are acquired, enforced, and licensed.*

N.J. Reimers, R.G. Ditzel and W.P. O'Neill Stanford University, California; University of California, Berkeley; DNAX Research Institute, Palo Alto, California

*Problems in enforcing patents and in commercializing patented subject matter in the genetic engineering field.*

A.H. MacPherson, Skjerven, Morrill, Jensen, MacPherson, & Drucker, Santa Clara, California

*Surviving in an industry that largely eschews patents- electronics.*



THE BANBURY CENTER  
Cold Spring Harbor Laboratory

**Session 4: Open Forum on Legal Issues**

Chairperson: Hon. G. Rich, U.S. Court of Customs and Patent Appeals, Washington, DC  
Discussants: G.M. Gould, Hoffmann-La Roche, Inc., Nutley, New Jersey  
C. H. Herr, E.I. duPont de Nemours & Company, Wilmington, Delaware  
A.E. Tanenholz, U.S. Department of Commerce, PTO, Washington, DC

**Session 5: Revision in Patent Law and the Patent Court System Affecting the Patenting of Life Forms**

Discussants: N.E. Noonan, House Committee on Science and Technology, Washington, DC  
E.L. Bernard, Bernard, Rothwell & Brown, Washington, DC  
G.M. Kary, Office of Technology Assessment, US Congress, Washington, DC



## PATENTING OF LIFE FORMS: Participants

<b>Eugene Bernard</b> Bernard, Rothwell & Brown USA	<b>Sydney Brenner</b> Cambridge University United Kingdom	<b>Norman Carey</b> Celltech United Kingdom
<b>Carlo Croce</b> Wistar Institute USA	<b>Julian Davies</b> Biogen, S.A. Switzerland	<b>Roger Ditzel</b> University of California USA
<b>George Gould</b> Hoffman-LaRoche, Inc USA	<b>C. Harold Herr</b> E.I. duPont deNemours & Company USA	<b>Herbert Heyneker</b> Genentech, Inc USA
<b>James Hicks</b> Cold Spring Harbor Laboratory USA	<b>Geoffrey Kary</b> US Congress, Office of Technology Assessment USA	<b>Thomas Kiley</b> Genentech, Inc. USA
<b>Alan MacPherson</b> Skjerven, Morill, Jensen, MacPherson & Drucker USA	<b>Norine Noonan</b> House Committee on Science and Technology USA	<b>William O'Neill</b> DNAX Research Institute USA
<b>David Plant</b> Fish & Neave USA	<b>Niels Reimers</b> Stanford University USA	<b>Giles Rich</b> US Court of Customs & Patent Appeals USA
<b>Bertram Rowland</b> Townsend and Townsend USA	<b>Joseph Sambrook</b> Cold Spring Harbor Laboratory USA	<b>Matthew Scharff</b> Albert Einstein College of Medicine USA
<b>John Schlicher</b> Genentech, Inc USA	<b>Philip Sharp</b> Massachusetts Institute of Technology USA	<b>Alvin Tanenholtz</b> US Department of Commerce Patent & Trademark Office USA
<b>Axel Ullrich</b> Genentech, Inc USA	<b>Volker Vossius</b> Vossius, Tauchner, Heunemann, Rauh Germany	<b>Norton Zinder</b> Rockefeller University USA