

## Understanding a Context for the Conflict: A Response to Roger McEowen

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I have given considerable thought to what I might use my limited time to accomplish. Professor McEowen has given us a very detailed look at some of the problems of genetically modified organisms (GMOs) with which our agricultural system is dealing. His presentation and outline are very thorough and, I think, will become a valuable resource to anyone who struggles with these kinds of problems. The difficult question is always where to begin, and that is what I would like to address.

It should be apparent from Professor McEowen's presentation that the matter of GMOs is one in which our system has been forced to invest a lot of energy. It should also be apparent that this is an area in which the legal issues are many and are very complex. There is yet much to be resolved. I choose as my role to provide a portion of the often-unrecognized context that helps us understand why things tend to configure the way they have. This will help us assign value to some of the strategies used by our system, as well as to help us navigate through the morass of different legal choices that are used.

One of the first things that we need to note is that the question of GMOs is but a small subset of a much larger concern relating to the application of emergent technology to the human life and environment. A Hungarian engineer coined the term "biotechnology" in 1919 to describe the use of living organisms or their products to modify the human environment.<sup>1</sup> In the years since its inception, the ideas associated with biotechnology have had a very broad application, from science to practical living. In many respects, the use of such ideas is so commonplace that it is often not considered problematic. On the other hand, recent developments in the nature of gene-splicing and recombinant DNA technologies have raised difficult legal and moral questions. Many of the questions are associated not only with the propriety of making such modifications but also regarding the long-term consequences of such changes. Thus, most of us take for granted the long-term development of better varieties of food plants and animal breeds but become skeptical about allowing for the "invention" of new organisms that may mix and match genetic material

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1. Linda R. Judge, *Biotechnology: Highlights of the Science and Law Shaping the Industry*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 79, 79 (2003).

of one species with that of another. Many of us are also skeptical about the “cloning” of replica editions of any species.

In this larger area of biotechnology, for a number of years, we have heard debated such questions as whether man can truly play God regarding his own species and whether it is ethical or safe to interfere with fundamental life processes. Of course, most of these debates are more philosophical than “legal.” As a result, there was little comfort taken in the announcement by the Patent Office several years ago that it would not accept applications for patents on new human life forms. Most disquieting, perhaps, was that there was no assertion that such applications would be contrary to law, only that, as a matter of policy, they would not be accepted. Obviously, such policies do not deny the possibility that technology can indeed create such new life forms, whether they are patented or not. Nor do these policies deny that our system, if it chooses, could give protection to such life forms. In a similar vein, few took comfort in an announcement of about the same vintage that the federal government would not fund research leading to such developments. Clearly, research is, and can be, conducted without public funding.

Also within this larger area, of course, is the matter of disease control. Here the concerns involve an extremely wide spectrum of topics, ranging from the artificial extension of life to man’s ability to control the quality of life. In between are such concerns as whether the public should bear any of the costs associated with the eradication of life-threatening diseases where the technology used is controlled by for-profit companies and whether the availability of substances that offer benefits to humankind should be restricted because of uncertainties regarding their side effects. All of this suggests that not only will the commitment of energy to problem-solving be substantial but also will likely expand significantly in the future. What is interesting about the debate that has been ongoing for the past decade is that it has not generated a national policy consensus regarding the propriety of biotech/GMO technology. Nor has anyone developed a comprehensive and coordinated framework for regulation of these new technologies. Undoubtedly, much of this springs from the difficult, contextual dilemmas that these matters raise.

With regard specifically to the question of GMOs upon which Professor McEowen has focused, a number of specific contextual matters need to be understood in order to appreciate the complexity of the problem and the difficulty of synthesizing a comprehensive policy to deal with it. Many of these contextual concerns lurk in the background and tend to shape our responses without being clearly articulated. First, there is the problem of whether the production of GMOs

should be allowed at all. This issue is driven largely by fear of the broad unknown. We wonder whether we are potentially unleashing monsters that we will not ultimately be able to control.

When I was a youth, I remember seeing a movie that we considered quite frightening. It was named *The Beginning of the End*, and the plot revolved around a mid-west research project that subjected tomatoes to radiation in order to increase their size and the overall productivity of the plant.<sup>2</sup> Unbeknownst to the scientists, a number of grasshoppers that were on the irradiated plants were also exposed to the radiation and grew to an enormous size. The grasshoppers then invaded Chicago and threatened to destroy the city. The discovery that saved the world was found by chance. Someone noted that the grasshoppers had an irresistible affinity for a particular sound. A speaker was rigged on a boat. The sound lured the grasshoppers to their destruction in Lake Michigan. The point here, of course, is not that there may be a serendipitous discovery that will avoid the dark side of technology. Indeed, what is feared is that there will not be and that the technology that is seen initially as harmless and lifesaving may in fact be the source of a new version of Frankenstein's monster. It is surprising, perhaps, just how extensively the "fear factor" underwrites our concerns about technology. We may irrationally blame it on the Frankenstein story or the rogue "Hal" in the movie *2001: A Space Odyssey* or any other movies seen as children or on any of a number of other possibilities. Nevertheless, fear of the unknown, when the subject matter is technology that is not within the ken of most, is a deep-seated and very real fear. This fear drives policy development and often colors legal decision making.

