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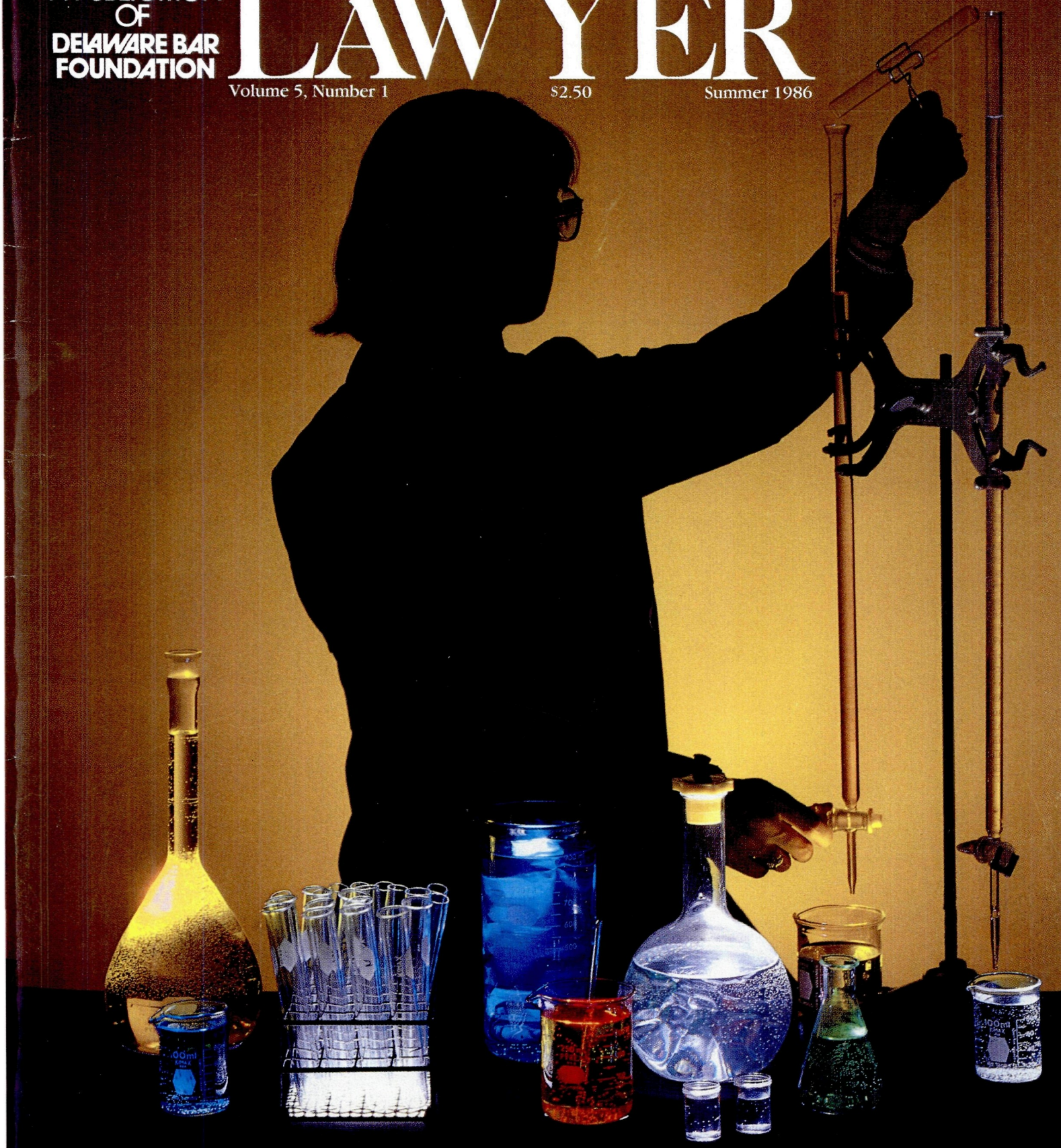

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EDITORS' PAGE

Paula Lehrer

In the movie *Star Trek II,* Hollywood's spacemen in the white suits did intergalactic battle with the evil forces of Khan. Spock, Kirk, *et al* were preserving for future generations a contraption, code named "Genesis"—part of a new technology that could bring bloom to dead planets and bring life as we know it where it could never have existed before.

Science fiction? A millenium or two into the future? Hollywood? Not really. Some of the basic science that someday could make "Genesis" come to life is going on right now in biotechnology labs across the country.* And that's what this issue of *DELAWARE LAWYER* is all about!

Writing an introduction to a magazine that deals with a topic about which one knows very little is a fairly difficult task, but I am faced with that situation and will do my best! It is a strange series of circumstances that led me to become the editor of the Summer issue of *DELAWARE LAWYER,* but nonetheless, I am very pleased and honored to find myself in this position.

When I was asked to be on the Editorial Board, it was primarily because of my association with the Delaware General Assembly where I am employed as an Administrative Assistant to the House of Representatives. The connection with law is fairly understandable, but biotechnology? Anyone who has lived with a duPont scientist for almost thirty years will understand that technology is very often part of conversation at the dinner table. And so it happened that my husband and I were talking about the great impact that this new field, biotechnology, was sure to have on the legal world. Thus, the topic for this issue!

I should like to express my sincere appreciation to Donald Kerr, an attorney for the du Pont Company, who was invaluable in conceptualizing this issue and in helping me to find the gifted people who wrote the articles it contains. It is amazing how when one begins to learn about a subject, one invariably finds more and more in newspapers and magazines that relates to that topic. So it has been with me. It seems that every day I pick up something else about the subject of biotechnology. I hope that after reading this issue, you will have similar experiences.

I have tried to arrange the articles in this issue in such a way that it will be easy for you to understand what is probably a new subject for you too. First, there is an explanation—what exactly is biotechnology? Then we examine some of the existing problems of regulation and of ethical or legal import. Finally, we look at what might be the future interaction of biotechnology and the law. This is a complex question, and one that we shall shortly be unable to avoid.

Let me close with a quote from an editorial in *Chemical and Engineering News* (August 13, 1984):

> *The issue of how to allow a science and its related technology the freedom necessary to develop their fullest potential for the common good, while at the same time containing the common costs of their inadvertent or deliberate misuse, is certainly not a new one...*
>
> *Genetic engineering is the next field to face this challenge. The contributions that . . . biotechnology eventually will make in basic research, medicine, agriculture, industry, and a host of other areas are unquestionably enormous. But seemingly equally enormous—at least to some—is a host of related environmental, regulatory, ethical, and national security concerns.*

Those concerns are what you will read about in the rest of this magazine—enjoy and learn!

**Taken from University of Maryland Alumni newsletter, May 1985.*

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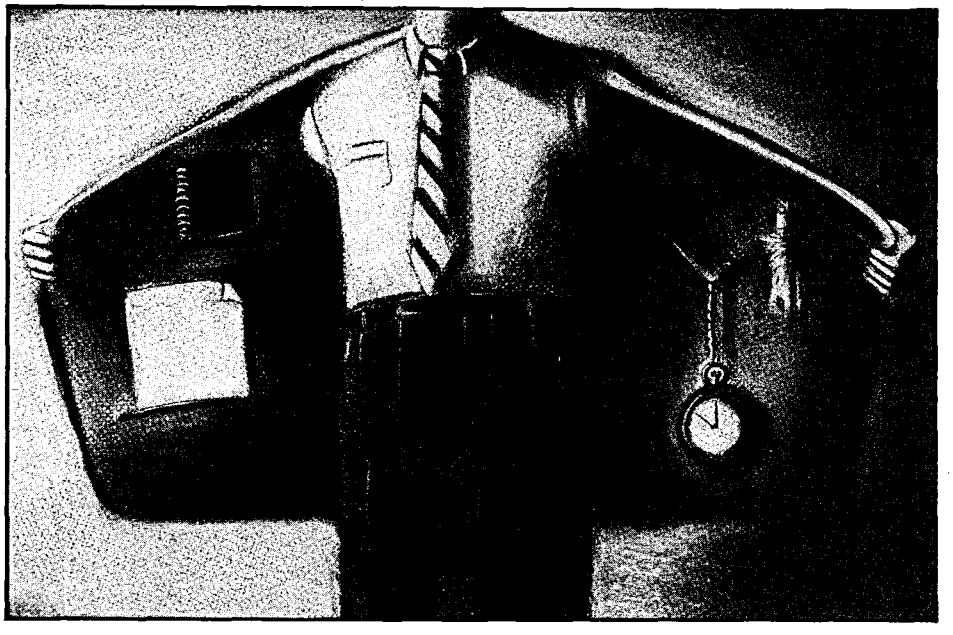

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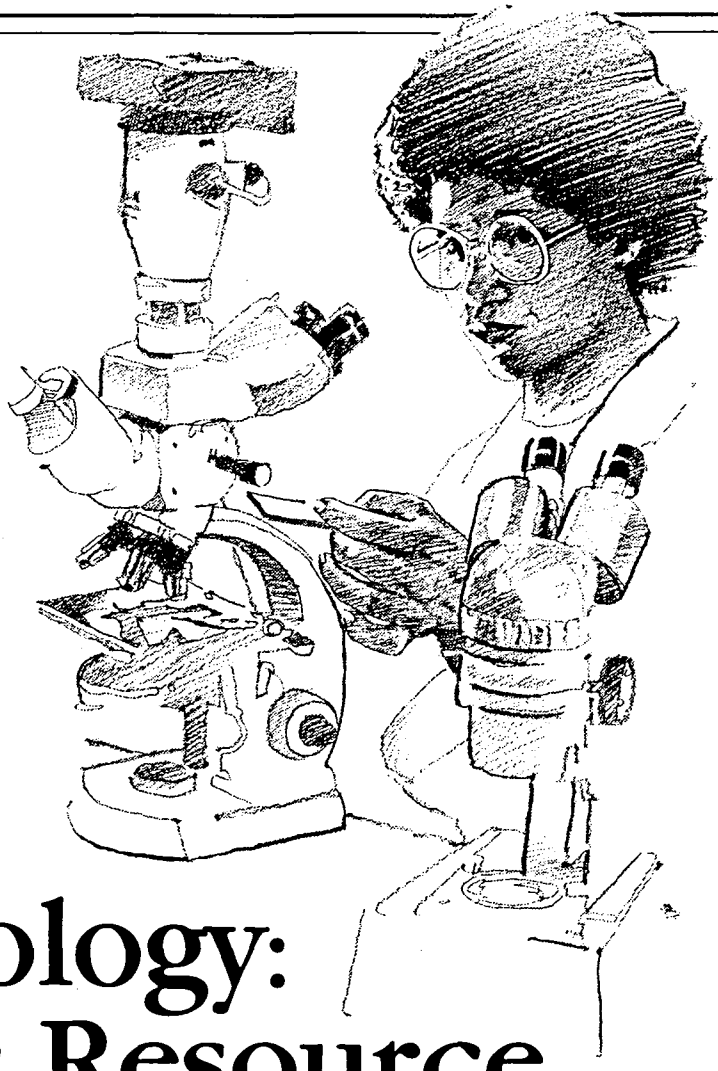

Biotechnology: A Dynamic Resource for Medicine

Richard Holsten

Mankind has probed the causes and sought alleviation of the symptoms of disease for thousands of years. Only in the past century, however, have scientific discoveries provided a foundation for the development of diagnostic and therapeutic advances which could not even be imagined before. Progress in developing improved health care has accelerated at an almost phenomenal rate in the past decade through the application of the techniques of biotechnology.

Genetics, the primal principle in determining biological structure and function, and a key element of modern medicine and biotechnology, has played a pivotal role in shaping the biological world. The basic genetic system, functional in the first living organism, has operated in unaltered fashion for millenia. Man's recognition, understanding, and manipulation of genetics, however, has only occurred within the past century. Fortified with basic genetic knowledge and manipulative skills, we now stand at the threshold of discoveries and technologies that will have profound consequences for generations to come. Nowhere is this more true than in the field of medicine, where diagnosis, prevention, treatment, and cure of disease will all make dramatic strides.

Diagnosis

The body's immune system functions as a watchdog on guard against foreign invaders intent on disrupting the homeostasis of the organism. When confronted by foreign invaders—bacteria, viruses, pollens,—the immune system responds by defense and counterattack. One measure is the production of substances called antibodies, which seek out and neutralize the invaders. Antibody producing cells of the immune system respond to each challenge by producing a single antibody type called a monoclonal antibody. The antibody recognizes the specific foreign challenger and no other. This exquisite selectivity provides not only a primary defense mechanism for the organism but a tool for biotechnology.

Since antibodies recognize specific foreign substances, they can be used to identify an etiologic agent of disease. In some cases, they can also be used to seek out and destroy the disease agent. Clinical laboratory tests using monoclonal antibodies as recognition agents have already been developed to diagnose bacterial, viral, parasitic, and fungal diseases as well as some genetic disorders. They are also being used in tests to determine levels of hormones, therapeutic and illicit drugs, and the presence of abnormal cells such as those associated with cancers.

The future of antibodies in medicine is one of significant untapped potential. Applications in clinical diagnosis, with even greater specificity being achieved through genetic engineering, will expand to encompass a much broader range of conditions. Therapeutic interventions with antibodies will also be forthcoming with potentially even more profound consequences. Therapies will be both extracorporeal—utilizing antibodies as a means to cleanse body fluids of toxic or pathogenic agents—

and *in vivo,* where antibody specificity will be used to deliver agents to specific sites. Delivery of cytotoxic (chemotherapeutic) agents to tumors is one of many therapeutic potentials currently under clinical evaluation.

Prevention

Prevention of disease is the first line of medical defense. Preventive medicine will be a significant beneficiary of biotechnology through the development of improved vaccines.

Smallpox as a human disease has been eliminated throughout the world as a result of the development and use of an effective prophylactic vaccine. Application of the technologies being developed in biotechnology to vaccine development will mean that other diseases will also be effectively eradicated or controlled within the next decade.

Biotechnology offers at least two significant advances for new vaccine development.

Viruses, significant agents of morbidity and death throughout the world for both human and animal populations, are prime candidates for prophylaxis by vaccine. To be effective, vaccines must elicit an immunological response within the host organism, priming it against future attack by the disease-causing entity, but they must not *produce* the disease.

Historically vaccines such as those for smallpox, polio, and rabies have used preparations of live, although attentuated, or killed viruses as the immunological priming agent. They are not always adequately effective or entirely safe. Some vaccine preparations may not produce a satisfactory degree of prophylaxis in the host because of insufficient immunogenic response. Likewise, if virus attenuation or killing is not completely effective during vaccine manufacture, the vaccine may produce disease in the recipient. Biotechnology provides means to mitigate both of these shortcomings.

There are techniques to isolate and dissect a disease-causing viral agent so as to find the most immunogenic portion. This may be a part of the genetic information contained within the virus or a part of the external envelope. Once identified and characterized, the immunogenic material can be used to produce what is called a "subunit" vaccine, that is, a vaccine derived from a portion of the disease producing agent. This selective use results in a safe and effective product. The immune response is narrowed to a limited, highly specific, portion of the complex invading organism, and it is safe because the vaccine contains only a portion of the etiologic agent incapable of reproducing itself and causing disease. Subunit vaccines will be the agents of choice for diseases where efficacy and safety are paramount concerns (e.g. AIDS and hepatitis).

Improved and expanded vaccine development promise dramatic social impact. For example, in 1986 it is estimated that over 4 million people worldwide will die from malaria—a parasitic disease. Successful development of an effective vaccine against malaria would spare countless people the debilitating effects and death associated with this disease. Through genetic engineering, the first steps in development of a malaria vaccine have already been taken. Clinical trials of a potential subunit vaccine are expected in 1986.

Treatment and Cure

What potential for therapeutics does biotechnology offer? One prospect is new therapeutic agents, improved agents, or both.

