Biotechnology: New benefits, new questions

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In the last 25 years, scientists have learned to modify genetic material with increasing skill and refinement. Crossing 'the species barrier,' scientists can now endow a bacterium, a sheep or a corn plant with virtually any gene from any organism. This possibility has raised ethical issues, especially for human gene manipulation; it has also yielded profound benefits, such as the reliable production of insulin by bacteria instead of from swine pancreas tissue.

In its broadest sense, biotechnology — the application of biology to solve technological problems — is as old as the earliest use of medicinal plants and plant breeding. But beginning a quarter century ago, scientists gained the ability to modify the basic molecule of heredity, DNA (deoxyribonucleic acid) generally known as recombinant DNA or rDNA. Modern applications include medical diagnostics and treatments, forensic applications including establishment of parental identity, detection of pathogens and food contaminants, prognosis for inherited diseases and physiological malfunctions, and improvement of crop plants and livestock.

Many of the steps required for genetic transformation are protected by U.S. patents held by both private and public institutions. Protection of intellectual property is required to develop and market a product competitively. This has raised issues, such as who owns the genes, since genetic resources were traditionally freely available and held as a common public good.

UC has advanced biotechnology through many basic discoveries in molecular biology. Our scientists are required to disclose their discoveries to the University. The University licenses the patented discoveries to organizations that can further develop and market useful consumer products. UC may choose to collect royalties on the marketed product or make other agreements. Inventors may receive a share of the royalty income. Since UC does not generally develop market products, many, if not most, discoveries would remain undeveloped if arrangements for product development and marketing were not made.

UC's longstanding intellectual property policies have not changed with the advent of modern biotechnology. However, recent aggressive licensing by the UC Office of Technology Transfer has resulted in a significant annual return for all intellectual property, amounting to about $60 million in 1996, which was divided among UC, the State of California, and the inventors.

In the last three decades, scientists in the Division of Agriculture and Natural Resources (DANR) have become more dependent upon extramural sources of funds to fulfill their research missions. Today DANR, through state appropriations, provides needed infrastructure, including faculty salaries and facilities, but only limited funds for research operations. Federal, and to a small extent, state agencies offer competitive grants. Other extramural sources include agricultural commodity boards, which have consistently provided funds to support specific research needs; and private foundations and individual donors.

However, the cost of performing biotechnology research has increased dramatically, partly due to the necessity of acquiring licenses and sophisticated instrumentation and molecular tools. UC scientists have looked toward the private sector for partnerships in research. Several types of collaborations have evolved:

- Individual scientists have entered agreements with private or public entities for access to DNA clones or for substantial financing of a mutually interesting project;
- Individual companies or consortia of private organizations have provided financial support for a general research area;
- A single company has provided general funding in return for defined access to discoveries of a single department or research group, such as the recent agreement of UC Berkeley's Department of Plant and Microbial Biology and Novartis;
- A unique UC program called BioSTAR has provided grant funds on a competitive basis for UC faculty along with matching funds from a company.

All such arrangements are reviewed and approved by University administration, since they often require agreement for priority access to the technology by the organization providing funds. We expect to see more agreements with the private sector for specific research projects.

With these arrangements come numerous questions of the true role of the public University and how the traditional academic practice of accumulation and sharing of knowledge can be protected. Some examples:

- Is the UC research agenda dictated by public need or availability of funds?
- How are research benefits apportioned if several sources of funds support the research?
- How can open discussion and collegiality among UC scientists be retained if research contracts require secrecy and delay of publication of findings?
- Will the training of graduate students be hindered or helped by agreements entered into by their academic advisors?
- How should UC address ethical, moral, and perceived safety issues raised by biotechnology in its research, instruction, and outreach programs?

It is essential that the University community addresses these questions and, at the same time, remains at the forefront of creative research. As we enter the 21st century we must ensure that UC continues to advance research in the public domain. If we do so, at the end of the 21st century Californians will still have a public university dedicated to public service and the pursuit of knowledge.