

# THE LAST WORD

## SOCIAL POLICY MATTERS

by Sheryl A. Blair and Andrew N. Rowan

In 1988 the United States Patent and Trademark Office (PTO) issued the first patent on a vertebrate animal—the “Harvard mouse.” The PTO decision aroused considerable public response and protest, both upon review of the application and after granting the actual patent. While the decision is landmark, it also is in step with a series of preceding cases that reflect legislative trends concerning the patenting of living organisms.

The 1930 Plant Protection Act—under which Congress extended patent protection to certain forms of plants (specifically those that propagate asexually)—acknowledged that not all plants are the products of nature and that it is possible to develop new varieties. In 1970, Congress passed the Plant Variety Protection Act (PVPA), granting patent-like protection for sexually reproduced plants. And ten years later, the Supreme Court ruled in a 5-4 decision that a microorganism created by human ingenuity could be patented. Prior to this ruling—the *Chakrabarty* decision—microorganisms were regarded as products of nature and thus were not patentable.

In 1987, following the precedent set by the Court's rulings in *Chakrabarty*, the PTO Board of Patent Appeals and Interferences ruled that a polyploid Pacific oyster was patentable. Although the Board rejected the patent application, holding that the oyster did not satisfy one of the criteria for patentability (nonobviousness), it announced that it would consider patent applications involving non-naturally occurring, nonhuman organisms. Critics of this decision have been plentiful, with their general concerns usually falling into four categories: sanctity of life issues; animal welfare; environmental concerns; and the possible adverse impact on the family farm.

Various religious denominations protesting against altering of animals by manipulating their genes seem to accept the idea of that God conceived immutable “kinds” of animals; some categorically oppose the rearrangement of genes for any purpose. Others argue that scientists violate the integrity of the species when genes are commingled—especially from widely different organisms. Species classification is a human construct, however, developed to help us better organize and understand our world: It is not divine decree.

Other groups fear that using genetic engineering techniques promotes a view of living organisms as little more than machines to be manipulated by human beings, with patenting perceived as reinforcing that position. While the legal issue is whether something is a product of nature versus a product of human ingenuity, the social issues and the impact of the new technology on our views of life cannot be swept under the carpet.

Consequences of genetic manipulation—short of the literal rearrangement of genes—have focused renewed public attention on animal welfare. The issue must be taken seriously in view of the fact that the animal protection movement has increased its membership at least five-fold in the last ten years. Yet these concerns are not necessarily new. Society has for some time accepted at least the same degree of threat to animal welfare as is

posed by today's applications of genetic engineering. Selective breeding has produced animals that suffer, and the human desire to raise these animals has persisted despite welfare aspects. Take, for example, short-nosed breeds of dogs that have respiratory problems or large headed breeds that have been born by Caesarian section because the birth canal is too narrow.

Another main concern over genetic engineering is the dilemma over the potential for accelerating genomic change and destroying the ecosystem's delicate balance. Via natural selection, the indigenous species have adapted to particular, subtle conditions, e.g. the salmon's broad diversity of genetic stock—each adapted to breeding in its own river or even its own stretch of the river. Pharmed salmon escaping into the indigenous population threaten such diversity, but adequate experimental controls—rather than an outright ban—can address these problems.

Just as the environmentalists value the pure qualities of the natural world, Americans value the traditional family farm and all that the image conjures up. There are those who worry that the emergence of genetic engineering and the other tools of biotechnology heralds the downfall of this idealized, romanticized American institution. These concerns are genuine yet, at the same time, the trend toward consolidation that has affected American farming patterns has emerged independent of biotechnology. Economies of scale demanding significant capital investment offer monetary advantages to the larger operations.

Some farmers also are wary of the impact of genetic engineering on breeding stock. They worry that if patents are granted for genetically engineered stock, they might have to pay royalty fees on their animals. Yet this is an issue of economics, not of the ethics of applying new technologies.

Many of the concerns surrounding biotechnology seem to have ended up in the PTO when, in fact, patenting has merely been the lightning rod for broader policy questions: The PTO has never presented itself as the place that should lead a profound debate on ethics and societal attitudes. The debate rightfully belongs in the proper regulatory or legislative arena where the variety of public voices and real concerns can be accorded the attention they deserve.

We need to pay more attention to social and political issues, and not be swept along by a tidal wave of enthusiasm of what is technologically feasible. The techniques permitting genetic manipulation are so overpowering that we are compelled to exercise great diligence while considering their many ecological, social, and ethical questions and implications. While we await their promised, but as-yet unrealized, benefits.

**Sheryl A. Blair and Andrew N. Rowan are affiliated with the Tufts Center for Animals and Public Policy, Tufts University School of Veterinary Medicine, 200 Westboro Rd., North Grafton, MA 01536. These opinions are the authors' own and do not necessarily reflect those of *Bio/Technology*.**