One example of product improvement through biotechnology is human insulin. Until the recent introduction of a genetically engineered human product, insulin was routinely produced from beef or porcine pancreatic tissue. Initial isolation was followed by processing to yield a product suitable for human use. However, even after purification to remove extraneous materials, the non-human product was perceived as "foreign" by the human immune system. Over time the immune system's normal defensive response leads to an allergic condition in some insulin users, making continued use of animal-based material difficult and dangerous. Yet without insulin, the diabetic patient cannot survive.

Employing the techniques of recombinant DNA technology, the DNA message specifying human insulin has been isolated from human pancreatic cells and introduced into microorganisms. The code translating the product synthesis mechanisms of the microorganism are then activated to produce the human product using another technique of biotechnology—fermentation. This allows large-scale production of the human material in processes similar to those of the brewing industry. Thus large amounts of human insulin can be produced by a relatively simple and efficient surrogate biological production system. A similar scheme has been employed to produce human growth hormone (HGH)—designed to treat hypopituitary dwarfism. Previously the hormone was available only from the pituitary glands of cadavers. The available material was insufficient. With fermentation-based production supplies should become ample for therapeutic needs.

These are only the first products to come from the application of recombinant DNA technology to the needs of therapeutic medicine. A long list of others, currently in various stages of development, will enter the marketplace over the next 10 to 15 years.

Therapeutic products such as insulin and HGH are not cures. They only alleviate physiological consequences. Genetic engineering, however, can address fundamental causes and effect true cures. This potential to confront genetic disease carries with it challenge, hope, and concern.

There are more than 3,000 genetic disorders known to medical science today. Although traceable to the cellular genetic material—the DNA—of the sufferer, in many cases the precise defects

Richard Holstein has a doctorate in plant physiology from Cornell, where he taught before joining the Central Research and Development Department of the DuPont Company in 1966. For the last three years he has held the title Staff Manager, Molecular Biology. He also serves DuPont as Vice Chairman of the Institutional Bio-safety Committee and as Chairman of the Experimental Station Bio-safety Committee. His extensive technical and business backgrounds are manifest in the accompanying article.

have not yet been characterized. Furthermore, some genetic disorders are transmitted through the reproductive cycle (inherited) while others arise from changes in a previously normal genetic constitution.

Cystic fibrosis is an example of an inherited genetic defect. It afflicts about one in 2,000 Caucasian infants. Most victims die in their teenage years. There is no cure. The disease is carried as a recessive genetic trait—that is one in which the defective gene is carried (but not expressed) by both parents. Union of two recessive genes (one from each parent) in the fertilized egg means the genetic trait will be expressed and the disease produced. One in 20 carries the defective gene.

Biotechnology has developed techniques to detect the carriers of genetic defects using probes to analyze DNA. This is the diagnostic stage. Evaluation and counseling can inform prospective parents of the potential consequences for as yet unborn children who may inherit a defective gene. But since these are recessive genetic traits, not every child of such a pair will inherit *two* defective genes and express the disorder. Prospective parents are faced with choices potentially affecting the unborn child, themselves, and society as a whole. These include fetal testing through anmiocentesis with potential abortion of the genetically defective embryo or care for a severely affected child. The future may provide better alternatives.

What of those who inherit a genetic disorder? Can the defect be corrected? Today, bone marrow transplants of normal cells from compatible donors are used to correct some of these defects. In the future, correction of the defect in the patient's own cells using genetic engineering techniques will expand the potential for cure dramatically. Many diseases of genetic etiology will yield to correction.

The ability to correct a genetic defect in hand, does not end the problem. If the defect is corrected in the somatic cells of an afflicted individual, the trait is still coded within the DNA which he will transmit to his offspring. This produces an even greater ethical difficulty should a change be made in his genetic constitution so that only a corrected gene will be passed on to future offspring. Engineering such permanent genetic changes, while technically feasible, has been criticized as prone to abuse by those with other than ethical intents. Although the debate on the genetic engineering of reproductive cells will not soon end, genetic engineering will surely be applied to the alleviation of genetic disease.

Medicine and biotechnology will enjoy a beneficiary- benefactor relationship in the future even more than in the past. Improved diagnosis, more effective prevention, expanded therapies, better health care—the next decade will see dramatic results in each through biotechnology. ■

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Ethics and the New Biotechnology

Paul T. Durbin, Ph.D.

In this short discussion, I am going to assume that readers are familiar with the 1970s public controversy over recombinant DNA. I want to use that controversy as a lesson in discussing the ethics of biotechnology.

I use the term "ethics" here as it is commonly used among academic philosophers today. Ethics provides a reasonable justification for a course of action or for a moral evaluation; that is, ethics today does not mean moralizing or preaching against evil. I believe that all the courses of action proposed for the control of biotechnology are rationally justifiable, but I will maintain that one approach is more reasonable than the others.

In my opinion, almost all the participants in the recombinant DNA debate lost. (For a good though not unbiased account, see Sheldon Krimsky's *Genetic Alchemy,* MIT Press, 1982.) Researchers lost time; some were so affected by the controversy that they say they'd never get involved in such a public issue again; and many chafe at the quite limited regulations enforced in the wake of the controversy. (See *Science,* 16 August 1985, p. 634.) The most outspoken opponents, such as the Science for the People group in Cambridge, Massachusetts, were quickly dubbed extreme alarmists—that charge affected even eminent scientific opponents such as Robert Sinsheimer and Erwin Chargaff—and the citizen control of potentially harmful research that they sought never materialized. Politicians who took up the issue lost face. Even ethicists were upbraided for turning the debate into a media event. But most of all, alert citizens interested in gaining control of what appeared to them to be dangerous developments in biological research lost. True, individual cities set restrictions and the National Institutes of Health developed guidelines, but after a brief hiatus the research moved ahead as if there had been no moratorium.

Why were there so many losers in the recombinant DNA debate? And can any lessons be learned that could be extended to other areas of biotechnology? I want to argue here that the issue was miscast. Among most of the scientists I know, it was, and still is thought of as an issue of *risk.* Is it reasonable for non-scientists—perhaps through their elected representatives or through the courts—to control biological research that represents a threat to citizens at large? One particularly strong scientific statement is quoted by Krimsky:

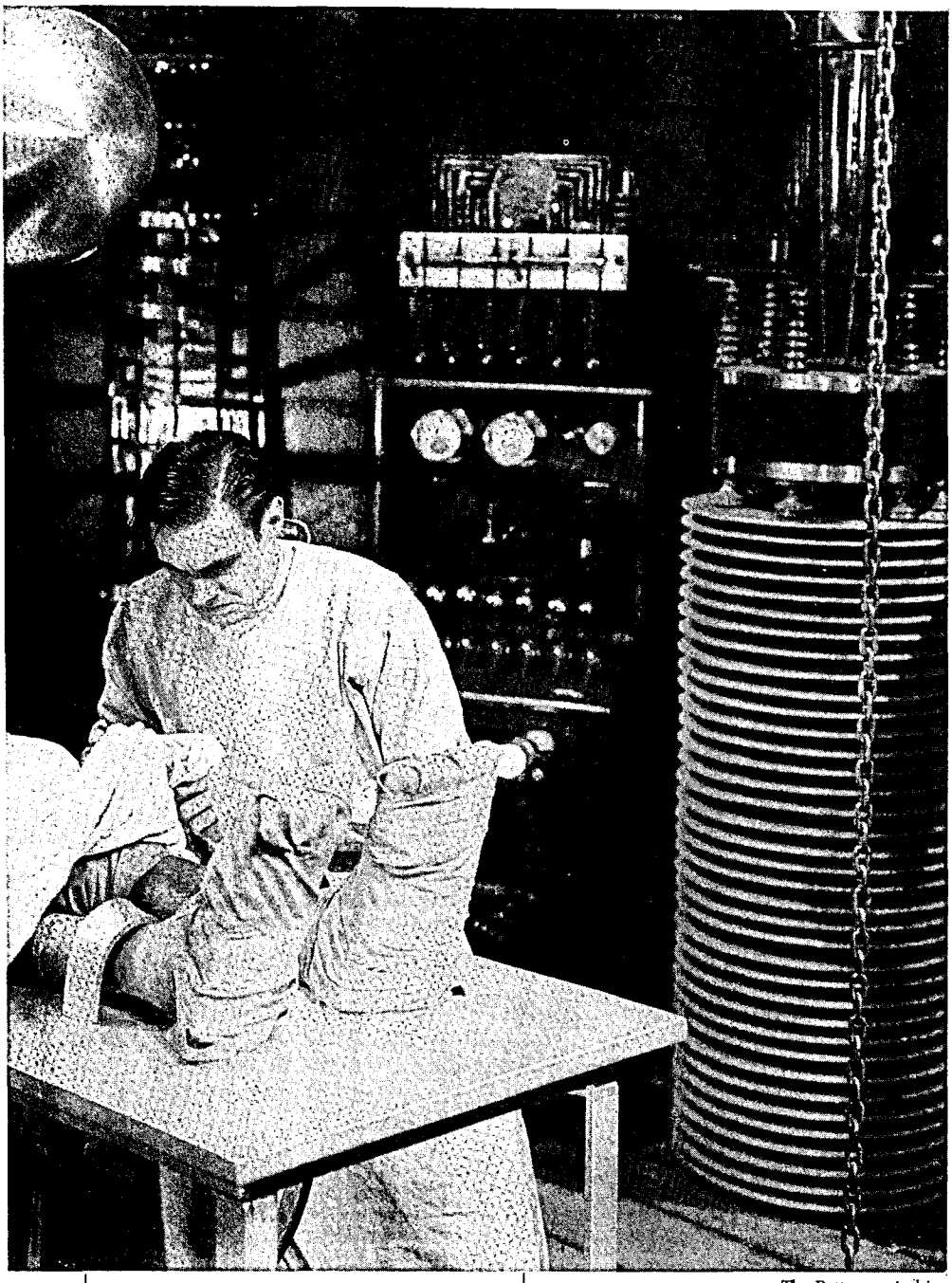
> *Biologists are spending their time in the halls of Congress trying to prevent the establishment of the first commission to be appointed to regulate basic research. I believe that our success or failure will determine whether America continues to have a tradition of free inquiry into matters of science or falls under the fist of orthodoxy"* (David Baltimore in *Science,* 20 January 1978, p. 274).

The reason this formulation is wrong is that it allowed the scientists so easily to assure people that there is no genuine risk—so they could continue to go about their business.

In my view the issue ought never to have been thought of as one of risk (or not primarily that), but as one of *control.** Is it reasonable for non-scientists, through their elected representatives,

to exercise control over scientific research, whether it is risky or not? On this issue, there are at least three reasonable ethical stands that might be taken. The

Some might say the issue is neither risk nor control but* ***accountability.* *I am certainly sympathetic with that alternative. I would say, however, that the accountability issue can be distorted in the same way the risk issue was: scientists should be accountable if they cause undue risk or harm. So if the issue is cast in terms of accountability, I'd want to defend the view that scientists should* ***always*** *be accountable to the people or to their elected representatives —not alone when they are involved in possibly risky or harmful ventures.*



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very cautious might well argue, reasonably, that when scientists and engineers are tinkering with life, the public has every right to know what is going on, and even to restrict what are perceived to be excesses. Enthusiastic supporters of scientific progress might argue equally reasonably that the unfettered search for truth ought never to be constrained; and genetic entrepreneurs might add their reasonable argument in favor of a free market. What I claim is that an ethical case can be made for democratic control of research of all sorts. Such control in fact is exercised all the time in our society. And that is as it should be in a democracy.

I should like to make the factual case first—or, more precisely, to let others make the case for me. An excellent recent study of this issue, by William Lowrance in *Modern Science and Human Values* (Oxford University Press, 1985) documents the myriad ways in which our society currently regulates scientific inquiry, taking special note of medical experimentation and social science investigations (Chapter 6). Even more impressive is the documentation provided by Edward Lawless in *Technology and Social Shock (Rutgers University Press, 1977).* Lawyers studied fifty celebrated technology cases and found: (1) in over half, state and local agencies became involved; (2) in ninety percent, one or more federal regulatory agencies got involved; (3) Congress dealt in one way or another with two-thirds of the cases; and (4) half of the cases ended up in court.

Scientists might, nonetheless, object. Perhaps that's the way things are, but, they might say, it shouldn't be. With respect to biotechnology, a recent editorial in *Science* (20 September, 1985) had this to say:

> *The Japanese biotechnology industry introduced six times as many drugs per dollar spent on research and development as did comparable U.S. companies. Those in the United States who read this and the recent news items describing increasingly bureaucratic procedures for control of recombinant DNA in this country . . . may find it hard to hold back tears.*

What I'd claim is that, with all due respect to the Japanese and their efficiency, our slower, more heavily regulated system is ethically preferable. The most important argument to that effect, in my opinion, is based on conflicting interests, conflict of interest (in the narrow sense), and the moral case that can be made for democratic adjudication of conflict.

Very early in the recombinant DNA controversy it was noted how many leading scientists had gotten into commercial ventures or had secured huge government contracts for their research. Whether there was (or is) conflict of interest in the technical sense, there was and is the potential for it—or at least for the appearance of conflict of interest. Biotechnologists of all sorts have interests that can easily be at odds with those of other segments of society: social science researchers, humanists or artists who need public funding, broad public interests outside academia, including Social Security, welfare, etc.—even in the health area, better care or prevention versus more research. Scientists and bioengineers can almost always describe their projects in terms of laudable motives: cheaper insulin, cures for genetic diseases, higher-yield plants, and so on. But in a democratic society even such noble aspirations as curing cancer and feeding a hungry world have always been viewed as particular interests of particular groups, which must compete for public dollars with the interests of others.

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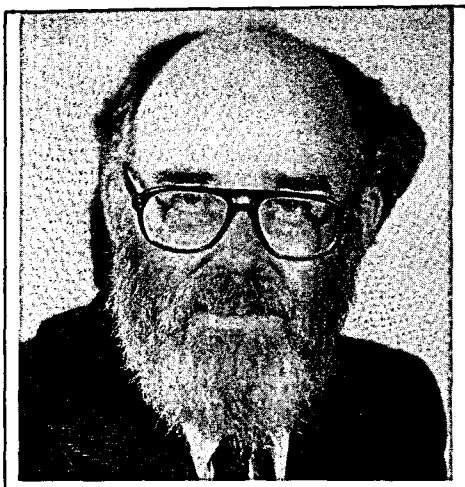


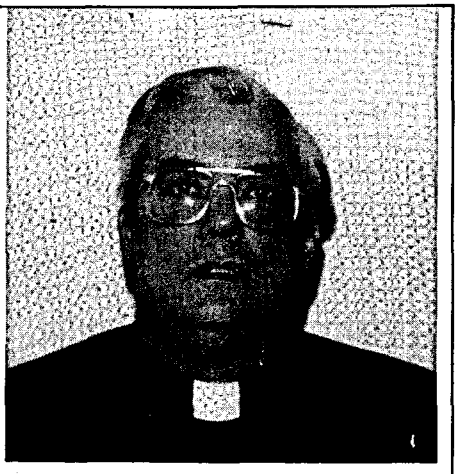
Dr. Paul Durbin (Aquinas Institute) of the philosophy department and Center for Science and Culture at the University of Delaware has edited A Guide to the Culture of Science, Technology, and Medicine *(Free Press, 1980; paperback 1984) and the series* Research and Philosophy & Technology *(JAI Press, 8 volumes from 1985). His article and Reverend Howe's, which accompanies it, confront the theme of this issue from a refreshingly different point of view.*

As an academic, I certainly hope the public will always recognize the inherent worth of research and scholarship, but I do not believe researchers in biotechnology or any other discipline should be freed from having to seek public support through public funding (including philanthropies under the latter heading). If the public supports a venture, it has every right to demand accountability in the way funds are spent. If this means slow—sometimes even ponderously slow—public regulation, so be it. That is the price to be paid in a democracy of competing interests.

