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Living Inventions: Biotechnology and the Public[4]

This presentation will provide an overview of the broad set of public concerns about animal biotechnology that have been expressed both in the U.S. and in the European Community (EC). I will also assess the meaning of biotechnology disputes for recent policy decisions concerning regulation.

The Bush Administration policy on regulating biotechnology defined and limited the scope of statutory authority of federal agencies. To facilitate federal approval of new products and, thereby, to enhance the competitiveness of the American biotechnology industry, the Council on Competitiveness in the Office of the Vice President limited regulatory authority to the issue of "reasonably foreseeable risk to health or the environment." The Council's policies for biotechnology for the 1990s would focus on encouraging economic competitiveness over other concerns.

Limiting regulation to narrow questions of risk was welcomed by some for its economic benefits, but it was promptly attacked by others for ignoring the troublesome implications of creating genetically engineered organisms. These implications have been the source of continuing disputes over issues extending far beyond the question of "reasonably foreseeable risk." The range of these issues suggests that the narrowly focused Bush administration policy and its arguments for the urgency of economic competitiveness are unlikely to ease the growing tensions over biotechnology developments and, indeed, may increase the "intuitive mistrust" that has long marked public attitudes towards genetic manipulation.

THE PUBLIC ANIMAL PATENTING DISPUTES

The patenting of living organisms has become an important focus of these tensions in both the U.S. and in Western Europe. A 1987 decision by the U.S. Patent and Trademark Office held that animals altered by genetic engineering were patentable. However, the European Patent Office decided, in 1989, that it could not grant patents on animals under the terms of the European *

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Patent Convention. Currently the issue is the focus of intense debate in several European countries. It is also the subject of debate in the European Parliament as it responds to a legal appeal against the patenting of a genetically engineered human hormone called Relaxid, and considers legislation on the legal protection of biotechnological inventions.

Normally business in a patent office is viewed as technical and hardly a subject for public debate, but the granting of patents to living inventions has spurred a storm of protest from a broad range of interests. The outraged response reveals the complex set of concerns that has more broadly marked public attitudes towards genetic engineering and raises questions about the viability of limiting the scope of regulation.

The debate over the patenting of genetically engineered animals offers a window on the range of concerns that have followed the diffusion of new biotechnology developments since the 1970s when recombinant DNA research evoked fears of the escape of lethal organisms into the environment. Subsequently, critics have mobilized to oppose the field testing of genetically engineered bacteria designed to inhibit frost damage, the creation of genetically altered fish, the development of disease-resistant crops, the use of bovine growth hormones and many other biotechnology applications. Such disputes are likely to amplify in response to advances in human genetics, especially as scientists seek to patent human genetic material.

To explore the nature and diversity of these concerns, I find it useful to present the views expressed by participants in a Congressional hearing and by the literature disseminated by several European Green groups. From there, I am able to provide suggestions regarding the kinds of strategies that may help to develop acceptable policies concerning a technology with significant economic and ethical implications.

Disputes over genetic manipulation of animals have been smoldering in both the U.S. and Western Europe since the 1980 Supreme Court ruling on patenting living organisms. Researchers in both academia and industry have maintained that patent protection of transgenic animals is essential for the development and diffusion of promising medical and agricultural benefits to society and, in its 1987 decision, the U.S. Patent and Trademark Office concurred. After this decision, applications flooded the Office, but so too did protests—from farmers, religious leaders, environmentalists and animal rights activists who were concerned about the consequences of this technology. Farmers believe that the high cost of raising, breeding and owning genetically altered livestock would cause small farm foreclosures. Others believe that patenting animals is immoral because it defines complex, living organisms as profit-making machines. Still others worry that the institutional collaborations between industry and universities involved in the development of biotechnology will compromise the quality and integrity of research.

