Chapter 7

Patenting of Animals—Economic Considerations

‘*Farmers, and agriculture in general, are the obvious losers in the patenting of animals. This massive transfer o! farmer decision making power regarding livestock, to a few large corporations, along with royalty payments to these patent holders, will further erode family farmers’ chances of survival. ”

John Kinsman
Wisconsin Family Farm Defense Fund

“Improved breeds that produce more milk with a lower cost of production, or that resist common diseases, will help the small farmer stay competitive by reducing farm costs and/or increasing the value of the commodity. ”

Richard Godown
Industrial Biotechnology Association

"At the moment, if our food survival was dependent on transgenics, we would be eating fish and mice. ”

Neal First
University of Wisconsin—Madison

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INTRODUCTION

Evaluation of the patent system is in one sense a cost-benefit analysis, weighing the benefits of patents against the cost of creating statutory monopolies. Patents may stimulate new research, hasten product development, and enlarge the pool of inventors in certain areas. However, patents may also raise barriers to market entry or impede the flow of information and mobility of production factors (4).

To begin to understand the economic implications of permitting or prohibiting the patenting of animals, it is necessary to consider the likely consequences of either policy for inventors, producers, and consumers of patented animals. Rescinding the present protection of transgenic animals as intellectual property would result in market forces acting in different ways than if animals continue to be patentable. An evaluation of the manner in which these market forces might react requires a review of the salient features of the major market sectors likely to be affected. The market for agricultural livestock is foremost among these, including the poultry, dairy, and red meat sectors. Because animals are used as models in the study of diseases and for product testing, the pharmaceutical and biomedical research communities also stand to be affected by animal patent decisions. And although progress in research on transgenic fish makes it possible that aquiculture markets might be affected relatively early, these markets are smaller in size. No examination of the likely impacts of patented animals in aquiculture markets is ventured in this chapter.

Building upon a brief review of these major market sectors, this chapter presents a preliminary survey of impacts that might be expected from animal patenting, as well as some expected difficulties in royalty collection posed by various market structures.

THE MAJOR LIVESTOCK MARKET SECTORS

Livestock, including poultry, is the largest component of the agriculture sector in the United States. In 1982 this large and widespread market produced 53 percent of the cash value of all farm sales and involved more than two-thirds of all farms, distributed throughout all 50 states (12). The major market sectors are poultry (including broilers and eggs), dairy, and red meats (including cattle, hogs, and sheep) (table 7-l).

The Poultry Sector

Broiler Chickens

Post World War II developments in management, marketing, and poultry breeding led to the emergence of a new agricultural product, the broiler chicken. If present trends continue, by the turn of the century per capita consumption of chicken may surpass that of beef. The broiler market has two major components: producers and integrators/processors.

The birds are typically owned by integrators, who contract first with producers to raise the birds (taking about 7 weeks), which they sell then to processors. Processors are usually owned by integrators, or contract exclusively with them. Most production is concentrated in the Southeast and South-Central States where feed is easily accessible and the climate generally congenial. Market concentration among integrators, although historically low, has increased in recent years. The largest four integrators are estimated to account for approximately 50 percent of U.S. broiler production (8). Market competition exists between large supermarket buyers. In 1982, 80 percent of broilers produced came from one-third of the nearly 53,000 farms involved (7).

Concentration is even higher among breeders who sell chicks to the integrators, who in turn supply contract producers. Three breeding firms control 90

Table 7-l--Commercial Slaughter, 1986

Chickens	5,437,024,000	(hatched)
	4,646,312,000	(raised)
Turkeys	225,380,000	(hatched)
	204,216,000	(raised)
Hogs	79,598,200	
Cattle	37,288,300	
Sheep & Lambs.	5,635,000	

SOURCE" U S Department of Agriculture, *Agricultural Statistics* 1987

Photo credit: U S Department of Agriculture

percent of the market in female birds, while the same proportion of male birds is controlled by four firms.