That much said, I should like to conclude with a very brief comment about specific regulatory mechanisms. In the diagnosis of genetic diseases or even gene therapies using recombinant DNA techniques or results thereof, I'm confident that the current system of ethical oversight for biomedical research is adequate and reasonably expeditious. (I'm on the human rights subcommittee of the research committee of the Medical Center of Delaware, and I feel we do a reasonably good job—as do institutional review boards throughout the country.) As for industrial research in the agricultural or pharmaceutical domain I should not oppose the transformation of the current system of voluntary compliance with Department of Agriculture, NIH, and NSF guidelines into a compulsory one. (Defenders of the developing system—see the letter to the editor in *Science,* 25 October 1985, from J. P. Jordan of USDA—don't go that far, but a democratic ethic could support them if they did.) Finally, if it ever comes to a question of cloning humans, I hope we'll see a full-scale public airing of exactly the sort we saw over recombinant DNA. Scientists may be gun-shy after the earlier controversy, but it seems to me that cloning and similar issues that strike to the essentials of what it means to be human are so fundamental that every segment of a democratic society ought to have a vote not just on the outcome but on the undertaking of such a scientific adventure. ■

Theological Reflections on the Biotechnological Revolution

Reverend Gregory M. Howe



The Reverend Gregory Howe, a native New Yorker, is today the Rector of Christ Church, Dover Delaware. His has a broad and interesting educational background, consistent with the wide range of interests and sympathies for which he is distinguished. After graduating from Columbia College of the University of Columbia in 1961, he attended General Theological Seminary, where he received an STB (a baccalaureate in sacred theology) in 1964. He has also studied at Saint George's College in Jerusalem. Reverend Howe is especially well suited by knowledge and experience to write for this issue of DELAWARE LAWYER: he is a member of the Health and Social Service Organ Donor Transplant Committee. We take great pleasure in welcoming him to our pages.

The space available here provides little room to articulate the major moral questions prompted by the present biotechnical revolution, much less to suggest answers. Yet the invitation is a welcome challenge.

A general statement of the ethical question that arises out of that revolution may be drawn from ecology:

> *In the grand scale enterprise of man's utilization of natural resources through his mechanical intervention into the natural environmental process, he creates devastating feed-back, mainly because he does not know what will happen if he does something.* Kenneth Vaux, *Biomedical Ethics,* p. 44.

Vaux is speaking here of DDT and its consequences, but the observation seems no less pertinent to the horrors of landfill management, the future of genetic manipulation, or the determination of the limits of life itself.

We find ourselves on a scientific, legal, and theological frontier at once rich in wonder, excitement, fear, and confusion. The "new philosophy" does not seem to fit the old principles and categories. Yet this is not completely new. Lawyers and theologians have been struggling with the problem of new philosophies and new frontiers since the twelfth century, and were joined by scientists in a significant way at least three hundred years ago. James Russell Lowell put the issues in terse terms in an 1845 poem:

> *. . . New occasions teach new duties*
> *Time makes ancient good uncouth.*[1]

What new duties has the biotechnical revolution created? Has time or scientific progress really made ancient good uncouth? The primary ethical task of the theologian, or for that matter, the lawyer, physician or scientist, is to try to order the present in relation to the future.

As Vaux puts it:

> *The future is the most baffling, yet most critical direction from which our ethical insight must come today. I had to create a neologism for this insight: prespective. The dominance of this category in the current discussion is at once hope-engendering and frightening. We are obsessive about the future in America. We live progressively. We contort and distort the present in the forward looking compulsiveness that is our engrained Puritan heritage. Nevertheless, the magnitude of the problems demands of us this painful reading of, and responsiveness to the future.* Vaux, at p.43.

Vaux would suggest that our Puritan heritage encourages a somewhat confusing divided response to the ethical questions before us. We rush for the future, convinced that it will be better and more desirable than the present. Yet, in specific cases there is a tendency to say "no" to new initiatives or to hedge them with severe restrictions. Unless our ethical priorities are very clear, theologians do not always make good choices. Beginning with the trial of Galileo we have a history of saying "no" when we should say "yes" and of missing some of the big negatives.

The theological basis of this strange dichotomy might be expressed in reference to the great stories found in the beginning of Genesis. The potential capability of genetic engineering makes it seem that we are at the threshold of the great Faustian question—by our science we shall be as gods, able once again to manage the natural world as God originally intended. The Tree of Life itself seems within our grasp. The Tower of Babel failed to scale the heights of heaven. May we not do it with a DNA Ladder?

What are the new duties of our new occasions? Some time ago, the Cambridge (Mass.) City Council became the butt of much journalistic mirth when it held hearings on the limitations and boundaries for genetic research to be conducted by neighboring universities. There were many self-righteous (and perhaps even self-serving) pronouncements about the presumption of local political yahoos to attempt to dictate terms to their scientific betters. Yet, given our unhappy record of near* nuclear accidents, have not local governments a responsibility to protect their

**This was written before the Kiev horror.* ▶

citizens against possible biological accidents for which we have even less effective warning and coping systems?

One of the first principles of ethical and theological analysis of the impact of the biotechnical revolution is the identity and use of technology. Much discussion about technology, pro and con, has an unpleasant undertone of idolatry. Technology, for better or worse, is not a deity to be worshipped.

> *. . . Technology is a tool to create the new, to make the future. Because of control and communication (the feedback mechanism) more aspects of human life are claimed from the realm of chance and programmed with predictability.*
>
> *The future sends ethical signals in two ways. First, there is the insight that comes from man's hope to be something, his possibility. What man can become is now a very powerful determinant of what he decides to do. Secondly, there is the signal of consequence. Technology gives us the capacity to predict or foresee the consequences of certain decisions. This new fact will have staggering ethical import in the next decades.*
>
> *One of the most powerful zones of convergence of theology and science today is the element of the future. If God is the power of the future (Moltmann) and man is the creator of the future, new theological definitions of co-creativity and responsibility are needed.* Vaux at p.44.

I submit that Vaux's insight about control and communication is central to appropriate management of technology. Where there is serious confusion about control and communication, lawyers, scientists and theologians can spend much time and energy in rather pointless, unrewarding struggle with small benefit to anyone.

A significant example of such confusion is the determination of death. The present conundrum is described in the *Hastings Center Reports* as prudent medical practice in California but homicide in New Jersey. There is model legislation on determination of death with language adopted by the American Medical Association, the American Bar Association, and the National Conference of Commissioners on Uniform State Laws. It is designed to provide a uniform legal standard for determining biological death in the midst of a sophisticated medical technology that can give a body the semblance of life almost indefinitely, long after natural death would have occurred several decades ago.

The effect of this statute would be to extend legal *protection* and *direction* to attending physicians, as well as guidance in certain instances in the domain of criminal law—and in some tort actions. As this paper was being written, the local version of the determination of death model—S.B. 171, May 7, 1985—had been submitted to the Delaware House, where objections by spokespersons for a major religious group opposed its passage. The bill in question did pass and was signed into law, but the objections are worth noting:

1) The judgment, by criteria of classical natural theology that the "philosophy" of brain death is flawed—that is, that the criteria of cerebral death proposed by a committee of the Harvard Medical School and endorsed by the American Medical Association, the American Bar Association, and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research is somehow morally deficient.
2) The original question, noted above, extended to doubts about the adequacy of current technology for testing for brain death.
3) Finally, and one suspects, most significant, there was objection not so much to the content of the legislation as presented, but that it might be open to abuse—presumably by morally deficient physicians removing organs from apparently dead patients—thus producing the morally undesirable effect of intentional euthanasia.

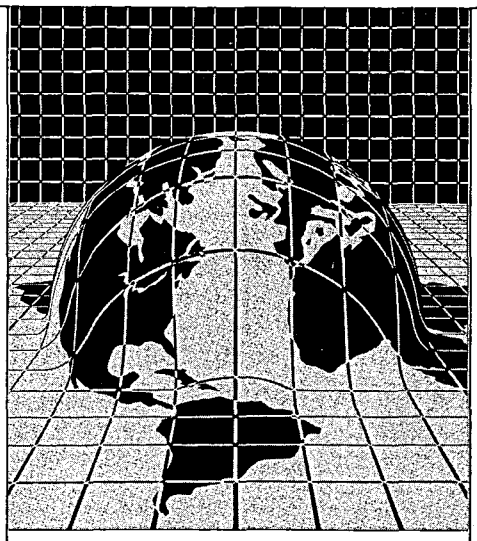
These points became especially interesting when compared to the strict constructionist views of certain distinguished Roman Catholic teachers. "Pius XII (1957) long ago spoke in an approving tone about families who bring pressure to bear upon the attending physician 'to remove the respirators so as to allow the patient, already virtually dead, to depart in peace.' Medical progress must not deny a person his ethical right to die in human dignity."[2]

These objections to current criteria for determination of death seem to have the effect of contradicting Pope Pius's recommendation to physicians. If the Determination of Death Act had been defeated, many Delaware physicians would have had serious reservations about the termination of extraordinary treatment. This would certainly have had the effect of insuring against premature organ removal, but how would the moral theologian responsibly justify the high emotional and financial cost to families? Finally, such a posture tends to make organ donation difficult and frequently impossible.

Given the principles of control and communication noted above, this case raises several important issues. The pronouncement of death is, by law, a medical act and ought to be controlled by physicians, with the best technology available to them. Theologians have the right to doubt "philosophies" of brain death or even to question the adequacy of current methods of testing. We are not all that far from an era in which a mirror held to the mouth and nose was generally accepted as an adequate test for determination of death. Sometime in the future our standards will probably seem just as quaint. Nevertheless, this possibility does not seem to support theological doubt as a just reason to limit the legal rights of physicians in our society.

The one possible defense for the apparent position described above lies in Bernard Haring's citation of a distinguished Protestant theologian, H. Thielicke: "If we speak about the duty of the doctor to preserve life, then not biological life as such is meant but *human* life. In order to characterize the life of man, other criteria are needed than those of the electrocardiograph and the electroencephalograph."[3] Of course, the theologian's first responsibility is to witness the primary importance of human vs. merely biological life. That is the presumed object of the criticism that has stonewalled needed legislation. It seems unfortunate that better attention has not been paid to the obligation to communicate. The moral theologian does need to attend to the issues at hand sufficiently to inform himself of the actual as well as the apparent matter before him.

This example is used, not to quarrel with esteemed colleagues, but to give local reality to the two major problems



...we are at the threshold of the great Faustian question—by our science we shall be as gods, able once again to manage the natural world as God originally intended.

facing those who pursue ethical questions in biotechnology. The first is control—who is in charge, who is accountable? When ethical questions are framed, to whom should they be addressed? As in the experience of the Cambridge City Council, local and state government is hard pressed to purchase the sophisticated expertise necessary to assist those who make decisions for the governed. Many local governments are forced to depend on *pro bono* advice from the same university and commercial personnel who direct or do the very experimental work in question.

On the Federal level the record is no more encouraging. The recent very helpful Presidential Commission has been terminated, as planned. A review of the *Hastings Center Reports* over the last year provides a grim litany of the outright abolition or financial strangulation of most governmental and quasi-governmental units addressing the ethical issues of the biotechnical revolution.

The ethical stress point of the biotechnical revolution is that we reward technological innovation, not nurture. From the classical example of the non-M.D. salesperson discovered to be doing orthopedic surgery while a perplexed surgeon looked on, to the recent facile criticism of our largest corporation for spending too much time and money on unprofitable basic research, we are confronted by a constant blizzard of new technical data and equipment, and immense pressure to bring a product to market quickly and profitably, before a competitor covers it at less expense—not having had the burden of basic research and development.

This is not a very encouraging climate for the enhancement of human vs. merely biological life. Since we have little else going for us, we need to make the communications process work as well as possible, so that the feedback process will be positive—so that we can avoid not knowing what will happen when we do something. As scientists, theologians, and lawyers all become more specialized, we run the considerable risk of becoming unable to understand each other or of losing the capability to use each other's work intelligently.

There are some small encouraging signs. Academic and non-profit special interest groups are providing quality continuing education to assist clergy and other helpers to be more effective genetic counsellors. The ethical future of the biotechnical revolution depends on the rapid dissemination of a new, complex, and rapidly shifting body of knowledge and a shift in reward value to balance the relationship of technological innovation and nurture in a more humane fashion.

The biotechnical revolution is inventing the future at a breathless pace. In an era of growing deregulation, the failure to ask the right questions in the right places at the right time will allow the pressure for the quick hit for the fast buck to become normative. This could bring us to a very bleak future. If we are not careful about control and communications among business and professional leaders, we could become the people to realize J. Robert Oppenheimer's stark vision after Trinity: "I am become death—the destroyer of worlds". The Judeo-Christian tradition calls us to something more hopeful and positive:

> . . . *this day, . . . I have set before you life and death, blessing and curse; therefore choose life, that you and your descendents may live* . . . (Deuteronomy 31:19b)

[1] *The Hymnal, 1940.* #519, v.3, The Church Pension Fund, New York.

[2] B. Haring, *Medical Ethics,* p.140, Fides, Notre Dame, 1973.

[3] *Ibid.* pp. 140-141.

Anguished Questions

John Golin

By the mid-1970's, a series of remarkable advances in the field of molecular biology had spawned the science of genetic engineering. Such progress, however, generated considerable anxiety among the general public. The graphic images of deadly bacteria and viruses created by gene cloning experiments resulted in several town meetings, proposals for legislation, and the sacrifice of whole forests to the paper requirements of the debate. Citizens in Cambridge, Massachusetts sought to stop such research at Harvard University. At Asilomar, a picturesque spot on the California coast, a group of distinguished biologists weighed the risks and benefits of continuing experiments with recombinant DNA.

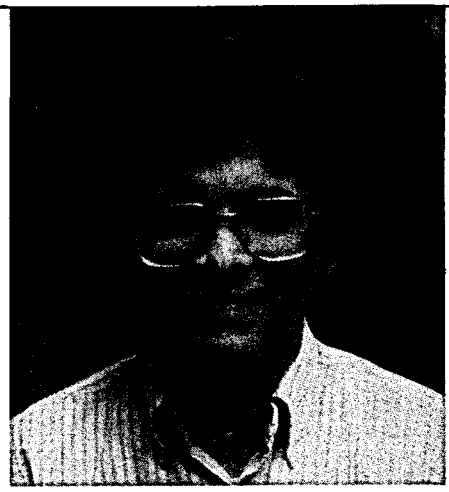
The eventual result of the debate was that the research went on, but under numerous rules and restrictions. Now, nearly ten years later, there seems little doubt that discoveries in this field have been beneficial. The production of insulin, growth hormones, and important vaccines rely heavily on biotechnology. The tremendous progress in our understanding of such diseases as sleeping sickness, hereditary anemias, cancer, and AIDS might not have been possible without gene cloning capabilities. Furthermore, there are no indications that this technology is unsafe. Today, it is performed in countless laboratories (including my own) without incident.

It would be easy to remain sanguine about the use of recombinant DNA techniques. However, as a science matures, its applications become broader and increasingly elaborate. Herein lie the moral uncertainties.

Recently, the distinguished research journal *Cell*[1] published a landmark article on genetic engineering by a group of scientists at the University of Utah. The principal investigator, Dr. Mario Capecchi, is an excellent scientist, whose studies are always imaginative, carefully organized, and reproducible. The experiments described in the paper entail gene replacement in cultured cells originally obtained from various mammals, although they are propagated in a nutrient media for many generations outside these organisms.

The Capecchi group grew cell lines that contained an alteration, or mutation, in one of perhaps 100,000 genes. (A gene is a segment of DNA carrying out a cell's arsenal of metabolic activities.) Using recombinant DNA technology, the scientists were able to obtain a non-mutant equivalent of the gene and, by microinjecting it into cells with a fine needle, replace the dysfunctional (mutant) copy. This was successful about once in a thousand attempts.