These issues were played out in the U.S. at Congressional hearings and in Europe in appeals against the European Economic Community (EEC) directive on biological patents. These animal patent disputes aired a set of controversial questions: Would the effects of biotechnology on agricultural production destroy small farms unable to pay royalties? What does patenting imply for the integrity of species and the moral obligation to preserve nature? What would be the effect of patenting on scientific research? The decision to patent transgenic animals has generated economic speculations about the current pace of research in internationally competitive scientific fields and the impact of new technology on the traditional farm sector. Biotechnology and pharmaceutical firms regard patent protection as essential to fueling invention by the private sector, particularly because federal support for agricultural research has declined steadily since the second World War.

American corporate interests, for example, view patenting as necessary if the U.S. is to effectively compete worldwide for the products emerging from biotechnology research. In the Congressional hearings of 1988, Richard Godown, president of the Industrial Biotechnology Association (IBA) pointed out that: "A Japanese company has genetically engineered silkworms to produce a hepatitis vaccine" and "the United Kingdom and Ireland may be in the lead in animal biotechnology." Even China, he observed, is already test marketing low-fat pigs produced by growth hormone injection. Another scientist asked the Congress: "How are our farmers going to feel when that ham, which is 70 percent fat-free, comes here in cans and is sold in the United States?"

Farmers, however, are deeply divided on the issue. The American Farm Bureau Federation, representing 3.5 million member families, has long favored free market policies and innovation in farming technology, and emphasizes the potential benefits of genetic engineering. They anticipate that new biotechnologies will reduce farm costs and expand the utilization of farm products—transgenic livestock would grow faster and be brought to market sooner than conventional breeds; genetically lean and disease-resistant animals would provide healthier meat to consumers than the fatty livestock injected with antibiotics sold today. According to the Farm Bureau, patents and exclusive licensing to the private sector were the only ways to ensure the development of biotechnology discoveries and the commercialization of new agricultural products.

Other farmers' groups, however, oppose animal patents on the grounds that large corporations would usurp the ownership of livestock—a resource presently controlled by the farmers themselves. These farmers predict dire consequences for traditional breeding techniques and they worry about the continued demise of the small family farm. "Will animal patenting result in greater concentration in those who produce breeding stock as it has created in the seed industry in recent years? ...We are an industry that has seen our

numbers drop drastically in the past two years and there are not enough of us left to take chances on a major mistake," said the president of the National Farmers Union (NFU) in his testimony at the hearings. Representing about 300,000 farming families, this organization believes that "The small business structure of the family farm is the nation's bulwark against communism and fascism. It is essential to the democratic way of life." This has frequently translated into opposition to technological changes that would harm the small farmer.

The National Farmers Organization, the American Agriculture Movement, the Coalition to Save the Family and the League of Rural Voters joined the NFU in its concerns about the economic implications of genetic engineering. They played on the popular myth of the family farm as a foundation of American values and the fear that patents would force further corporate concentration of agriculture. European groups, for example, the UK's Compassion in World Farming, oppose patenting for similar reasons. "The losers would be the smaller plant and animal breeders who are not able to embark on research or pay the royalties....This makes the farmer more dependent on the chemical industry that currently controls biotechnology." It would further divide the farming community into winners (those who can afford to adopt these expensive technologies) and losers (those who cannot). In Europe, as in the U.S., opposition focused on issues of equity, drawing from the growing concern about monopolistic practices in the agribusiness, pharmaceutical and chemical sectors.

While farm interests have focused on the economic consequences of animal patenting, an unlikely coalition of religious, environmental and animal rights groups have raised a set of moral concerns. These groups attack the issue from different perspectives reflecting their own moral agendas, but they all reject the definition of animals as resources, or, in the language of patent law, "compositions of matter." Jeremy Rifkin, a persistent critic of biotechnology research, has accused the U.S. Patent and Trademark Office of reducing "the entire animal kingdom of this planet to the lowly status of a commercial commodity—a technological product indistinguishable from electric toasters, automobiles, tennis balls, or any other patented product." While most visible, Rifkin is not alone; indeed, his influence as a biotechnology "gadfly" reflects the wide appeal of his ideas. Representatives from an array of citizen's groups are questioning the moral authority of scientists to alter the state of nature.

