15 Prospects for Agricultural Biotechnology—A View from Industry

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Most of the objections raised to biotechnology, particularly those from an environmental or public health point of view, get the calculation of costs and benefits inverted from reality. That leads to the question of why all the fuss, given the facts. I think the answer to that question is an extremely important one. In many respects biotechnology serves as a lightening rod for a lot of concerns and issues. Even if biotechnology could be made to vanish and we did not know what DNA was or how to manipulate it, most of these issues would still be with us. Issues of concentration in the agricultural sector and industry have been going on for generations. Biotechnology has not caused it, although it has been an element of it. The issues associated with globalization are not unique to biotechnology, nor are they contingent on biotechnology.

Intellectual Property

The intellectual property system in the United States was devised by Thomas Jefferson. His writings on it are very illuminating. Intellectual property protection is basically a Faustian bargain between the conflicting objectives of stimulating and rewarding innovation and ensuring public disclosure that enables further technological developments.

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The choice is, as Jefferson envisioned it, between honoring trade secrets, which are conspicuous for not stimulating the cross-pollination of ideas, and granting limited monopolies, which empower the patent holder to prevent a competitor from practicing an innovation for a limited period of time. With this in mind, and given the Supreme Court decisions on what is and is not patentable, there should be little controversy over extending patent protection to innovations in biotechnological arenas, as there has been in other areas.

But some have raised concerns about the ethical permissibility of the commodification of life, which biotechnology has been held to epitomize. In fact, we have commodified life for thousands of years. You cannot go into the grocery store and pick off the shelf whatever you want and walk out the door with it; you have to pay for it. Issues of pricing and ownership are with us and they are not unique to biotechnology. In objections raised to intellectual property protection for biotechnological innovations, particularly in the food arena, we often lose sight of the fact that in order to receive a patent certain criteria must be met. The innovation must be new, it must actually be innovative (that is, something that has not been done before), it must be useful, and it must be non-obvious. These criteria of novelty, utility, and non-obviousness are bedrock criteria for patentability that the Patent and Trademark Office enforces. Indeed, some patents have been wrongly issued and some of those that have been wrongly issued have been challenged on the basis of these criteria.

The challenge that the Patent Office faces in examining these patents has been exacerbated because of the influx of innovation. The tidal wave of innovation in biotechnology has been so great that it has created a conspicuous human resources challenge for the Patent Office. Almost as soon as an examiner becomes properly trained by the Patent Office, he or she is hired away by industry. But the Office is doing a better job than we have reason to expect given the number of patent applications it gets.

But that does not address the additional ethical issues that are raised about patenting and intellectual property for biotechnology innovations. Again, these issues of ethics and the ownership of biological materials are not issues that are unique to biotechnology. They are issues that we have been grappling with for hundreds, if not thousands, of years. They are issues on which society has made decisions long ago, although not all members of society agree with all the decisions that we

together have made. It is appropriate to raise them anew. But I think that much of the discussion generates more heat than light and is not likely to lead to new breakthroughs in understanding.

Sharing Technology with Developing Nations

Sharing technology with the developing world generally gets into some complicated areas, but in some ways things get much simpler, from the biotechnology industry's point of view. Agricultural biotechnology companies have a fiduciary responsibility to their shareholders to make money. That is what companies exist to do. Our member companies try to do this by providing new and innovative products that will improve the lives of people, not only in the United States, but around the world, primarily in the markets to which they sell. Most of the markets to which our companies sell are in the industrial world because that is where most of the money is.

Companies are not in the business of philanthropy, but we do work very closely with organizations that are in that business. Recently, Monsanto announced that they have completed a working draft of the sequence of the rice genome and they are putting that into the public domain, making the data available to researchers free of charge. They reserve only the right to a nonexclusive license should this research result in a product that could be patented and marketed. Even in areas where a great deal of proprietary work has been done and private funds have been invested to produce innovations, there are ripe opportunities for sharing. But, for obvious fiduciary reasons, there are limits to that.

Industry Funding of University Research

Some people have raised substantial concerns that the influx of private sector money into support for researchers and universities has disrupted traditional relationships between scientists and the journals in which they publish. It also affects the way in which scientists collaborate and exchange information with one another. Because of industry funding, there are constraints based on concerns for intellectual property protection and proprietary research information. These concerns have some legitimacy. The solution is not to decrease the collaboration between industry and academia, which is fruitful and beneficial to both parties and to society at large, but rather to ask why the financial rela-

tionship between private companies and academia is so much more prominent now than it was 20 years ago. We must keep in mind that this increase has brought both positive and negative consequences.

The reason for the increased participation by industry identifies a more fundamental problem that we should all work together to solve. By "all" I mean everyone, not just scientists, but also activists who are passionately opposed to biotechnology or who have various concerns about globalization. The reason for increased industry funding is the steady decline in the proportion of the public sector's research support dedicated to fundamental research in the life sciences, particularly agriculture.

If you look at the appropriations Congress has dedicated to research in the life sciences over the past generation, you will see steady declines in the areas related to basic agricultural research with the result that vast areas of vital importance have been neglected and underfunded for years. Key experts are getting old and whole disciplines are at risk of vanishing.

The solution is very simple. We should all be more eloquent in identifying the reasons that this research support is needed and beneficial to society and in articulating those arguments to our congressional representatives. We must reverse this funding decline and make good the shortfalls that we have been dealing with for at least two generations now.

Food Labels

Another important topic is the issue of labeling foods derived from crops developed through biotechnology. Critics have discussed this issue in a variety of ways. Industry has been characterized as being opposed to labeling. This is incorrect: Industry is strongly supportive of labeling. Companies have been implementing the 1992 policy published by the Food and Drug Administration (FDA). That policy requires that information mandated by the federal government must be accurate, informative, and not misleading. FDA requires that any time a material change is made to a food, particularly changes where health, safety, or nutrition are involved, that information must be indicated on the label. Industry is fully supportive of these provisions.

If, for example, a food were to be modified in such a way that an allergen were introduced, the food industry is required to put on that information on the label. (Both from my personal contacts with people who are developing crops improved through biotechnology and through consulting various databases I am unable to find any work that

involves transferring allergens from known allergenic sources into foods where they had not previously been. The only research I can find in this area is being done by the University of California system. This research is designed to use the tools of biotechnology to delete, for example, from peanuts the gene that encodes for the protein that causes the allergic response that threatens the lives of a number of people. Biotechnology is in fact, in this case and in many others, the solution or at least the partial solution to the problems that are so often laid at its feet.)

Conclusion

Children today have a very good chance of living to be 100 because of our increased understanding of nutrition and our increased understanding of genomes. The significance of the latter is almost impossible to over-estimate, both in terms of human medical implications and in the potential for improving crop plants and producing foods with increased nutritional value and health effects.

I believe that within probably 20 years my children and yours will be going into a doctor's office and routinely getting a drop of blood taken, which will be assayed on a DNA-associated microchip as they wait. Their proclivity for one hereditary disease or another will be identified, and they will get a prescription to eat certain foods or take certain medicines that will dramatically delay the onset of degenerative conditions that now plague humanity.

The potential from these sorts of advances and others is there for us to grab if we have the vision to do so. That is what we in the industry are working to bring to pass.