While Dr. Capecchi experimented on isolated cells and not whole organisms, the implications were certainly clear. It may one day be possible to employ this methodology to correct serious human genetic defects such as sickle cell anemia or Tay Sach's disease. While such a scenario is certainly exciting and potentially beneficial, it is frightening as well. Scientists may have to perform such gene therapy on an egg just after fertilization. This creates a number of potential problems. This article can address just a few.



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First, immediately following fertilization, there is presently no way to know whether the embryo even carries the defective gene needing replacement. In most cases, the odds are 25 per cent that it does. Since the injection procedure (or any method used) will undoubtedly create risks, occasional infection and trauma will probably occur in what would otherwise be a normally developing fetus. Also, the most effective and convenient technology may require the use of several fertilized eggs, and the discard of all but one, which will then be allowed to gestate. The use and destruction of these already fertilized eggs poses moral problems to some.

Because of the costs of research and the eventual cost of the procedures, there may ensue the usual political pressures to decide which diseases should be cured first, and who will have access to those cures. Furthermore, while the low efficiency rate in Dr. Capecchi's experiments will probably improve dramatically, it is unlikely to reach 100 per cent. As a result mutant individuals will be born, despite the very best intentions and interventions.

Or will they? Are families becoming so dependent on medical miracles, so intolerant of anything less than perfection in babies, that they will insist on aborting those fetuses that genetic engineering has not rendered perfect, or be psychologically incapable of accepting and caring for those who slip through the net? I have met many people who insist they "could not" handle the trauma of bearing a Down's Syndrome child,

(Continued on page 36)

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Hard Choices: Playing Statutory Catch-up With Medical Progress

Edward F. Kafader

I. A comatose patient lies lifeless in a surgical intensive care unit, connected to a respirator. For the past few days the patient's neurosurgeon has noted that there are no longer signs that his brain is functioning. An electroencephalogram also demonstrates a lack of brain function. A consulting neurologist who has examined the patient agrees that he is brain dead.

The neurosurgeon has spoken with the family and informed them that the patient's brain is no longer functioning on any level and that there is no hope that he will recover to a point where the respirator can be removed. The patient is for all intents and purposes dead, and it is just a matter of hours or days until his heart stops beating. The family tells the neurosurgeon that, although the patient often stated he did not want to be maintained by a respirator when there was no hope of his recovery, he never executed a living will. The family requests that the respirator be removed so that they can begin the process of grieving.

The neurosurgeon agrees that the respirator should be removed. However, before it is removed, one more person must be consulted. It is not another physician or a member of the family. It is the Attorney General of Delaware.

Until recently there was no Delaware law defining death by reference to neurological criteria. It was necessary to secure the assurance of the Attorney General that no criminal prosecution would be undertaken against the attending physician for prematurely removing the respirator.

The foregoing scenario, performed with regularity in Delaware hospitals, demonstrates eloquently a difficult issue that must be resolved by legislators and judges: advances in medical technology occur at an astounding rate while legal solutions to the problems they create lag behind, leaving patients and their families in difficult situations. In dealing with those problems, legislators and judges must consider the extent to which the State should be involved in treating critically ill patients and at the same time set up procedures giving people some control over their lives and deaths without disregarding the sanctity of life.

The maintenance of a terminally ill comatose patient on a respirator or other life support systems is one of the more difficult issues. It first drew national attention in 1975 in the case of Karen Ann Quinlan. Delaware Courts faced the same issues two years later. In December 1979, Mary Reeser Severns suffered a brain injury just before or as a result of a one-car accident. While she lay comatose with no hope of regaining consciousness, her family filed a petition on her behalf in Chancery requesting that the respirator, which performed her breathing function, be disconnected.[1] Tom Herlihy gave an excellent account of the Severns litigation in the Summer, 1983 edition of *DELAWARE LAWYER*.[2] The Severns decisions established that guardians appointed for terminally ill comatose patients might direct the removal of life support systems where there was no reasonable hope of recovery. There is now a procedure that permits the Court of Chancery to act expeditiously in such cases.

As I have already said, these are difficult decisions for judges and legislators. They must address moral considerations that involve measuring the quality of life. They present a delicate task of fashioning relief that will allow people some control over their destinies while ensuring protection to the infirm. Courts considering the issue usually couch their decisions in terms of a State's interest in preserving the life of the patient. For example, in *Quinlan* the New Jersey Supreme Court made the following comment: "We think that the State's interest *contra* weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims."[3] In weighing the State's interest in preserving life against the individual's right to privacy, judges must form some opinion as to whether the quality of any continued life that the patient will enjoy through heroic measures is such that he should be permitted, by a guardian, to reject it.

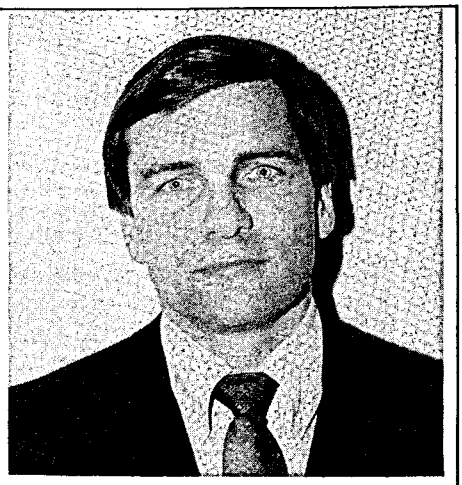
In 1982 the Delaware General Assembly provided a more simplified procedure regarding the withdrawal or non-institution of maintenance medical treatment for the terminally ill. In July of that year the Delaware Death With Dignity Act (16 *Del C.* ch. 25) became law. The Act recognizes the right to make one's own determination concerning medical treatment and gives legal recognition to

a living will directing that maintenance medical treatment not be put in place or that it be withdrawn if the patient is terminally ill with no reasonable medical expectation of recovery. The Act allows the patient to select an alternate procedure of executing a living will, which appoints a third party to act on his behalf in the event he becomes terminally ill and is unable to choose for himself.

A living will obviates the appointment of a guardian if the testator becomes terminally ill. It can spare his family the heartache of a court proceeding for the appointment of a guardian while the patient remains on a respirator.

The brain dead patient presents additional issues that must be considered. There is a distinction to be made between the patient who is comatose, but demonstrates some brain function and a patient who is dead by neurological criteria—"brain dead". A patient can remain unconscious for an indefinite period if his brain stem, which controls the breathing and circulatory functions, is operating properly. Such a patient does not have irreversible cessation of all functions of the brain. But a patient whose brain stem is no longer functioning at all will never survive without a respirator. Indeed, once there has been a cessation of brain function it is usually just a matter of days until the patient's system becomes overloaded and the heart stops beating. Such a patient is, in reality, dead. Until recently, however, the common law definition of death, i.e., the cessation of the circulatory function, was the only criterion of death formally recognized in Delaware. Senate Bill No. 171, which is now designated as 24 *Del. C.* §1760, legally enlarged the definition of "death" to include death by neurological criteria. With the passage of Senate Bill 171, it is no longer necessary for the Attorney General to be involved in the removal of life support systems from a patient who is dead by neurological criteria. However, the Attorney General will review a specific case before removal of maintenance equipment if requested by the patient's physician.

II. The Delaware General Assembly has enacted several statutes governing organ transplantation, intended principally to ensure an adequate supply of replacement organs. The Delaware Uniform Anatomical Gift Act gives legal effect to donor's designation of organs▶



Ed Kafader, who practices law with the firm of Biggs and Battaglia, served for some years in the Department of Justice as a Deputy Attorney General. In that role he represented the state in some extremely varied and important litigation, ranging from anti-trust to the Severns case discussed in Ed's article. The broad experience he brings to the practice of law includes two years as a loan officer at Wilmington Trust Company.

for transplantation or other purposes.[4] In addition, even when the donor has not executed an anatomical gift in the prescribed manner, his family may donate an organ in the manner prescribed by the statute. The General Assembly has also authorized the Division of Motor Vehicles to place a notation on the license of a would-be donor of an anatomical gift so that he can be quickly identified.[5] The State Medical Examiner may now remove corneas from bodies under his jurisdiction if the next of kin haven't registered an objection.[6]

Two further bills pending before the General Assembly deal with issues raised by transplantation. Senate Bill 313 would authorize hospital administrators to consent to donation of organs on behalf of a deceased patient, but only if there is no actual notice of objection thereto (a) previously expressed by the deceased or (b) by family members.

Senate Bill 236 deals with an aspect of transplantation that can be controversial. It establishes an organ transplantation fund to defray the cost of surgery for those whose medical insurance does not cover transplantation.The Bill was introduced shortly after the death of Carolyn Grey, who needed a liver transplant but whose medical insurance did not cover the cost of such surgery. The cost of transplantation surgery is burdensome. For example, the bill for a liver transplant can range between $70,000.00 and $150,000.00. The cost of heart and lung transplantation is more, kidney transplantation less. Given the State's resources, cost of transplantation poses difficult problems. It is often argued that such money would be better spent in providing more conventional medicine for the needy. On the other hand failure to defray the cost of such surgery will usually result in death. The economic and moral questions that must be resolved regarding transplantation surgery are extremely difficult.

The law has struggled to keep pace with advances in medical technology over the last several years. Unfortunately, patients and their families who find themselves on the cutting edge of the law may experience real anguish when they find that no procedures have been established at law to deal with their situation. By the same token, there is a need to proceed deliberately to insure that those unable to fend for themselves are protected. ■

1 *See Severns v. Wilmington Medical Center, Inc.,* Del Supr. 421 A.2d 1334 (1980) and *In re Mary Reeser Severns,* Del. Ch., 425 A.2d 156 (1980).

2 Herlihy, *The Impetus of a Tragedy,* DELAWARE LAWYER, Summer, 1983 at 34.

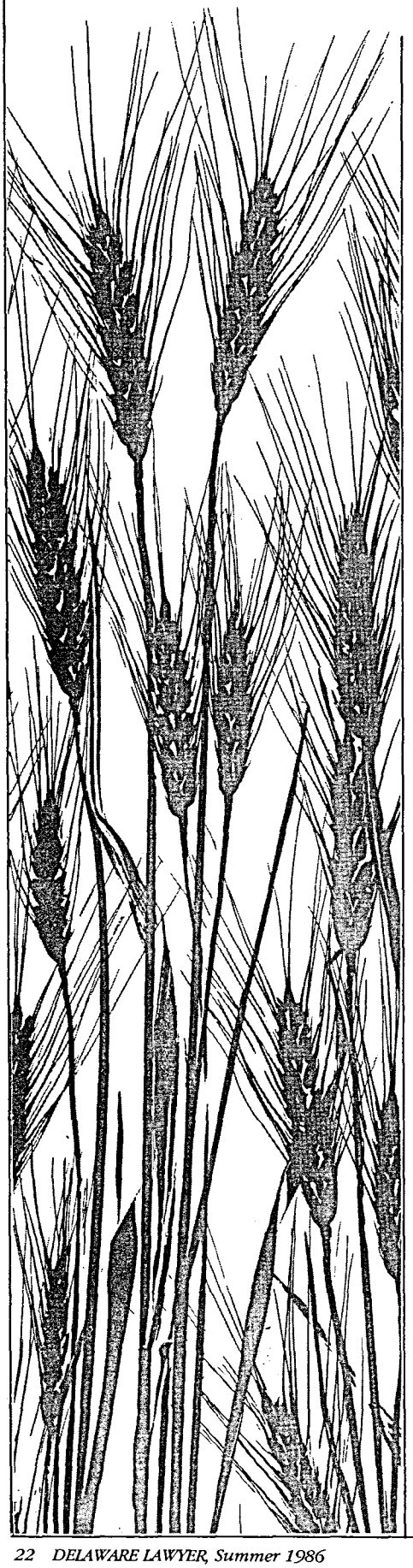
3 *Matter of Quinlan,* N.J. Supr., 355 A.2d 647, 664 cert. denied, 429 U.S. 922 (1976).

4 See 24 *Del.C.* §1780 *et seq.*

5 See 21 *Del. C.* §2718(b).

6 See 29 *Del. C.* §4711.

Meanwhile, back at the ranch...



Agriculture and Biotechnology

Donald Franklin Crossan

According to the May 31 edition of the NEW YORK TIMES, Agracetus, a biotechnology company in Wisconsin, has made a test planting of gene-altered tobacco plants. They are said to be resistant to crown gall, a bacterial disease. "The company would not disclose the location of the site because it feared the experiment could be sabotaged by protestors."

Biotechnology, the "in" word for the 1980s, which means the use of living organisms or their components in industrial processes is not new to the agricultural scientist, who has used many biotechniques to improve animals and plants. But today emerging techniques allow manipulation of living cells in a way that was either impossible or very difficult a few years ago. The new techniques include plant cell and protoplast (the basic cellular material devoid of a cell wall) culture, animal embryo splitting and transfer, and the recombining of basic genetic material by direct action on the hereditary units (genes) of all cells. These approaches to biotechnical research have resulted in modification of microbial and plant cells to an extent not possible before. For example, nearly fifty difficult-to-propogate species of plants have been regenerated from protoplasts, i.e. single naked cells originating from the tissue of a mother plant. A single cell can be manipulated to produce sister cells and finally a whole plant. This opens up the possibility of fusing naked protoplasts from different plants and creating shared genetic backgrounds, a process both difficult and time consuming to carry out by normal pollination techniques. It is also possible to detect genetic diversity in the protoplasts that might not be expressed in the whole plant. Varieties of corn have been developed by this technique that are resistant to damage by a specific herbicide. This in turn allows for a more efficient spectrum of weed control in that crop. A common problem in regular pollination between related species of plants is a tendency to genetic incompatability and the consequent abortion of embryos. Through the technique of tissue culture it has been possible to culture the embryo tissue before abortion. Using this application, new varieties of citrus have been developed that otherwise would not have been possible from normal genetic approaches.

As noted above, one biotechnology application directly manipulates genetic material in a cell. It derives from research termed "molecular genetics" and includes the removal of genetic material from one organism and the insertion of it into the cell of another. There are many technical barriers to overcome before this is a regular laboratory possibility, but there have been some successes. It has been possible to transfer a gene that controls the breakdown of an antibiotic by a bacterium into a petunia protoplast, which was subsequently induced to form cells and a new petunia plant. When tested, the cells of the petunia plant contained the bacterial gene for the breakdown of the antibiotic. Using similar techniques, a gene that controls production of a specific protein in bean was transferred to sunflower cells. Those cells were regenerated into sunflowers capable of manufacturing the bean protein. Tissue culture and cell fusion techniques used in plant propagation have the potential to promote quicker and more economical productivity gains than do the more traditional methods of plant breeding. Continued progress will depend upon our understanding of molecular structure and the chemistry of the life processes themselves.

In animals, embryo transfer and manipulation now permit production of more offspring of superior genetic back-

grounds. The use of recombinant DNA techniques with viruses opens up the potential for producing more efficient vaccines against serious viral diseases afflicting animals. Viral genes that are responsible for development of immunity to an infection by producing protein antigens may be identified, chemically isolated, introduced into a bacterial host, and the bacterium used to produce commercial quantities of the antigen. Similarly, it is possible through this type of biotechnology to place genes that influence growth or feed efficiency into bacterial cells and subsequently produce quantities of the growth-regulating substances. They can be injected into animals or fed to them to increase growth and feed conversion efficiency.

There are many agricultural applications of biotechnology that seem possible in the near future. For example, genetically improving the digestion of cellulose by microbes in the rumen of cattle could lead to use of wood pulp or paper waste as feed. The addition of genes for fecundity into embryos could lead to increased reproduction in domesticated animals. Gene insertion into harmful species of insects that would alter the production of sexual attractant hormones, and subsequent mating would reduce those harmful populations. But all of these and many, many more potentially useful applications are dependent upon the acquisition by agricultural scientists of the fundamental knowledge necessary to work at the cellular and molecular level. Biotechnology is a science in transition that makes use of the combined knowledge of biochemistry, cell biology, immunology, physiology, molecular genetics, and more.