Closely related to the somewhat nebulous fear issue is the question of safety. The issue of safety in GMOs is generally more clearly articulated. Though largely understood, our views probably tend to polarize around the dilemma of whether it is better to starve or to eat something that might kill us. The use of GMO technology has not been thoroughly tested in all of its dimensions, especially regarding its impacts over time. In fact, present life-improving gains may be offset by later serious harm. I remember when a new artificial sweetener was a common sweetener in sodas. Someone calculated that when the

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2. Movies and stories of this type have been legion. Stories popularly begin with Mary Shelley's novel, *FRANKENSTEIN: THE MODERN PROMETHEUS* (1816). Perhaps lesser remembered movies include *THE ANDROMEDA STRAIN* (MCA/Universal Pictures 1971); *A CLOCKWORK ORANGE* (Stanley Kubrick Productions 1971); *THE INCREDIBLE SHRINKING MAN* (Universal Pictures 1957); *INVASION OF THE BODYSNATCHERS* (Allied Artists 1956); *THE LAST MAN ON EARTH* (American International Pictures 1964); *NO BLADE OF GRASS* (MGM 1970); *THE OMEGA MAN* (Warner Brothers 1971); *ON THE BEACH* (United Artists 1959); *THE QUARTERMASS EXPERIMENT* (United Artists 1955); *THE SEVEN FACES OF DR. LAO* (MGM 1963); *SOYLENT GREEN* (MGM 1973); *THE TERMINAL MAN* (Warner Brothers 1974); *THEM!* (Warner Brothers 1954); and *WESTWORLD* (MGM 1973).

life-prolonging impact of not consuming the high calories of sugar was offset against the life-shortening threat of cancer from the sweetener, a net life extension of a few days or weeks might be realized by the shift from sugar-flavored soda to that containing the artificial sweetener.

We do not always have a good response to these dilemmas of fear and safety. Is it better to take the risks associated with increased production capacity because that most likely holds world starvation at bay, or should the grim hoary head of hunger be countenanced simply because the food itself portends unknown future health risks? Is it better to make decisions based on anticipated short-term effects or forestall everything, pending an accurate assessment of future impacts?

Some of the underlying concerns are structural. With respect to the many agricultural marketing issues that Professor McEowen addresses, we need to note that agriculture as an industry chronically suffers from supply-demand curve inflexibility. That is, we can easily produce enough of what can be grown in this country to supply our food and fiber needs. This, of course, does not necessarily mean that our products will be cheaper for the consumer than products produced elsewhere. However, it has led some to suggest that the real marketplace here is limited by the effective size of the human stomach. It is simply not possible to produce more in order to make more money as a producer—unless a market is found for the additional production. This has led to the suggestion that the only real flexibility in the agricultural marketplace lies in the external, not domestic, markets. Thus, the issue of producing genetically modified plants and animals is keyed into their acceptability in the marketplace, particularly the international marketplace. How other countries have responded to the questions of GMOs is a large concern for us because many countries have been reluctant to allow the importation of such products. This impact has been felt in both the local market and the local production base. Indeed, it is largely this issue that has driven the labeling and contract problems that Professor McEowen addressed. It is interesting how far afield the impacts have ranged—from the need to interpret or modify Uniform Commercial Code provisions, to questions of liability in contract for the presence or absence of GMO products, to implied and express warranties regarding the goods themselves, to questions of trespass, nuisance, and negligence.

A second, related structural issue is the question of who should be given the responsibility of regulating research, marketing, and other activities associated with GMOs. Historically, there has not been a clear strategy. Unfortunately, no single government entity

possesses the requisite mandate to properly govern GMOs effectively. There have been temporizing efforts to manage matters that are the result of federally funded research or other specific concerns. Additionally, there has been some focus on the manner in which material is released into the environment and even some reliance upon our intellectual property regime to police these matters. Some matters are addressed by the United States Department of Agriculture (USDA), some by the Environmental Protection Agency (EPA), some by the National Institutes of Health, some by the National Science Foundation, some by what has come to be known as the “Coordinated Framework for the Regulation of Biotechnology,”<sup>3</sup> some by state agencies, and some most recently by the courts. As a result of this fractured governance, responses to problems that arise with respect to GMO matters tend to be very individualized and often spring from particular factual problems that require judicial resolution. The choices, as Professor McEowen suggests, tend to make for a rather ill-defined body of law to which one may look for guidance. Further, the vehicles for bringing these matters into the system widely range from interpersonal liability lawsuits to suits against manufacturing companies for product liability.

