

Roman Saliwanchik

**PROTECTING
BIOTECHNOLOGY
INVENTIONS**

A Guide for Scientists

Brock/Springer Series in Contemporary Bioscience

Roman Saliwanchik

Protecting Biotechnology Inventions

A Guide for Scientists

With 19 Figures



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PROTECTING BIOTECHNOLOGY INVENTIONS: A Guide for
Scientists

Foreword

On the basis of my many years of experience, first in industry and then in academia, I believe that scientists will find reading this book to be very rewarding. During my years as an industrial research scientist, I learned first-hand of the urgency of adequate protection measures at an *early stage* in the research process. I saw the rights to important inventions lost because researchers had not adequately maintained their records and files. Later, during my years as a university professor, I found it essential to teach my research students how to keep records.

However, the adequate protection of a biotechnology invention requires more than just keeping correct records. There is a whole series of procedures that must be followed. Now that biotechnology research is of such great economic importance, all researchers in this area have a vital interest in protecting the products of their research. In the present book a noted patent attorney with many years of experience in biotechnology—as both a researcher and a lawyer—presents a concise, authoritative, and easy-to-read guide to the protection of scientific inventions.

Although this book concentrates on biotechnology, the information presented is applicable to any activity in which intellectual property is created. Every researcher, whether working in industry or in an academic setting, should own and read this book, which clearly outlines the essential procedures and the common pitfalls involved in the protection

of the results of scientific activity. Clearly illustrated with many flow diagrams and examples, the book expertly guides the uninitiated through the maze of patent law and trade secret protection. The author points out that if a researcher and/or an employer wishes to protect new discoveries, confidentiality must be maintained from the moment the idea is first conceived.

Although this book is written with the researcher in mind, the business person and legal technician will also find the information of value. The author, Roman Saliwanchik, is the senior partner in a Florida law firm that specializes in patent and trademark law. He was previously Senior Patent Lawyer for the Upjohn Company, and before that a microbiologist-chemist with Eli Lilly. Among his publications is *Legal Protection for Microbiological and Genetic Engineering Inventions* (Addison-Wesley, 1982). The present book offers advice that Saliwanchik has gleaned from his actual experience of over 25 years of practice in patent law. The distillation of this experience into a concise, action-oriented work will come as a boon to researchers, as well as to students, instructors, practicing lawyers, and industry executives.

Thomas D. Brock
University of Wisconsin-Madison

Preface

In the course of my work as a patent attorney for over 25 years, first at a major biomedical corporation and then in private practice, I have frequently been surprised at how little most scientists know about protecting the legal rights to their inventions. I have also witnessed the frustration of scientists who have unwittingly given up their legal rights simply because they were not aware of the proper procedures for protecting these rights. This ignorance has often led to financial loss for both scientists and their employers; it has also hindered the professional advancement of many scientists because they did not receive proper recognition for the discoveries they made.

Therefore, my primary motive for writing this book was to educate scientists about how to protect their intellectual property rights—their inventions and discoveries—and how to do so in the best way possible. In order to increase the reader's chances of successfully protecting his or her rights, I have included very specific suggestions about the proper procedures for:

- keeping laboratory records,
- maintaining confidentiality,
- making a confidential disclosure to a third party,
- disclosing data to a government agency,
- selecting a patent attorney,

and many other things that researchers should know in order to protect their work.

I have addressed this book primarily to scientists in the field of biotechnology, since this is the field in which I was trained in my first career as a scientist and also in which I practice law. As evidenced by the large number of patents and patent applications in biotechnology, this discipline is now one of the most fertile areas for new discoveries. However, I believe that this book will be very useful for scientists in other fields as well; researchers in every field should know how to protect their intellectual property rights. Ideally, all scientists should carry out their research in such a way that they do not jeopardize their rights.

In addition, from the perspective of a patent attorney, I can say unequivocally that the better informed the inventor is about the legal protection process, the more likely it is that the inventor's patent attorney can obtain protection for the invention. However, this knowledge does not obviate the need for the services of the patent lawyer. On the contrary, a well-informed inventor will be much more likely to retain patent counsel at an early stage of the patent process than will an inventor not having such knowledge.