The opportunity to apply biotechnology to improving agricultural productivity and efficiency is evident, but there are some social aspects to consider as well. The scientific community is well aware of the need for responsible research processes to assess the biological and environmental impacts of cellular manipulation, including the genetic stability of altered genomes and interactive aspects of releasing genetically altered organisms into the environment. Legal responsibility for releases into the environment must be considered by researchers and those who view, regulate, and assess them. Legal rules governing liability for harm or injury must be considered at all levels, from research through development and regulation.

What are the consequences for the economic well-being of the agricultural sector? For example, consider the use of gene insertion into embryos to produce cows that give significantly more milk without increased feed consumption. We overproduce milk at the present time and our government buys and stores large quantities of dried milk and other dairy products. Will the new technology, if it is cost effective, lend impetus to the lowering of dairy support prices, an even faster decrease in the number of dairy farmers, and an increase in the complexity and size of the profitable dairy farm? Questions such as these must be faced.

Irrespective of these considerations, significant applications of biotechnology in agriculture are already here. Further changes in plants and animals are almost beyond comprehension. The challenge is to use them wisely for the benefit of mankind. ■

Donald Franklin Crossan, a professor at the University of Delaware since 1965, has a special interest in the biology and control of vegetable and ornamental plant pathogens. Since 1977 he has been Dean of the College of Agricultural Sciences and Director of the Agricultural Experiment Station at the University. He serves as a member of the Board of Trustees of Longwood Gardens and as Chairman of the Coastal Zone Industrial Control Board. Photo: Eric Crossan

Biotechnology: Regulatory and Legislative Concerns

Francia Ehrlich Isakoff

Our increasing ability to manipulate the gene has resulted in a new commercial biotechnology, which promises safer and more efficient products. Some of these, designed to lessen human suffering or to make life more pleasant, have already begun to trickle through the regulatory process. The flood cannot be far behind. The Office of Science and Technology described the promise of modern technology in a 1984 Federal Register Notice.

> *Biotechnology already has successfully produced new drugs and improved existing drugs such as human insulin interferons and vaccines. Exciting research is under way in agricultural applications to enhance plant and animal productivity to help feed the world's people. Within reach of commercial applicability are products to diagnose, prevent, and treat animal diseases, to improve animal breeds and to improve specific plant characteristics. Microorganisms have also been developed in research laboratories to degrade pollutants, enhance oil recovery, convert biomass to energy, leach minerals, and concentrate metals.* (footnote 1, 49 FR at 50856, December 31, 1984)

This advance has raised concerns in the scientific, legal, and consumer communities, and it has generated the politics often attached to an issue of such widespread governmental interest.

In the early 1970s, the emergence of recombinant DNA procedures generated a flurry of meetings to explore the associated benefits and risks. In 1974, the Recombinant DNA Advisory Committee (RAC) was chartered by the National Institutes of Health (NIH) to provide guidance for technological advances while assuring safety. In June 1976, this Committee issued guidelines that endorsed a cautious approach. Deliberate release of recombinant DNA was barred, as were five types of laboratory experiments. As experience showed many concerns to be unwarranted, the guidelines were modified and oversight lessened. The revised guide allowed the NIH director to make exceptions for experiments of compelling social or scientific value. For the last ten years, the RAC has served as the informal review mechanism for federally funded institutions and (noncompulsory) for industry and others not receiving government funding.

...are the policies of our government agencies efficient enough and are our existing laws and regulations adequate to allow U.S. industry to compete worldwide?

In the 1970s, emphasis was on the safety of laboratory research. The main concern was loss of control of the products of that research. Governmental interest and oversight were confined to a subcabinet level, the research arm of government, the National Institutes of Health.

The past ten years have seen a change of emphasis and, consequently, a different group of concerns and a different approach to remedies. Commercial applications of the basic research of the 1970s have become the byword of the 1980s. Both domestic and international competition have heightened. In 1982, U.S. investment in biotechnology firms reached $2.5 billion. The issue has become the safety of products as they leave the confines of the laboratory and enter our environment through clinical testing and commercial application.

An additional worry has arisen and been expressed with such vehemence that it shares equal billing with safety issues: are the policies of our government agencies efficient enough and are our existing laws and regulations adequate to allow U.S. industry to compete worldwide? The International Trade Commission has projected that exports of antibiotics and biologicals produced by the new processes could total $2.9 billion by the year 2000, while imports may reach only $700 million. The prospect of this favorable balance is a key reason that the administration and Congress have raised questions regarding the ability of the regulatory agencies to keep up with the rapid, advancing technology without delaying approvals.

In April 1984, the Cabinet Council on Natural Resources and the Environment established an Interagency Working Group*, charged with reviewing and coordinating policy for biotechnological products. It inaugurated a review plan including inquiries into procedures for granting patents for biotechnological products and federal activities that affect commercialization and worldwide competition.

The results published in December 1984 as a Notice for Public Comment by The White House Office of Science and Technology Policy concluded: ". . . At the present time, existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology" (50 FR at 50858). The

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working group found: ". . . The current scientific review apparatus is, however, not designed to respond to all the scientific issues surrounding commercialization of biotechnology including the health and broad environmental effects of new commercial processes and products" (50 FR at 50904).

The Notice proposed a framework for the regulation of biotechnology. It outlined the existing federal laws relating to biotechnology and described a scientific advisory mechanism for the assessment of important issues and iteragency coordination.

It recommended a two-tiered structure consisting of five agency-based scientific Advisory Committees under a coordinating Board. The Advisory Committees were to provide a detailed, scientific review of specific applications submitted to them by any federal agency. The Committees chartered by the FDA, EPA, and USDA were to concern themselves mainly with commercial applications. The NIH RAC was to continue to advise on research involving recombinant DNA, and The National Science Foundation was to charter a Committee to examine potential effects of environmentally related basic research.

The proposal established a parent body, the Biotechnology Science Board, reporting to the Assistant Secretary for Health in the Department of Health and Human Services. The Board was to include members from each agency-based Advisory Committee. It was to evaluate the review procedures established by those committees, conduct analyses of issues of broad concern regarding rDNA, rRNA and cell fusion, develop guidelines, and provide a public forum.

The proposal also contained draft statements describing the regulatory policies applicable to biotechnology of the Food and Drug Administration, the Environmental Protection Agency, and the Department of Agriculture. All three felt the existing regulatory framework of their agencies would prove adequate. In a separate Notice on April 12, 1985 (50 FR at 14468), the Occupational Safety and Health Administration proposed that it would consider specific regulations in the event that new biotechnology processes presented a significant hazard that could not be accommodated under present standards.

Reaction was immediate and varied both in the media and in responses to the formal notice and comment procedure. The FDA received a majority of comments supportive of their current regulatory policy. One Washington law firm pointed out that the FDA had not been specific about its approach to approved products made by conventional processes that could now be produced by biotechnology. The FDA was urged to begin rule making to determine whether previously cleared products should undergo new premarket procedures, simply because they are now made by a new technique. Many comments supported the FDA's view that the existing framework need not be augmented, and that attention should be directed to new products, rather than the technology used to create them.

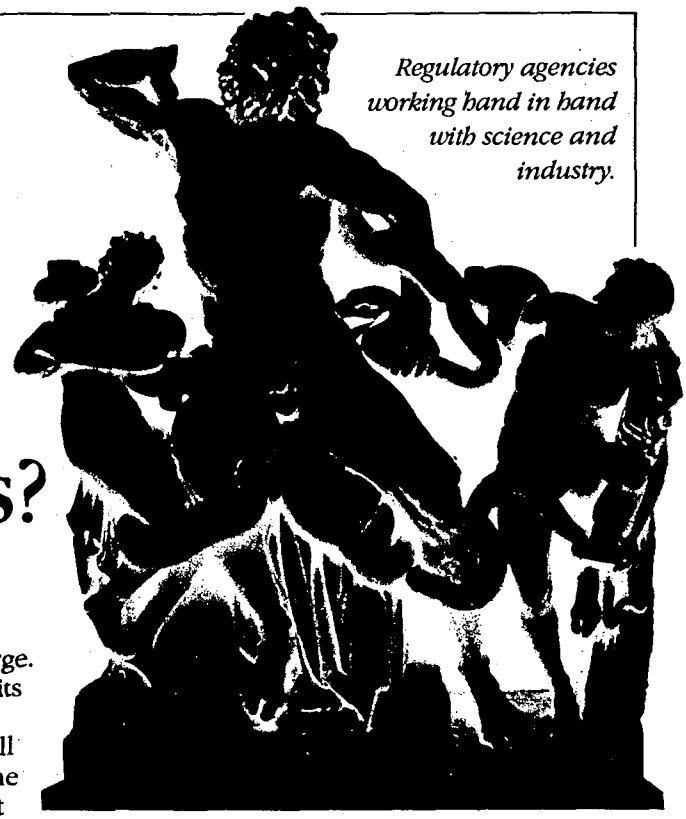
Nonetheless, some raised questions about the FDA's case-by-case approach. FDA plans to give each reviewing Division the responsibility for the evaluation of products under its jurisdiction drew criticism. The Association of Biotechnology Companies expressed concern because of the differing capabilities to grasp the nuances of biotechnology within the various reviewing Divisions. The hope that the FDA's technical capabilities will be raised by an infusion of new technical expertise seems futile. The FDA's 1986 budget calls for the elimination of 101 positions, with the only increased staffing in the generic drug area.

(Continued on page 37)

M-mm, m-mm, good?
Uncle Sam's Soup is
m-mm, m-mm, good?

Illustration: Lois M. Rasys

Francia Ehrlich Isakoff is one of those multi-talented people so plainly needed to confront the dauntingly sophisticated subject matter of this issue of DELAWARE LAWYER. She is trained both as a chemist and as a lawyer. Armed with more than twenty years working experience as a chemist, she is now manager of drug regulatory affairs in the department of that name at the Stuart Pharmaceuticals Division of ICI Americas, Inc. here in Wilmington. Despite her commitment to full time professional emplo-ment she has rendered distinguished service to the community, and has been repeatedly honored by the Jewish Federation of Delaware. She renders further welcome service with her lucid account of the apprehensions and bureaucratic complexities attendant upon the biotechnological revolution.



Regulatory agencies working hand in hand with science and industry.

Biotechnology Law: Public Protection or Stifled Progress?

Stephen R. Permut

Over the last 40 years biotechnology has made major strides toward the cure or control of many diseases, injuries, and congenital abnormalities, which would have ended, shortened, or disabled the lives of their victims. The future seems to hold no bounds to further prolonging life and improving the quality of life through the control of disease. From genetic engineering to the development of artificial organs to the development of new drugs and vaccines, there seems to be no limit to progress.

Most of these advances, however, require the development of new drugs and devices, and with new products come the consequences of the law of product liability. This branch of the law, developed by the courts to protect consumers from defective products, may actually prove harmful to consumers by erecting a barrier to biotechnological progress.[1] [2] [3] The protection provided by the various theories of product liability is achieved through money judgments for injured consumers and by deterrents to manufacturers who produce defective products. The challenge facing the law is to develop mechanisms that will provide adequate protection for the public from unreasonably dangerous advances in biotechnology without fettering progress.[4]

Product liability law has put research and development in biotechnology under a cloud. I propose to address those problems and some of the solutions that have been suggested.

Problems

In examining biotechnology it is important to appreciate the fact that it represents a major industry in this country and in the world at large. If our legal system inhibits this industry, it is likely that other countries will take up the slack. If the United States does not develop a legal system and climate in which the industries participating in biotechnology can safely and predictably develop and test new products, it is likely that the rest of the world will become the guinea pigs for the development of products that will ultimately be used in this country. This is already occurring: newly developed drugs are often commonly in use in other countries years before they are approved in the United States.

Another problem confronting biotechnological industries arises from the traditional products liability framework: scientific innovations that alleviate the effects of disease, injury, or congenital abnormality can never be free of side-effects. Furthermore, an advance in this field will often be a product with fewer side-effects, not one totally free of them.[5] If the subsequent design improvement rationale for recall of medical devises were to apply, the absurd possibility would exist of recommending the change of one medical implant, which is functioning properly, for a new one, simply because the new one may present fewer problems in the future. Consider the case of a cardiologist who has a patient with Brand X Model #999 pacemaker implanted in him. Three years later Brand X comes out with Model #1000 which in the laboratory has a 2 or 3% lower failure rate than Model #999. The patient is doing fine, but the current product liability climate puts the cardiologist and the manufacturer in a quandary. Should the cardiologist recommend that the patient undergo another surgical procedure to obtain this 2 or 3% benefit? Should the manufacturer issue a recall of Model #999?[6]

Recent product liability suits that American pharmaceutical corporations have faced because of drugs used in pregnancies will make it unlikely that any of these companies will put much effort into developing new drugs for pregnant women. The case of DES (diethylstilbesterol) is a perfect example. DES, a synthetic hormone, was a drug used in the 1950's and 1960's to prevent miscarriages. Subsequently it was discovered that some of the female offspring of these pregnancies tend to develop tumors (including cancer) of the vagina. Hence, DES is a drug whose complications do not become evident until a generation after it is administered. The major producers of this drug have been found liable for these tumors. What is even more difficult for the companies facing such liability to comprehend is that they have been found liable even though the use of the drug occurred so long ago that the plaintiffs were unable to prove that a specific defendant drug company manufactured the medication the plaintiffs actually took. In the DES cases the courts formulated the "market share" theory of liability, under which a manufacturer of a substantial proportion of a product dur-

ing the time the plaintiff claims to have been injured can be found liable even though the plaintiff can not prove that the defendant actually used the defendant's product. What adds insult to injury in the DES cases is that the drug was actually being used to ensure that the plaintiffs would be born. Some of these plaintiffs have actually brought wrongful life actions. However, to date none of those have been successful. Imagine a drug company that proposes to develop a new drug for use in pregnancy and then contemplates the DES situation. That company would never let the drug get off the drawing board.[7] The manufacturer of Bendectin, a drug used for nausea in pregnancy, was forced to remove it from the market, even though the company was ultimately vindicated and despite the fact that the scientific community was never able to prove that the drug was harmful to pregnant women.

The problems faced by manufacturers of drugs used in pregnancy make it easy to understand how companies engaged in genetic engineering feel pressured by the uncertainties of liability delayed for generations. How can any company plan for such uncertainties? How can any insurer price such a risk? In fact, such companies are finding it difficult, extremely expensive, or impossible to obtain insurance.[8]

Solutions

What solutions are there to such problems for so vital an industry?

Perhaps the most obvious solution is to build upon the strengths of the FDA. With strict compliance to FDA regulations for the research, development, manufacture, marketing, and warnings associated with a new product, a manufacturer, distributor, hospital, or physician would be granted immunity from tort liability for that product.[9] For persons harmed by such an unavoidably unsafe biotechnological product recovery could be obtained through a "Biotech Superfund". Injured parties could seek redress in the courts against companies not adhering to FDA requirements in good faith, and the companies would also face statutory penalties.

Another suggestion has been to adopt seriated trials for products liability litigation related to biotechnological products. Seriated trials would allow experts in the field to decide scientific issues too complex for a lay jury. Once they were resolved, the lay jury could address the alleged defect, any injury that resulted, and any associated damages.[10]

A suggestion that takes the seriated trial one step further is to develop a "science court" similar to the Patent Court, which would allow an expert determination of all issues in such cases.[11]

A final suggestion has been not to change the system of recovery for injuries caused by biotechnological problems but to shorten the lag time (which in the case of DES was more than twenty years) between the introduction of a product and the recognition of the injuries it causes. This suggestion entails development of a computerized registry of injuries associated with biotechnological products by manufacturer, hospital, physician, social security records, workers' compensation files, and litigation claims, which would allow the earliest possible recognition of problems associated with these products so that they could be improved or taken off the market in a timely manner.[12] ▶

Stephen Permut is a member of the Pennsylvania Bar. But that distinction is only one instance of an extraordinary record of accomplishment and service. Since 1975 he has also been a practicing physician engaged in family medicine and consulting general internal medicine. He currently serves as Medical Director of Total Health Plus in Wilmington. His record of public service is no less impressive: in addition to a variety of memberships in medical organizations, he belongs to the Advisory Committee of the Delaware League for Planned Parenthood and to the Board of Directors of the Children's Bureau of Delaware, Inc.