Although humans have owned and used animals for millennia, the idea of patented ownership has invited renewed scrutiny of the human-animal relationship. Animal rights group in the U.S. and in Western Europe are enjoying extraordinary expansion and public visibility. They maintain that tinkering with an animal's genes violated "species integrity" and, in typical animal rights language, "the inherent sanctity of every unique being and the

recognition of the ecological and spiritual interconnectedness of life." Expressing these assumptions at the Congressional hearing, John Barnes, a veterinarian testifying for the Alliance for Animals, suggested that animal ownership has traditionally implied the responsibility of stewardship. This responsibility would be lost with corporate ownership.

Animal rightists usually see themselves in conflict with those who espouse a Judeo-Christian ethic supporting human domination over animals, but on this issue these groups concur. Reverend Wesley Granberg-Michaelson of the National Council of Churches said, "A real shift in how humanity relates to the natural environment is occurring when we face this issue." From his religious perspective: "The Judeo-Christian view says that the Creation is, in essence, held in trust...We have a responsibility to see that its integrity is preserved."

The notion of "species integrity" has raised the question of what is, or is not, natural. Genetic engineering, sanctioned by patents, seems to some a profoundly unnatural act. "We are engineering ourselves away from natural selection into a mechanical selection of traits," said Representative Charles Rose (D-NC), who had introduced legislation for a moratorium on animal patents. Granberg-Michaelson stated this idea in graphic terms: "Cows do not mate with fish. Humans do not mate with pigs. Fireflies do not mate with tobacco plants. These combinations are more than what can be called simply'natural occurrences.'" Similarly, European activists have objected to the view of "living factories rather than sentient beings." They reject the very principle of patenting of life as reflecting "a highly questionable relationship of Humanity to Nature." It would "undermine any last thread of respect for nature in our already artificialized world...forcing upon us a reductionist and materialistic concept of life." Thus, this dimension of the debate reflects fundamental philosophical differences concerning the essential nature of living beings.

Some concerns about biotechnology have focused more concretely on the effect of patenting on the research agenda and on the use of government supported science. Is it right that private biotechnology companies will profit by building on a base of publicly funded research? Will academic scientists, in dealing closely with industry, be appropriately accountable for their work?

In the U.S. Congressional hearings, the president of the Farmers' Milk Marketing Cooperative, addressed the issue of profit: "...if most of the research and development costs in the production of some super animal have been paid for from public coffers, is it proper to grant a monopoly market position for giant corporations for 17 years? Furthermore, is all of this necessary to promote alleged scientific progress?" In fact, current laws deliberately encourage private exploitation of publicly funded research as the most effective means of diffusion; but this policy continues to confront opposition

mainly from groups concerned about the general direction of technological change.

Many scientists favor the growing industry-university collaborations in commercially useful research. They minimize the risks of such ventures based on traditional assumptions about scientific neutrality and the ability of scientists to regulate themselves. They do not believe patenting would distort the research agenda of scientists which is shaped by intellectual interests and controlled through peer review and the values of their scientific disciplines. Others, however, suspect that the profit motive would, indeed, affect research. Jack Doyle of the Environmental Policy Institute, suggested at the hearings that industry-university collaboration in research and development "is worrisome because it blurs the roles of government as regulator and the university as society's natural arbiter and adviser." Such collaboration would disturb the traditional checks and balances on scientific knowledge and its application and shape the direction of future research. Critics doubt the ability of scientists to control the direction and use of their own research. "Allowing patent protection at this time will sever the contact between research and the public interest," said the Wisconsin Farm Unity Alliance. "It will mean that biotech corporations will be able to finance a much more accelerated level of research and development with little concern for the need to build public understanding and support and even less concern about meaningful regulation." This view was especially troubling in Europe where private industry funding of research in public institutions is a recent practice. Opponents fear the privatization of public research and suspect that patenting would lead to restricted information exchange among scientists and further limit public access to scientific information. They feel that only private industry would benefit.