Finally, well-informed scientists will know that the time to think about legal protection begins when an idea is first conceived and not when the invention is finally realized. They will be able to avoid numerous pitfalls and will be much more likely to receive both financial and professional rewards for their work than scientists who are unaware of the proper procedures for protecting their legal rights.

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Roman Saliwanchik

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Protecting Biotechnology Inventions

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1

Preserving Property Rights in Biotechnology

The scope and application of biotechnology research is extremely broad. The techniques used in this research are derived largely from the classical fields of physics, chemistry, biology, and molecular biology. The fruits of this research promise to have a profound effect on numerous disciplines including pharmaceutical, agricultural, medicinal, and environmental sciences.

Although biotechnological research has garnered a tremendous amount of attention in recent years, and the prospects for future developments are exciting, this field of research is by no means new. Biological organisms have been used for centuries for fermentation, degradation of wastes, and many other tasks. The utility of microorganisms in making wine, sauerkraut, soy sauce, and other fermentation products has long been recognized. Despite this long and illustrious heritage, it has only been within the last fifty years that biotechnology has emerged as an industrial tool of monumental

significance. The origins of this emergence can be traced back to the advent of antibiotics during and immediately following World War II. After the war, antibiotics rapidly became an enormously important, and profitable, health care product. The so-called antibiotic era that followed lasted for at least 25 to 35 years. Although the production of antibiotics by fermentation is still the backbone of a number of large pharmaceutical companies and generic drug supply operations, there is little dispute that the antibiotic era is waning.

One development from the early days of antibiotic research accelerated the growth of this industry beyond the level attainable by use of fermentation technology alone. This was the discovery and development of biologically inactive moieties which could be prepared by fermentation means and then chemically converted to biologically active antibiotic compounds having unique and desirable medicinal properties. Scientists who discovered the presence of 6-aminopenicillanic acid (6-APA) in penicillin G fermentation beers laid open a whole new assortment of second-generation antibiotic compounds which quickly achieved success in antibiotic therapy.

Antibiotic inventions provided the impetus for many research and industrial concerns to grow and prosper. The protection of the rights to inventions was of vital importance to these concerns. Many of the inventions involved the use of microorganisms which were akin to highly efficient factories in making new and useful products. Also, new products in the antibiotic and steroid sciences were being discovered and brought to the market place at a rapid pace. There were a multitude of inventions which required new legal procedures for developing and maintaining the legal rights of the inventors. One result of this tumultuous period of research and pursuit of patent protection was the creation of a large body of law dealing with many complex situations. Some of the many patents which have been issued for biotechnology inventions are listed in Appendix C.

Much of the research and development work in the era of antibiotics and steroids was carried out in industrial laboratories, or in well-funded academic laboratories. Legal rights were pursued within large industrial settings where legal services were readily available. Corporate lawyers were accessible from the beginning of projects to advise scientists, to set up protective procedures, and to procure legal rights to the inventions. The net result was that the majority of legal rights established in those "early" areas of concerted biotechnology research and development, inured to industry, and also, in some cases, to well-funded academic laboratories.

Both the scientific community and the legal system have benefited from this activity. Many rules and guidelines were formulated for future guidance for obtaining legal rights in new inventions. Without this expenditure of time and resources by the industrial laboratories to establish legal rights, the scientific/legal community today would be forced to operate in a state of uncertainty. Despite the legal foundations which have been laid during the past 40 years, there are still areas of uncertainty as to whether certain biotechnology inventions can or cannot be protected by certain legal procedures. Today's "newer" biotechnology has many complexities which do not readily fit into the rules and guidelines of the older biotechnology. Thus, there remain many areas of uncertainty for the scientist and patent attorney to consider before deciding upon the best route for obtaining sound legal protection for biotechnology inventions. As the following chapters will show, unique, creative solutions are often required in order to realize a sound legal position.

Despite the new aspects of biotechnological research, many of the research fact situations attendant this newer biotechnology are analogous to the research settings of prior biotechnology. Thus, procedures designed to ensure the legal protection of research results in prior biotechnology work are often applicable to the newer research.