The health, safety, and quality of life of our nation will continue to be greatly influenced by advances in biotechnology. However, the threat of product liability litigation long after products are introduced is stifling progress. A number of solutions have been suggested, and the sooner a legal process that will both protect the public and allow scientific development can be achieved the sooner we can all benefit from biotechnological advances. ■

[1]Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts,* 85 Columb. L. Rev. 335-7, 277 (1985)

[2]Fern, *Evolving Tort Liability Theories: Are They Taking the Pharmaceutical Industry into an Era of Absolute Liability?* 29 St. Louis U.L.J. 785, 787 (1985)

[3]Wilson, *The Liability of Pharmaceutical Manufactures for Unforeseen Adverse Drug Reactions,* 48 Fordham L. Rev. 742, 735 (1980)

[4]Reed, *Products Liability Tort Reform: The Case for Federal Action,* 63 Neb. L. Rev. 435, 448, 389 (1984)

[5]Newpert, *Drugs During Pregnancy: Dangerous Business—The Continued Movement to Provide Adequate Warnings for the Consumer,* 62 Neb. L. Rev. 556, 526 (1983)

[6]Posner, *Implantable Medical Devices and Products Liability,* 28 Med. Trial Tech. Q. 272-3, 255 (1982)

[7]Fern, *Evolving Tort Liability Theories: Are They Taking the Pharmaceutical Industry into an Era of Absolute Liability?* 29 St. Louis U. L. J. 765, 787 (1985)

[8]Dahl, *Strict Product Liability For Injuries Caused by Recombinant DNA Bacteria,* 22 Santa Clara L. Rev. 122, 117 (1982)

[9]Hanson, *Can a Prescription Drug be Defectively Designed?—Brochu v. Ortho Pharmaceutical Corp.,* 31 DePaul L. Rev. 251, 27 (1981)

[10]Caldwell, *Products Liability and Medical Devices: Diagnosis and Cure,* 87 Dick. L. Rev. 804, 779 (1982)

[11]Cooper, *Scientists and Lawyers in the Legal Process,* 36 Food Drug Cosm. L. J. 25-6, 9 (1981)

[12]Glotta, *Learning From the Lessons of the Asbestos Tragedy: A Reform Proposal,* 19 Trial 71, 68 (Nov. 1983)

Patent Protection For Living Organisms

Rudolf E. Hutz

On June 16, 1980, the Supreme Court of the United States held that a living microorganism could be patented under the general provisions of the 1952 Patent Act.[1] Refusing to resolve public policy matters, which it deemed were the responsibility of Congress, the court found that the language of the Act fairly embraced Chakrabarty's microorganism invention.[2]

The decision by a sharply divided court (four Justices dissented) marked the first time that it had considered whether a living organism could be claimed in utility patents in the United States.[3] The court rejected the then popular conception that living things could be protected only under the relatively restricted provision of The Plant Patent Act ("PPA"—35 U.S.C. §161 *et seq.*) or under The Plant Variety Protection Act ("PVPA"—7 U.S.C. §2321 *et seq.*).

While the court speculated that the "grant or denial of patents on microorganisms is not likely to put an end to genetic research or its attendant risks",[4] the decision that living organisms *can* be the subject of a utility patent and the incentive of exclusivity have accelerated research in biotechnology.[5] Industry analysts have predicted that within the next ten years annual sales of biotech products will be in the tens of billions of dollars. In the last five years alone, some $3 billions in new investments have been made in biotech. Developments have application in chemicals, energy, agriculture, the environment—in almost every industrial section of the economy. Products already on the market include a diagnostic test for prostate cancer, a dysentery vaccine for swine, human insulin, and a human growth hormone. In the health field alone, more than 100 diagnostic and therapeutic products based on biotechnology are now reported pending before the Food and Drug Administration for approval.

In the last decade, the techniques of genetic engineering have thrust the science of microbiology into a new era. The *Chakrabarty* decision and its aftermath have similarly ushered in a new age of microbiological patent protection in the United States.

Statutory Schemes for Protecting Biotechnology Developments

Article 1, Section 8 of the United States Constitution granted Congress broad powers to legislate to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Congress has enacted three basic statutory schemes to provide at least some form of exclusive rights in biotechnology developments.

• **The Plant Variety Protection Act of 1970.** The PVPA, approved December 24, 1970, is administered by the United States Department of Agriculture, Plant Variety Protection Office. The PVPA authorizes the issuance of certificates to developers of novel varieties of sexually (by seed) reproduced plants. Exclusive rights are granted for a period of 18 years. Fungi, bacteria, and first generation hybrids are expressly excluded from protection (7 U.S.C. § 2402(a)).

A plant variety eligible for protection under the PVPA must be novel, which means the variety must be distinct, uniform, and stable. An application for certificate of plant variety protection requires the name of the variety, a description of its novelty and of its genealogy and breeding (if known), the deposit of its seed in a public depository, and a statement of the basis for applicant's ownership. Infringement of a certificate of plant variety protection may occur by such acts as sale or sexual reproduction of the protected variety, the use of the protected variety to produce a hybrid or different variety, and the import or export of the protected variety.

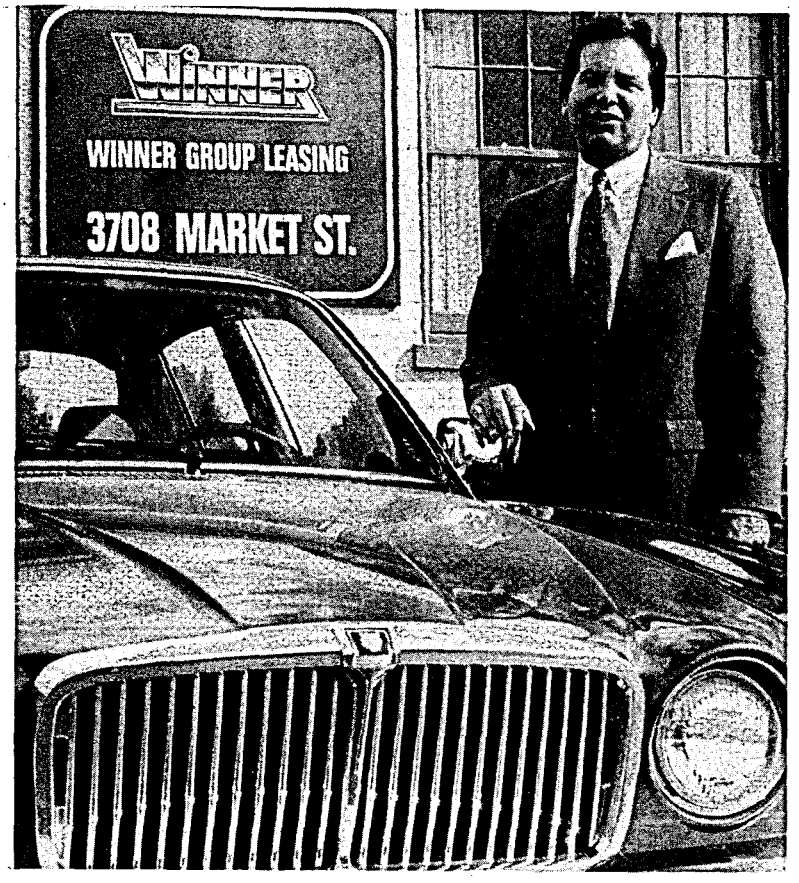
Protection under the PVPA is limited to one variety, and the Act contains a number of specific exemptions as well as a provision for compulsory licensing.

Rudolph Hutz, a member of the Wilmington firm of Connolly, Bove, Lodge and Hutz, conducts litigation in patent, trade secret, trademark, and anti-trust cases all the way from the trial level to the United States Supreme Court. He also prosecutes patent and trademark applications before the United States Patent and Trademark Office, and lectures widely on intellectual property topics both in this country and abroad.

• **The Plant Protection Act of 1930.** Plant patents may be granted to one who invents and asexually reproduces any distinct and new variety of plant, other than tuber-propagated plants or plants found in an uncultivated state.[6] Distinctiveness is usually shown by identifying some unique, visually observable characteristic, such as color, shape, vigor, productiveness, size, foliage, flavor, or resistance to disease, temperature, or drought. The description in a plant patent need only be "as complete as is reasonably possible" (35 U.S.C. § 162). The plant patentee need not provide a specification enabling one to "make" the plant, and the plant to be protected need not be put into a public depository.

Only one claim, to the distinct and new variety described, is permitted (35 U.S.C. §162). Less than 100 plant patents are granted by the United States Patent and Trademark Office ("PTO") per year. A plant patent grants the right to exclude others from asexually reproducing or selling or using the plant so reproduced (35 U.S.C. §163). The patentee has no right to prevent the sale of seed, flowers, or fruit produced by the plant unless the part of the plant sold can be used to propagate it.[7]

(Continued on page 32)



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• **The Patent Act of 1952.** Until *Chakrabarty,* the PTO's position was that claims to microorganisms *per se* were improper because microorganisms were "products of nature" and, as living things, not patentable subject matter under 35 U.S.C. §101.[8] The Supreme Court ultimately rejected both arguments, first because the Chakrabarty organism in question was human-made and genetically engineered and second because the organism was found to be a "manufacture" or "composition of matter" and thus expressly approved for patentability by 35 U.S.C. §101. The practical effect of this decision was greatly to expand not only the subject matter patentable under Section 101 but also the protection afforded to the creator of new biological materials.

In light of *Chakrabarty* it is not surprising that the PTO began issuing patents for genetically altered plants.[9] However, the PTO thereafter reversed its position and restricted patentable subject matter under Section 101 to living and genetically engineered products produced by "non-natural" processes. "Non-natural" meant the organism was produced only as a result of human intervention. If, however, the plant or parts of plants could be protected under the PPA or PVPA, the PTO applied a doctrine it called "preemption", and it refused patentability under the general patent laws. In addition, the PTO did not recognize life forms higher than microorganisms as patentable under the general patent law, thereby excluding patents on genetically modified humans or animals.[10]

The first test of the PTO's position occurred in *Ex parte Hibberd,* 227 U.S.P.Q. 443, a decision by the PTO Board of Appeals and Interferences, dated September 18, 1985. The Board rejected the PTO's "preemption" theory, and held that the PPA and PVPA were not the exclusive forms of protection for plant life covered by those acts. Absent reversal by a higher court, it should now be possible to protect plant life under both the general patent laws and, where applicable, either the PPA or the PVPA.

Special Problems Under The 1952 Patent Act

Unlike the PPA and the PVPA, the general patent law was not specifically drafted with an eye towards protecting living organisms. This has raised many complex questions of definition and claiming which are only now starting towards resolution. The practitioner in the biotechnology field is working from just a few court decisions. Future decisions will come piecemeal over a long period of time. The solution to these problems is rendered extremely difficult because of the newness and rapid development of biotechnology.

Terms that may have seemed definite and narrow at the time a patent application was filed frequently acquire different and broadened meanings when a patent issues or is subject to court review. Alternatively, because of the vast array of biological systems that are not well understood and the inherent limitations of the language, accepted or adequate terms to define or characterize the subject of a biotechnology invention may not exist. Thus, an applicant is at serious risk that, during examination by the PTO or in litigation before the courts, his language will be found defective even though no reasonable alternative existed when the application was written.

• **General Requirements of the 1952 Patent Act.** While *Chakrabarty* stands for the proposition that it is immaterial from the standpoint of patentability that the subject matter claimed is a live organism, all other statutory requirements under the general patent laws must be met. Consequently, patentable subject matter must be new or novel, useful, and nonobvious.[11] "Novelty" means that the identical subject matter did not exist in the prior art; "nonob-

viousness" means that, although differences do exist between the subject matter claimed and the prior art, the differences are such that the subject matter as a whole would not have been obvious to one skilled in the relevant art at the time the invention was made.[12]

Usefulness as applied to genetic engineering has potential implications far beyond the traditional conceptions associated with the Patent Laws. In *Chakrabarty,* the Supreme Court was asked to consider the "grave risks" that might be generated by research efforts in genetic engineering. Some responsible scientists suggested that such research posed a serious threat to the human race or, at the very least, the dangers of pollution and disease were far too substantial to permit the research to proceed apace at that time.[13] The court, however, did not consider what it called the "gruesome parade of horribles" as controlling, and it left amendments to language of the statute to Congress, if Congress deemed amendment necessary.[14] Thus, "usefulness" as applied to biotechnology is employed in the normal patent sense, and does not involve the question of safety unless the subject matter is so unsafe that it can have no possibility of practical use.

A patent applicant in the biotechnical field must, as all other applicants, comply with the disclosure and claiming requirements of 35 U.S.C. §112. This means that the application must describe the claimed invention in such a manner that one skilled in the relevant art can make and use it without undue experimentation or the exercise of independent inventive skills. Furthermore, the applicant is required to end the patent with one or more claims that particularly point out and distinctly claim the subject matter sought to be protected.

• **Deposit Requirements.** When an invention is directed to or employs new biological material, the invention may not be reproducible from a mere description. Where the invention depends on the use of a microorganism or other biological material not known and readily available to the public, the PTO has established the requirement that a physical sample be made available to the public as a condition to the patent grant.

The PTO's deposit requirements are set forth in Section 608.1(p)C of the Manual of Patent Examining Procedures ("MPEP"). The PTO will accept the following as complying with the description requirements of the statute: (1) the applicant, no later than the effective United States filing date of the application, deposits the biological material in a depository affording permanence of the deposit (a minimum of 30 years) and ready accessibility thereto by the public if the patent is granted, (2) the Commissioner of Patents has access to the material during the pendency of the application, (3) all restrictions on availability to the public are irrevocably removed upon the granting of the patent, (4) the deposit is referred to in the body of the application and is identified by deposit number, name and address of the depository and (5) the applicant provides assurance of permanent availability to the public.[15] The depository may be a private or public depository and may be located in the United States or abroad provided the necessary permanent availability and assurance of access upon issuance of the patent are present.[16]

The deposit requirement evolved as a nonstatutory remedy for the problem of inadequate written description in biologically oriented applications. Although the deposit requirement was limited initially to naturally occurring life forms (microorganisms), the emergence of new technologies, whereby life-forms can be modified through human intervention, has added a new element to the deposit requirements.

• **Claiming Biotechnology Under the 1952 Patent Act.** Before *Chakrabarty,* the PTO regularly issued patents to *processes* for producing biological materials and biological materials in association with carriers. Indeed, claims of this type had been allowed although the PTO refused to allow claims to the bacteria themselves.

Because the patent claims must particularly point out and distinctly claim what the applicant regards as the invention, continuing questions arise as to how claims to biotechnical inventions should be drafted. These questions are critical not only to ensure compliance with Section 112 but to afford adequate protection in the courts during infringement actions. ▶

While many patent claims initially have met the PTO's standards and have been allowed, it is almost impossible to predict how claims in the biotechnical field will be interpreted by the courts. This is particularly true under the so-called Doctrine of Equivalents which in proper circumstances, enables a patentee to expand the literal language of his or her claims to embrace subject matter that performs substantially the same function in substantially the same manner to yield substantially the same result.[17]

The many problems now facing the patent system due to the recent emergence of genetic engineering and other sophisticated biological techniques are as complex as the techniques themselves. The solutions are, however, essential to the continuing advance of this art, which holds such promise for the future. ■

1 *Diamond v. Chakrabarty,* 447 U.S. 303 (1980)

2 The applicable section, 35 U.S.C. §101, provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

The invention at issue in *Chakrabarty* was "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy generating plasmids, each of said plasmids providing a separate hydrocarbon degenerative pathway."