The USDA has created a new unit within its Animal and Plant Health Inspection Service Agency (APHIS) called Biotechnology Regulatory Service, which is designed to discharge the Department’s responsibility regarding biotechnology. Previously, this responsibility was divided between APHIS’ Plant Protection and Quarantine and Veterinary Services programs. In so doing, the USDA has announced its intention to update and strengthen its biotechnology regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. The process will begin with the preparation of a required environmental impact statement, followed by the development of a multi-tiered, risk-based permitting system, which would replace the current permit/notification system. As part of this reorganization of responsibility, the USDA established a Biotechnology Unit within APHIS, which will be involved in the analysis of environmental and ecological effects of field testing genetically engineered plants. The USDA also has announced the creation of a new Biological Compliance and Enforcement Unit within its Biotechnology Regulatory Services program.<sup>4</sup>

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3. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

4. For further discussion of the labeling requirements, see Gregory Conko, *Regulating Genetically Modified Foods: Is Mandatory Labeling the Right Answer?*, 10 RICH. J.L. & TECH. 13 (2004). See also Gregory A. Jaffe, *Plants as Factories for Pharmaceutical and Industrial Products*, SJ033 ALI-ABA 191 (Oct. 16-17, 2003).

Structural problems regarding marketing, regulation, and dispute resolution are such that it becomes virtually impossible to forecast where our system is headed. It is undoubtedly true that law always lags behind technology. This, of itself, suggests that much of the energy of the system, at least in the near future, will be directed to remediation rather than any sort of prophylaxis.

A final contextual concern raises the question of ownership. We tend to conceive of technology as a "thing," and in our system, "things" can be owned. This concept invokes the law of property, which addresses the basic question of ownership even though it does not directly address the question of propriety. However, ownership, in our system, tends to give varying degrees of monopolistic power over the exercise or enjoyment of things, an issue that tends to raise concerns. The conflict here is that, on the one hand, our system seeks to protect the value associated with property. Because of this, our system tends to treat decision making regarding property as something that ought to be as removed as possible from government oversight and restriction. On the other hand, because of our skepticism of monopolies, a counter-pressure is generated to either limit them or eradicate them.

Much of the subject matter of GMOs, as Professor McEowen has suggested, has been characterized not only as property but as intellectual property and hence makes our law of intellectual property the domain that addresses ownership issues. This means that many of the problems will be addressed as patent issues<sup>5</sup> or be given the copyright-like protection granted by the Plant Variety Protection Act of 1970.<sup>6</sup> This is the case despite the fact that the technology may be applied to living things.<sup>7</sup> Where formal protection of the system is not sought, the matter may be treated as a trade secret or covered by confidentiality agreements in contracts. In this area of the law, the value of the property is often seen as the incentive that stimulated its creation. Balanced against this notion is the system's strong commitment to free public access to innovation. What has emerged is a form of limited monopoly associated with property upon which is impressed a significant public interest. What is important from a policy point of view is that the system makes a judgment only as to the protectability of the technology, not the propriety of the same. As a result, this dimension of the system cannot easily be called upon to regulate the technology,

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5. Patent matters may be addressed as falling either under provisions of the law dealing with utility patents at 35 U.S.C. § 100 (2000) or as plant patents at 35 U.S.C. §§ 161-164 (2000). See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

6. 7 U.S.C. §§ 2321-2541 (2000).

7. Many systems of the world do not allow intellectual property protection for such matters. See generally *THE POLISH INDUSTRIAL PROPERTY LAW* (Tomasz Borkowski ed. 2002).

only the ramifications of ownership claims to it. Furthermore, the monopolies associated with intellectual property interests tend to be longer than the shelf life of the technology.

This structural disincentive makes public oversight even harder to invoke. Lurking in the background is the fundamental principle of property law that too much governmental regulation may constitute a “taking” in violation of the Constitution. Finally, positing the matter as a property question generates a number of assumptions regarding the extent to which these developments will, or should be, protected that may clash with our other underlying concerns. I understand Drew Kershen addresses this in more detail in his symposium article, so I will leave these matters to him.

Technology has been the historic means for pushing back the frontiers of human understanding. We are in the throes of a major technological revolution that affects nearly every aspect of human endeavor. Clearly, it is only one fractional part of that larger activity that concerns us here. We note in conclusion that technology is always a double-edged sword—capable at once of slashing both demons and allies. In this area, we are not yet sure which is friend or foe; we are not yet sure our gains are not, in the long term, losses. We are afraid that we do not know what to fear! Obviously, there is much to be sorted through here. As our system moves at its normal snail pace, going from one particularized dispute or problem to another, technology is racing onward. Whether a systematic framework is even possible has become a great concern. That the resolution of concerns must ultimately implicate others in the world makes the task daunting. All of this portends a great deal of excitement and development for our system.