ETHICAL, ECONOMIC AND POLITICAL CONCERNS

The patenting of animals has become a lightning rod for existing ethical, economic and political concerns in both the U.S. and Europe. It takes place when the plight of small farmers is a growing problem and technological changes in the farm community are a polarizing force. The issue has entered the public arena when animal rights groups are questioning the morality of vivisection and arguing against the instrumental values that allowed animals to be used as a resource. The decision also touches on controversial and widely publicized possibilities of commercializing human tissue for fetal research and human body parts for organ transplantation. It feeds existing worries about the effect of proliferating industry-university collaborations in biotechnology with their implications for the values of open scientific communication, professional responsibility and academic freedom.

The decision also resonates with the general uneasiness about genetic research which relates to vague, yet profound, fears of human genetic engineering. One should not underestimate the depth of public feelings about

tampering with genes. We have only to look at the long history of popular culture—films and science fiction—that play on the fear of radiation mutation and genetic manipulation to discover its archetypal roots. Recall, for example, the series of classic horror films in the 1950s (e.g., *The Fly, The Wasp)* and their images of mutant monsters resulting from radiation and tampering with genes: ants, wasps, spiders, scorpions mutated into the size of 747s. In Europe, the discourse on genetic engineering is colored by images of Nazi eugenics and human experimentation. These fears contribute to the opposition to genetic engineering and its popular image as technology out-of-control.

The biotechnology debate must be understood in the context of the many other policy controversies over science and technology, for example, over the practices of fetal research and animal experimentation, the teaching of evolution in the schools, the burial of nuclear wastes and the effects of technology on the environment. Such controversies reflect fundamental, and sometimes irreconcilable, values that are not easily resolved. In the case of animal patenting disputes, the small farmer, economically committed to the family farm and ideologically convinced that it is "essential to the democratic way of life," is not likely to be convinced that patenting is beneficial. Biotechnology is not the cause of the decline in family farming and a ban on animal patents would not reverse the trend. For some, this technology has come to symbolize the differential social and economic impacts of technological change. Similarly, arguments about the usefulness of transgenic animals for medicine and research are unlikely to stop the opposition of animal rights crusaders. Driven by anti-instrumental values and beliefs about the sanctity of nature, they are mobilized to oppose all use of animals as tools. They are particularly troubled by techniques of biotechnology that have blurred the boundaries between inert matter and living objects, techniques now recognized in law and reified by the decision to patent animals as living inventions.

Even the scientists who deny effects of commercialized research on the norms and practices of science base their position on fundamental beliefs about academic integrity. Convinced of the moral neutrality of science, they assert the ability of scientists to resist the lures of profit and to effectively regulate themselves. Though academic engagement in the development and diffusion of new technology surely weakens the credibility of the academy as an independent source of assessment, industry-university consortia in biotechnology have proliferated.

The controversy over biotechnology patents has developed out of a fundamental clash of moral values, conflicting visions of progress and competing world views. Based on beliefs about equality and justice and reflecting questions about the meaning of progress, such controversies cannot be resolved by simply assessing risk or claiming the necessity of greater competitiveness. Nor, in democratic societies, can they be simply dismissed, for

underlying protest is a troubling mistrust of the authorities responsible for technological development. A national survey conducted by the Office of Technology Assessment has indicated broad mistrust of the government's role in regulating biotechnology. In disputes involving statements concerning potential risks, Americans believe environmental groups over federal agencies by a margin of 63 percent to 26 percent. The picture is similar in Europe where opinion surveys carried out in the 12 member states of the EEC showed that 52 percent of the people trust environmental and consumer organizations "to tell the truth about biotechnology and genetic engineering." Only 20 percent chose public authorities and 6 percent chose industry as trustworthy guides.