3 Patents for living microorganisms had been granted long before *Chakrabarty,* including one to Louis Pasteur in 1873 for "yeast, free from organic germs of disease, as an article of manufacture".

4 447 U.S. 317

5 A utility patent grants to its owner the right to exclude others from making, using or selling the subject matter patented for 17 years from the date the patent is granted (35 U.S.C. §154).

6 As between the PPA and the PVPA, the critical factor that determines which act applies is the method required for true reproduction of the novel variety. If the variety is reproduced by seed, then the PVPA is applicable: if reproduction is by grafting or budding, the PPA applies.

7 *Yoder Brothers, Inc. v California-Florida Plans Corporation,* 537 F2d 1347 (5th Cir 1976).

8 447 U.S. 310-311

9 For example, United States Patent Nos. 4, 378,655 (Semi-dwarf hybrid sunflower seed and plant) and 4, 351, 130 (Rice plant).

10 In other words, according to the PTO, the PPA and PVPA provided the *exclusive* means of protecting certain plants, and alternative or dual means of protection under Section 101 would frustrate Congressional purpose. See address by Mr. Rene Tegtmeyer, Assistant Commissioner of Patents, to the Industrial Biotechnology Association on October 18, 1984.

11 35 U.S.C. §101-103

12 35 U.S.C. §103

13 447 U.S. 316-317

14 447 U.S. 317

15 See *In re Lundak,* 227 U.S.P.Q. 90 (Fed. Cir. 1985); *In re Arquodelis, et al,* 434 F2d 1390 (CCPA 1970).

16 *Feldman v. Aunstrup,* 517 F.2d 1351 (CCPA 1975), *cert denied,* 424 U.S. 912 (1976).

17 *Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 339 U.S. 605 (1950).

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even though these children often live to adulthood and bring many parents a great deal of love and fulfillment.

The above is not meant as advocating restriction of any individual woman's right to privacy and free choice, but to present some of the moral difficulties to be faced in making those choices in the future.

Of course, the scenario I have painted may not come to pass. Scientific breakthroughs can be rapid. Perhaps it will be possible to do low risk gene therapy after a baby is delivered. Alternatively, continued experimentation with non-human organisms may increase efficiency and lower risks before the techniques are attempted in humans.

Gene replacement therapy is only one of several related and controversial issues resulting from biotechnological gains. It is likely, for example, that it will be possible to use genetic markers to predict a myriad of diseases and then to abort fetuses who probably, though not certainly, will develop them. But will it be beneficial? Adin Steinsaltz, perhaps the greatest scholar of the *Talmud* of our day suffers from Gaucher's syndrome, a debilitating and sometimes lethal disorder. Jacquelin Du Pre, a magnificent cellist, has multiple sclerosis. Countless other members of our society, though stricken with illness that soon could be predicted, have lived useful lives.

Scientists are not theologians. And yet I worry that we don't think in such terms more often. While the goals of medical intervention are noble, the outcome can be unsuccessful or fraught with unforeseen repercussions. Can we brush such failures aside routinely? To do so, I believe, is to cheapen the value of human life.

1 Thomas, K. R. and M. R. Capecchi, 1986, "High frequency targeting of genes to specific sites in the Mammalian genone," *Cell*, vol.44, p.419-428.

Legislative/Regulatory Concerns

Almost 40 comments were addressed to the proposed coordinating structure, the Biotechnology Science Board. Most were critical of the two-tiered structure that would double the review procedure. Some felt the confidentiality of business information could not be adequately assured, others that the BSB would detract from the stature and function of the NIH's RAC. It was felt that the BSB should set policy, but not act as a review board.

On the whole, industry favored an Advisory Committee for each agency. However, there were fears that an interagency group would also slow the review process. According to the Grocery Manufacturers of America, "Additional levels of scientific review and regulatory bureaucracy can be counterproductive."

Congress, too, raised some issues. Before the December 1984 proposal Rep. John Dingell, Chairman of the Energy and Commerce's Subcommittee on Oversight and Investigations, questioned the view of FDA Commissioner Young and the Reagan Administration that existing rules sufficiently control the release of dangerous products into the environment. At a December 11, 1984 hearing on biotechnology, he suggested that change might be necessary. At that hearing, the Deputy Director of the White House Office of Science and Technology Policy, Dr. Bernadine Buckley Healy, responded to Dingell's concerns. She said the Administration was not totally wedded to the current regulatory policy, and that the working group on biotechnology had endorsed an expanded review structure.

After the publication of the working group's findings, Dingell, speaking at a Brookings Institute conference, discussed the possibility of legislation to fund basic research. According to Rep. Dingell, the rise of commercial interest coupled with the Administration's cut in research funding, may imperil basic research in academia. The proposal also did not allay Dingell's apprehension about safety. In an April 1985 speech, he stated that there was "inadequate attention" to the public health issues implicit in the production of biotechnological products.

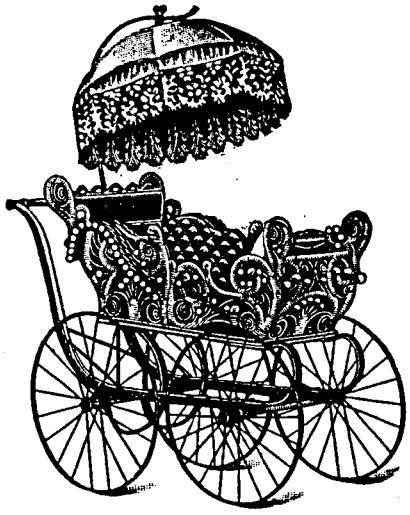
The final version of the coordinated framework for the regulation of biotechnology was published in the Federal Register on November 14, 1985 (50 FR 47174). In light of the concerns raised, the Biotechnology Science Board was replaced by an interagency coordinating committee, the Biotechnology Science Coordinating Committee. So not to raise issues of bias, the Committee was placed administratively within the Federal Coordinating Council for Science, Engineering and Technology (FCCSET). This group is a statutory interagency coordinating mechanism in the Office of Science and Technology Policy, Executive Office of the President. The Council is charged with coordinating federal science activities among the federal agencies and appears to be the appropriate place for such a committee. However, the demotion of this group to committee status and the removal of the reviewing authority previously proposed for the Biotechnology Science Board prompted Senator Gore to observe that the Committee was a discussion group with no authority. At a hearing on biotechnology held the same day the Final Notice was published, he predicted that battles between the agencies might render the present regulatory structure ineffective. With no superagency to resolve policy conflicts, Gore implied that legislation might be in order. On the other hand, the Industry Biotechnology Association said that the BSCC was a positive step that should not add another layer to the approval process.

Congressional concern persists: the House Science Investigation and Oversight Subcommittee met on December 4, 1985 to examine the present state of regulation of risks and the adequacy of risk assessment by the EPA and USDA. The hearing was prompted by an announcement by the EPA that the first of two field tests of genetically engineered organisms had been approved, and a GAO report that a significant number of intentional releases will occur in the next five years.

Since the revised statements of regulatory policy of the various agencies received a large number of detailed comments, more time was required to put policy in final form. The revised policy statements are expected to appear in the Federal Register shortly. However, there should be few surprises in the agency plans. Officials from various agencies have been discussing their views for some times. commissioner Young has expressed the FDA's sensitivity to the balance between too much and too little regulation. FDA and The National Science Foundation plan to use existing Advisory Committees. USDA and EPA are establishing new committees and the NIH RAC will continue.

Whether these attempts at balancing industry, administration, and congressional concerns will satisfy anyone remains to be seen.

All that is certain is that the debate goes on. ■



Lane Bryant To Go Co-ed?

The Wilmington Morning News of May 9, 1986 has announced a bit of scientific tinkering almost too grisly to contemplate. Since it is now possible to fertilize a human ovum outside the body, it is now proposed (in a twist of really nasty ingenuity) to implant the fertilized egg somewhere in the abdominal cavity of the sperm donor, who will then go through a full term pregnancy, ending in caesarian delivery. Enough, already! Male chauvinists of the world, unite! You have nothing to lose but your morning sickness!

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L'Envoi

Since the beginnings of recorded time one of the most durable tensions in western society has derived from our mixed feelings about knowledge, which simultaneously fascinates and terrifies. We carry around with us a huge ancestral baggage of myth and metaphor about the perils of intelligence.

Consider the mournful grandeur of Milton, deploring "the fruit of that forbidden tree whose mortal taste brought death into our world and all our woe". The tree, of course, is *knowledge.* And that's only for starters. Any inventory of anti-intellectual scare tactics must include The Tower of Babel, Pandora's Box, Prometheus, Faust, Bluebeard's wives (who just *would* peek into that closet), and the ultimate anatomical busybody, Dr. Frankenstein. Indeed, a mental image of the truth seeker as downright dangerous lurks in all of us who devoted the Saturday afternoons of our youth to attending double horror features. S.J. Perelman expressed it definitively:

> *Give me an underground laboratory, half a dozen atom smashers, and a beautiful girl in a diaphanous veil waiting to be turned into a chimpanzee, and I care not who writes the nation's laws.*

And so we bring to the dazzling possibilities of improved and lengthened life through scientific discovery a peasant superstition of the unknown and a conviction that it best remain so.

The articles in this issue of *DELAWARE LAWYER* evidence a large degree of such apprehension, some of it thoughtful, even philosophic, much of it bureaucratic, if not Luddite. We must not forget that any advance in knowledge will be accompanied by surprises, and occasionally disagreeable ones. But there is no reason why the intelligence that made the breakthrough cannot address the consequences as well. Any weighing of benefits against attendant evils will suggest that in the long run we shall gain through an unshackled exercise of curiosity and that, in a democracy there will always be an ample supply of vocal critics sufficient to preserve us from our own ingenuity. What is more important, there will be *lawyers.*

The Bhopal accident carried with it a lesson of how law can adjust the interests of a high technology society and the legitimate expectations of its members. Bhopal brought out in striking fashion the least appealing and the worthiest aspects of our profession. To hear his detractors, one would understand that that doughty old headline hunter, Mr. Melvin Belli, took to the media, frothing with well-rehearsed indignation, and then hustled off to India in a state of sepulchral glee to search out a clientele. Such a view is probably inaccurate and certainly unfair: if battening on human misery is unattractive, leaving it unsolaced is contemptible. The prospect of being brought to account for the negligent infliction of injury is prophylactic. Much of our security rests on the sensible fears of the powerful, who know that in a free society the law is always ready to confront the mightiest and say, "Buddy, you can't get away with it!"

The law in its present vigorous state is exceptionally well qualified to mediate between the uncontrolled excesses of genius and the pious obstructionism of the snail darter set. As lawyers we are trained to combine respect for technological disciplines beyond our scope with common sense insistence upon the protection of our fellows. We must all have felt a thrill of pride when former Attorney General Rogers, no authority on space shuttles, applied the searching analytic tools of our profession to ferret out esoteric error.

Nothing proclaims the irreplaceable usefulness of our calling so much as our trained ability to adjust the competing claims of progress and security. We should not let our detractors or the public forget it.

The second of what we hope will be a series of reminiscences about a distinguished Delaware lawyer by his talented and equally distinguished lawyer son...

Golf with Father

William Prickett

The Bettmann Archive

When I was growing up, my father was far too busy recuperating from the ravages of the depression to take the time to indulge in the usual suburban sports that occupied so much of the time of his contemporaries. Actually, until the fateful day around which this narrative centers, I never saw him swing a golf club. However, in the closet under the stairs of the old Victorian house on Delaware Avenue, there were two monstrous leather bags containing an array of old wooden clubs, one of which I knew belonged to him and one of which had belonged to my grandfather, Judge William Prickett. Grandfather had been an avid golfer. Somewhere in some bureau drawer, there is a family photo album containing several old brown photographs of Grandfather and his golfing companions on the links dressed in Edwardian golfing attire with toothy Teddy Roosevelt smiles and walrus mustaches. Indeed, Grandfather was the Club champion. In the trophy cases of the Wilmington Country Club, there are, I believe, still several brass and Sheffield cups commemorating forever his Sunday afternoon victories between 1907 and 1913. I knew my father had caddied in his youth for his father and had played some, but, as I say, I was an utter stranger to the links in my youth and never learned the art of driving, pitching or putting. However, when I was wasting my time and the taxpayers' money down in Camp LeJeune as a Second Lieutenant during the Korean War, I found one day that there was a golf course manicured by an army of privates (oh, the good old days!!) for the exclusive use of officers and their wives. Having nothing much to do on weekends in that godforbidden area of the world, I decided to make an effort to learn golf. My efforts met with a dismal lack of success, stemming from a lack of coordination coupled with impatience at the repeated necessity, not of animal energy, but of accuracy and control. Indeed, my budding career as the U.S. Marine Corps' answer to Arnold Palmer came to an abrupt end one day when in a fit of sudden anger at the unpredictable course of the white ball, I took an innocent nine-iron and bent it double by hitting it full force against a nearby and equally innocent swamp maple sapling. When the fat Staff Sergeant in charge of the link saw what I had done to the borrowed nine-iron, he reported me to the Chairman of the Golfing Committee and I got a stern military reprimand from a Colonel whose only duty seemed to be in perfecting his golfing technique.

Well, that particular war having come to an end, I returned to civilian life and eventually the practice of law with my father. One day, I idly complained that I had never been taught in my youth any of the suburban sports that so many of my contemporaries were now playing with ease and proficiency. My father decided at that point that golf was a social amenity that should now be added to my pitiful bag of social graces. As a matter of fact, having seen me stumbling about at a Country Club dance, my father sent me off to take an Arthur Murray dance course to improve my ballroom style. This led to a brief fling with a bosomy Arthur Murray instructress. However, when I took this somewhat voluptuous lady to the next Country Club dance, my father quickly terminated his financial support of that venture. With my financial support cut off, my temptress was no longer interested. Thus, my dancing style has not improved. However, that is another story.

Back to golf. My father, having decided on a course of action, was not apt to let time go by: he therefore suggested the very next day that we go out on Saturday to the links of the Wilmington Country Club. He and I were members and had supported the regular golfing fraternity by paying the monstrous club dues for years. I was mildly agreeable to the project but pointed out that we did not have any clubs. My father briskly brushed this objection aside pointing out that he still had his clubs and I could use my grandfather's clubs. I did not know much about golf but did know enough to know that these long wooden relics were not only brittle but were museum pieces rather than effective shiny metal instruments then in use. "Nonsense!," my father replied, pointing out that while the material out of which the clubs were made was apt to change from time to time, the form of the club had not changed at all since the game was invented back in Scotland centuries ago. He went down and got out the old golf bags, brushed off the cobwebs, blew away the dust, and wiped away the mildew that had grown up on the leather over the years. Then, to his delight, he found six old scarred golf balls in the dry-rotted pouch on one of the bags. As he pulled out the irons, he remarked that he was probably as rusty as the old clubs but said that his form would soon come back. "When I used to play," he said, "it was my goal to make a hole-in-one, but I always just missed." Thus equipped, we arrived at 2:00 p.m. on a hot Saturday afternoon in July. It took us a considerable amount of time to find the golf pro's shop. Once there, Father announced to the old Scotch pro, Alex Tate, and the assembled caddies, that he and I were going to play a round of nine holes. Mr. Tate tactfully suggested that perhaps I might want to commence by taking a few practice drives or perhaps putting a bit. My father rejected this well meant suggestion out of hand and said that I would get the feel as we went along. There were incredulous stares by the caddies at the sight of our ancient golfing weaponry and perhaps even a smile which instantly vanished at the stern look of Mr. Tate: he ruled his caddies with an iron hand and allowed no disrespect to members. Mr. Tate politely asked us if we wanted to use a caddy. Again, my father disdained the proffer, pointing out that the purpose of the game was exercise, and that he and I could easily manage the huge old leather bags. Though I now know that play on Saturdays requires not only a reservation but a foursome, Mr. Tate sized this twosome up as special and quickly pointed out the first tee to us, shouldering aside a serious foursome of fourteen-year old boys who were already proficient golfers.

My father saw no reason not to profit from this outing to get some sunburn. He therefore removed his shirt as we got to the first tee. His outfit consisted of knee length khaki shorts, an old golfing hat and some walking boots. Of course, in view of his back injury in a plane crash in France in 1918, he wore a back brace. For my part, I was wearing faded Marine greens and a fatigue cap. Though I knew he had not played for fully forty years, I knew that he never forgot any skill he ever acquired and I was sure that he would perform creditably. However, I had real reservations about how I would fare especially with his forceful coaching. However, nothing ventured, nothing gained, and on this note, we set out.

My father first gave me a few pointers. He then hauled out his driver and then stepped boldly up to a borrowed tee, having planted one of our precious six old golf balls on said tee. He took a vigorous swing at the ball. He hit the ball and it sailed one hundred yards squarely down the middle of the fairway and came to rest. My father motioned me to tee off. I managed to hit the ball on my first swing but I hit it with the side of the club because it sort of sailed up in a kind of lazy boomerang course and then came winging back down and came to rest almost at my feet. I could already see that I was not going to burn up any course records, nor indeed was I going to add any glory to my grandfather's record. Indeed, I sensed another golfing disaster in the offing and I wasn't far wrong as you will discover if you care to read further.

My father, sensing my mood, bravely pointed out that golf was a game that took a bit of persistence. He went on to assure me that by the third or fourth hole, if I paid attention, I should soon get the hang of the game. Well, we set out under the hot sun, each carrying our eighty-pound golf bags. I think that I managed to put my replacement golf

▶

The Bettmann Archive

ball in the first hole after fourteen or fifteen erratic shots. I say "replacement ball" because I lost three golf balls on the first hole. Indeed, I took the precaution of going all the way back to the golfmaster's house and purchasing another six white pellets because I could see at the rate I was going, we were not going to even get midway in our round: we would surely run out of the necessary white ammunition to continue the fight. Since these replacement golf balls cost $2.00 apiece, my father cautioned me to be prudent since he didn't want to run up the cost of this expedition by an inordinate expenditure on golf balls.

Time has softened and diminished the memory of all the details of the disastrous round that we played. I do remember that the fourteen-year old foursome, whom we had brusquely shouldered aside at the outset, came up behind us not long after we started. They were reasonably patient for two holes but then had the temerity to ask if they might play through. My father at first saw little reason for this but in the end he agreed. They played efficiently through and in a short time disappeared over the golfing horizon while I ineffectually batted my ball back and forth criss-cross across the green, only to end up inevitably in the tentacles of the huge sand traps that surrounded the small hole that was the object of my attention.

Not long after that, when I had finally "holed" my shot, we walked over to another tee and got ready to tee up for our next drive. All the while, my father was busy giving me a running critique of my form and instructions on what to do and what not to do. We could see the flag but, oddly enough, our drives would have to go over, through some fairly thick woods that lay between the tee and this particular flag. There was an arm waving and shouting from some other golfer some distance away. However, my father disregarded all this commotion and drove, and I followed him. To our great surprise, as I was getting ready for my fourth shot and my father for his second, a golf ball bounded down between us and lay there. We looked at each other in astonishment. Then, we saw four ladies with caddies bearing down on us on what was obviously a collision course with our line of play. My father remarked that the ladies were obviously "off course". The ladies were young matrons. They were

very polite to this now lobster-red older man wearing a back brace. They asked politely just where we were going. We pointed to a flag up ahead in the distance. They looked somewhat puzzled in the general direction from which we had just come but neither they nor their caddies said anything but simply swept on by.

It was only when we got closer to the flag itself that we noticed we were approaching the hole from a side that had no sandtraps. Suddenly it dawned on us that perhaps the ladies and the arm wavers had been right after all. Indeed, it turned out that at the last hole, we had teed off in the wrong direction and we had driven towards a pin that actually was on the second nine and across two other fairways. This accounted for the trees that we had had to play through. It also accounted for the fact that we had not encountered the usual sandy traps that had consumed so many fruitless strokes and had made it look like there had been a dog digging or a giant sand moving operation going on when I was trying to get out. However, even though we recognized now that we were somewhat off course, so to speak, my father decided that we should gamely play the hole out as sportsmen should. There was total confusion when, as I was completing my seventh putt, we were bombarded with accurately driven second shots that bounced smartly onto the green from the right direction. Indeed, my father was hit by one of these balls in the back, fortunately on its second bounce, and it caused him to misputt. He was momentarily angry, indicating that courtesy demanded the time-honored call of "fore". I pointed out to him that the golfers shooting for this pin obviously couldn't see us and had little reason to expect that somebody would be coming from the wrong side. My father agreed that I probably had a good legal point though he said that "fore" was simply a common precaution and courtesy. The golfers in question turned out to be a serious Saturday afternoon foursome who were probably betting a fair amount on each hole. They came storming up, sizzling mad. However, they tempered their threatening looks when they saw my father since they knew that in arguments, my father would take second best from no man. In the end, after our explanation, they gravely said that they could quite understand how this interesting situation had arisen and concluded that they were delighted to see that the son and grandson of a Club champion were coming back to reestablish our family's prowess on the golf links. The caddies, however, out from under the stern eye of Mr. Tate, were openly amused.

"Other golfers had come up and were now waiting patiently." Our thanks to Steve Smack at the Wilmington Country Club for this photograph. Photo: Lois M. Rasys

Author Prickett, a multi-media event. Photo: Albert C. Johns

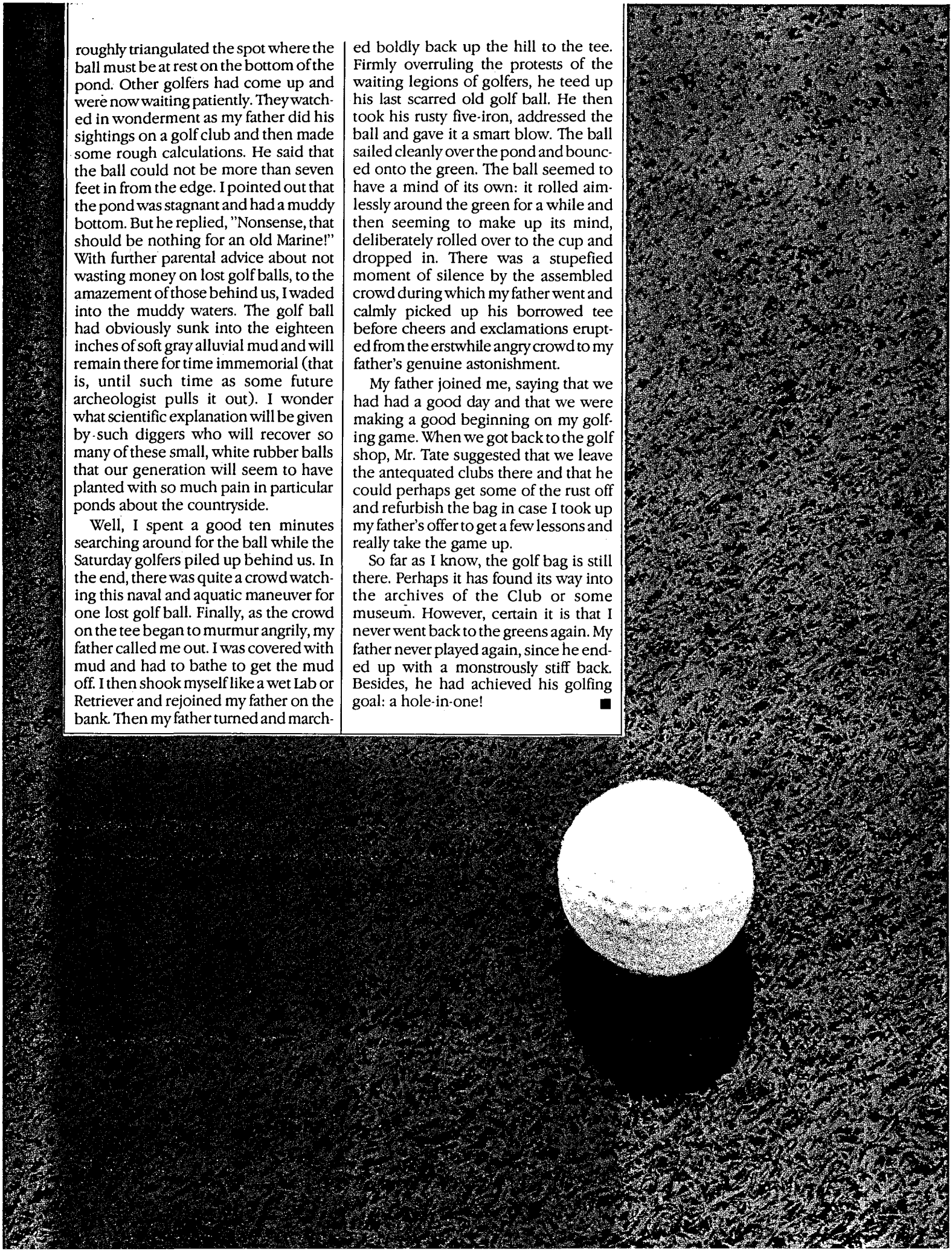
It was, however, the seventh or perhaps the eighth hole that is stamped forever in my memory. It was a water hole. The tee sat well above the hole and the water lay in between. The designer of the course had shrewdly posed a tactical question to the golfer as to whether to drive the ball cleanly over the water and onto the fairway just short of the green, or whether more prudently to take the short tap this side of the water and then on the second stroke lift the ball over the pond and so to the green. I was undecided as to how to play this obstacle. At this point, we had only two remaining balls. Obviously, if the water gobbled up our two balls, our play would be finished and we would be forced to march back in without having completed the nine. As I teed up, my father suggested that this was the sort of hole on which my grandfather had made several "holes-in-one". He said that if I would only follow his instructions, I ought to be able to put the ball on the green if not in the hole with one stroke. Of course, these well meant reminders of ancestral prowess and techniques did nothing for my coordination or self-confidence and it was reflected in my faltering stroke. I took careful but shaky aim at the ball with my five-iron. I must have again hit under the ball because it flew skyward and was lost to our upward gaze in the penetrating rays of the July sun. We both put our hands over our heads to avoid being pelted by my skyward shot in case of another "boomerang". However, the boomerang effect was not built into this shot. Instead, the ball came whistling down out of the clouds and splashed into the pond, raising a great cascade of water. My father immediately took a careful sight on the ball and suggested that I not tempt the fates by exposing our one remaining golf ball to a watery grave, but rather that we go down and retrieve the ball. Well, down we went and stood on the edge while my father, who was an ex-aerial artillery man,

roughly triangulated the spot where the ball must be at rest on the bottom of the pond. Other golfers had come up and were now waiting patiently. They watched in wonderment as my father did his sightings on a golf club and then made some rough calculations. He said that the ball could not be more than seven feet in from the edge. I pointed out that the pond was stagnant and had a muddy bottom. But he replied, "Nonsense, that should be nothing for an old Marine!" With further parental advice about not wasting money on lost golf balls, to the amazement of those behind us, I waded into the muddy waters. The golf ball had obviously sunk into the eighteen inches of soft gray alluvial mud and will remain there for time immemorial (that is, until such time as some future archeologist pulls it out). I wonder what scientific explanation will be given by such diggers who will recover so many of these small, white rubber balls that our generation will seem to have planted with so much pain in particular ponds about the countryside.

Well, I spent a good ten minutes searching around for the ball while the Saturday golfers piled up behind us. In the end, there was quite a crowd watching this naval and aquatic maneuver for one lost golf ball. Finally, as the crowd on the tee began to murmur angrily, my father called me out. I was covered with mud and had to bathe to get the mud off. I then shook myself like a wet Lab or Retriever and rejoined my father on the bank. Then my father turned and marched boldly back up the hill to the tee. Firmly overruling the protests of the waiting legions of golfers, he teed up his last scarred old golf ball. He then took his rusty five-iron, addressed the ball and gave it a smart blow. The ball sailed cleanly over the pond and bounced onto the green. The ball seemed to have a mind of its own: it rolled aimlessly around the green for a while and then seeming to make up its mind, deliberately rolled over to the cup and dropped in. There was a stupefied moment of silence by the assembled crowd during which my father went and calmly picked up his borrowed tee before cheers and exclamations erupted from the erstwhile angry crowd to my father's genuine astonishment.

My father joined me, saying that we had had a good day and that we were making a good beginning on my golfing game. When we got back to the golf shop, Mr. Tate suggested that we leave the antequated clubs there and that he could perhaps get some of the rust off and refurbish the bag in case I took up my father's offer to get a few lessons and really take the game up.

So far as I know, the golf bag is still there. Perhaps it has found its way into the archives of the Club or some museum. However, certain it is that I never went back to the greens again. My father never played again, since he ended up with a monstrously stiff back. Besides, he had achieved his golfing goal: a hole-in-one! ■



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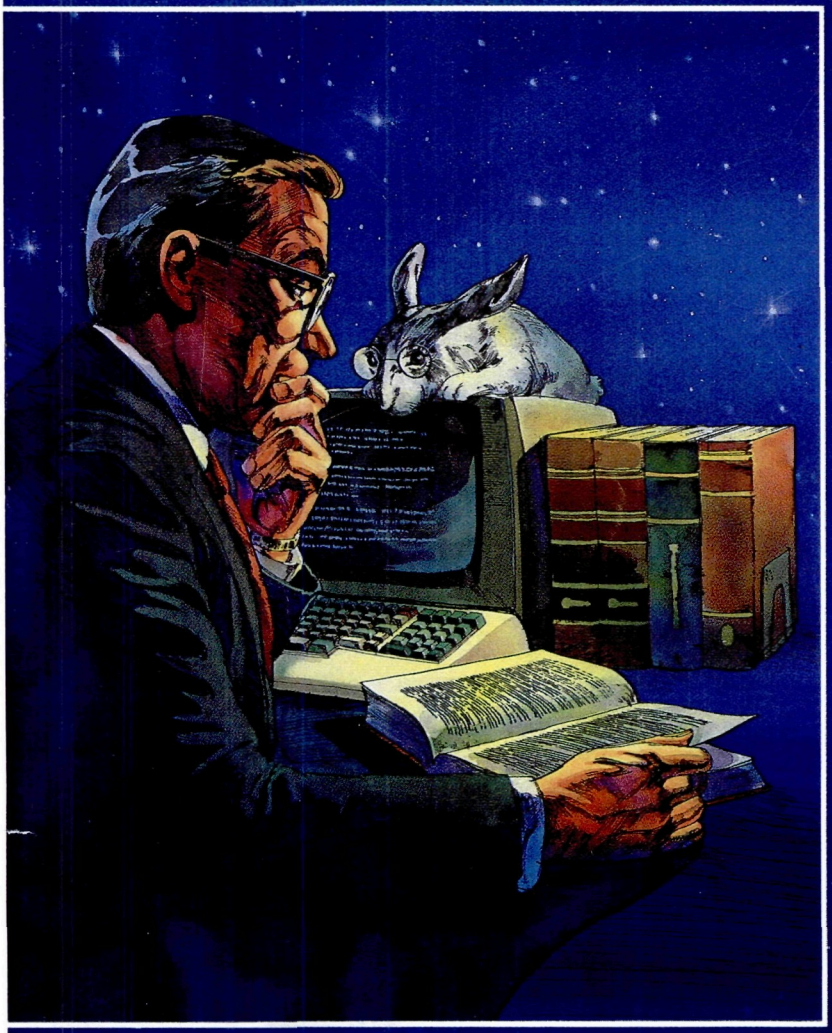

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