The critical questions, then, have to do with authority. Who should be making decisions about a technology with such broad economic, moral and political consequences? How can we develop policies for technology assessment that would include broader concerns about new biotechnology products and processes? The critical challenge in both the U.S. and the EC is how to develop mechanisms for conflict resolution in the face of intuitive mistrust, competing economic visions and philosophical disagreement about the costs and benefits of new technologies and their differential effects.

Since the early 1970s, similar challenges have been expressed in disputes over other technologies that present potential risks to health, environment or social values. Opposition to nuclear power; protests against the siting of airports, toxic waste dumps, chemical plants and other noxious facilities; and fights over the rules and standards regulating pollution, began in the early 1970s—most have persisted for several decades. To resolve these disputes, public agencies in both the U.S. and Western Europe during the 1970s encouraged greater public involvement in technological decisions on the assumption that this would foster public acceptance of technology and enhance the legitimacy of decision-making institutions. There followed a variety of efforts to involve citizens more directly in creating and implementing policies for technological change.

These efforts ranged from broadly participative inquiries to environmental mediation. They included complaint and consultation systems, citizen advisory groups, representation of citizens in review boards and special issue referenda. Some were intended to develop consensus among conflicting scientific groups as a means to advise decision-makers (e.g., science courts); others to educate the public. The process created depended on how the problem of public acceptance was defined. Where lack of public confidence was thought to arise from technical uncertainties (for example, about risk), the goal was to develop a scientific consensus among dissenting groups in order to improve the advice available to decision-makers. Where problems of acceptance were attributed to lack of public understanding, the task became one of public education. Where controversy was defined in

terms of alienation and mistrust, more participatory and consultative systems evolved.

The 1970s experiments had mixed success, depending in part on how realistically they defined the source of public opposition to technology policies. However, they helped to avoid the polarization and mistrust that is so evident in biotechnology disputes today. This polarization reflects, in part, the insistent focus on economic competitiveness as the central value overshadowing all other concerns—a focus that necessarily defines public participation as an impediment to technological change. This attitude, however, has only served to exclude issues of public concern and increase public resentment. European groups, for example, feel that "the public is being kept out of the discussion, as if it were merely a technical matter. This must stop! The patenting of life is too important to leave up to a handful of experts and corporate lobbyists."

CONCLUSION

I conclude by extracting some principles from the 1970s struggles to establish effective negotiations for the resolution of technological disputes. We learned from these struggles that:

—Negotiations must deal directly with issues of public concern including questions of ethics and equity as well as economics and risk. Thus, controversial issues must be defined in terms of problems to be solved rather than solutions to be accepted. Proponents of a technology, determined to implement preconceived decisions, try to deal with protest by co-opting public support rather than by expanding choice. Leaving little room for compromise, these attitudes often resulted in the transfer of conflict from public hearings to the courts and sometimes to the streets.

—We learned that effective negotiation requires that participants have a sense of political efficacy and choice over the issues that most concern them. Establishing political efficacy rests on widely distributed knowledge and access to expertise. High quality educational materials should be designed, not to promote the technology, but to open frank discussion and understanding of both benefits and costs. Thus, efforts to enhance the competence (and to avoid manipulation) of journalists is essential, for the media play a significant role in informing the public.

—Finally, developing trust is a long-term process built on evidence of reliability and openness established over time. The emerging field of biotechnology offers opportunities for policy negotiation early in the development of the technology, before significant choices are made. These choices should not, at this early stage, be limited to narrow, short-term questions of risk. The dispute over animal patents suggests that evaluation of the products and processes emerging from biotechnology must be developed with an eye to their differential social and economic impacts. The institutional procedures

for assessing these impacts must also involve those who are affected and concerned. The history of participatory procedures suggests this may not produce consensus; when technologies embody highly controversial political and social values, consensus is not a feasible goal. By sorting out conflicting values, they may reduce public mistrust of administrative institutions and, in the long run, encourage the development of equitable decisions.