Eggs

In the past 25 years, annual per capita consumption of eggs has fallen from 320 to 250, illustrating that egg production is a declining enterprise. In 1982 there were fewer than 10,000 producers (less than 4 percent of the total) maintaining more than 500,000 laying hens. An estimated 37 percent of all eggs produced come from large producers, some having more than 5 million birds in production (6). Declining consumption and economies of scale are likely to lead to an increase in market concentration. Economic statistics demonstrate that *earnings* are depressed, however, suggesting that competition continues to shape the markets. Pricing is closely linked to market reports from the United States Department of Agriculture (USDA) or commercial sources.

The Dairy Sector

The dairy sector differs fundamentally from either poultry or red meats due in part to the major importance of the Federal milk marketing order system (2,11). Efficiency has doubled over the past 20 years with the number of cows required to produce a given volume of milk decreasing by half.

Production occurs in all States (in part due to Federal pricing systems). The leading producers (by volume) are Wisconsin, California, New York, and Minnesota. Most dairy farms are small family operations, carrying between 40 and 100 head. Such operations are typically found throughout the Midwest and Northeast, and they differ markedly in scale from the larger operations common in the West and Southwest. In California it is not uncommon for operations to milk 600-800 cows (3). Virtually all operations breed their own replacement stock, with one breed (Holstein-Friesian) accounting for 90 percent of dairy cattle.

Dairy cattle must produce calves annually to remain productive. This leads to one of the important secondary products of the dairy industry, bull calves for dairy beef veal. Bulls for natural breeding are purchased locally, but 60 to 65 percent of the milking cows are bred artificially and 25 percent of the breeding age heifers are bred artificially. Semen producers are dominated by four major companies, two of which are cooperatives. About 20 percent of the registered herd operations produce breeding bulls which generate substantial income, often 50 percent or more of the total (6).

Photo credit: Library of Congress

Line drawing, Queen World Beater, which was copyrighted in 1892.

The Red Meat Sectors

Beef

The beef cattle subsector is the largest component of the market for agricultural livestock and the most complex. In 1982 there were 34.2 million beef cattle distributed among 1 million farms. Most farms are small, numbering fewer than 20 head. On such farms, cattle raising is typically an enterprise supplementary to other farming activity.

The complexity of the beef subsector can be attributed to its division into two major components—calf production and cattle feeding. Calf production involves beef cattle through the first 6-18 months of life, raised principally in the Dakotas, Texas, Oklahoma, and the Southeast. Calves are sold to feedlot operations where they are grain fed and fattened for slaughter. Feedlot operations are concentrated in the grain rich areas of the western corn belt States, the Texas high plains, Arizona, and California. About 5 percent of the total number of feedlots provided slightly more than 60 percent of the cattle slaughtered in 1982.

Because of the large numbers of producers geographically separated from the major feedlots, most cattle pass through the hands of several brokers and are sold multiple times between birth and slaughter. This factor makes it more difficult to track and monitor beef cattle individually than to track any other major agricultural animal.

Pork

Pork production has been consolidated significant y over the past decade. Coordinated operations that carry individual hogs from birth to slaughter ("farrow-to-finish”) account for 75 percent of all production. In 1982, 315,000 farms were listed as producing hogs, with 50 percent of total production contributed by 10 percent of the farms. This means that smaller farms, comprising 90 percent of total farms, produced only half of total production. The USDA estimates a 1988 herd size of 53.8 million head.

Lamb

Sheep comprise a small and diminishing subsector of the U.S. livestock market. Total herd size declined from 50 to 10 million between 1945 and 1985. In 1982, 100,000 farms raised a total of 12.4 million sheep. Half of these farms carried fewer than 50 head. Nearly 85 percent are sold directly from producers to one of only 14 sheep packers in the country.

LIKELY ECONOMIC IMPACTS

It is difficult to predict the manifold consequences of any particular approach to protecting intellectual property, especially across so wide a range of economic activity as that spanned by patentable animals. This range embraces diverse sectors of the agricultural livestock markets, pharmaceutical or other chemical production, and academic research or industrial testing. This section briefly examines likely impacts of patenting animals upon inventors, users or producers, and consumers.

The patent system was devised as a means to allow inventors and innovators a method of recoup-

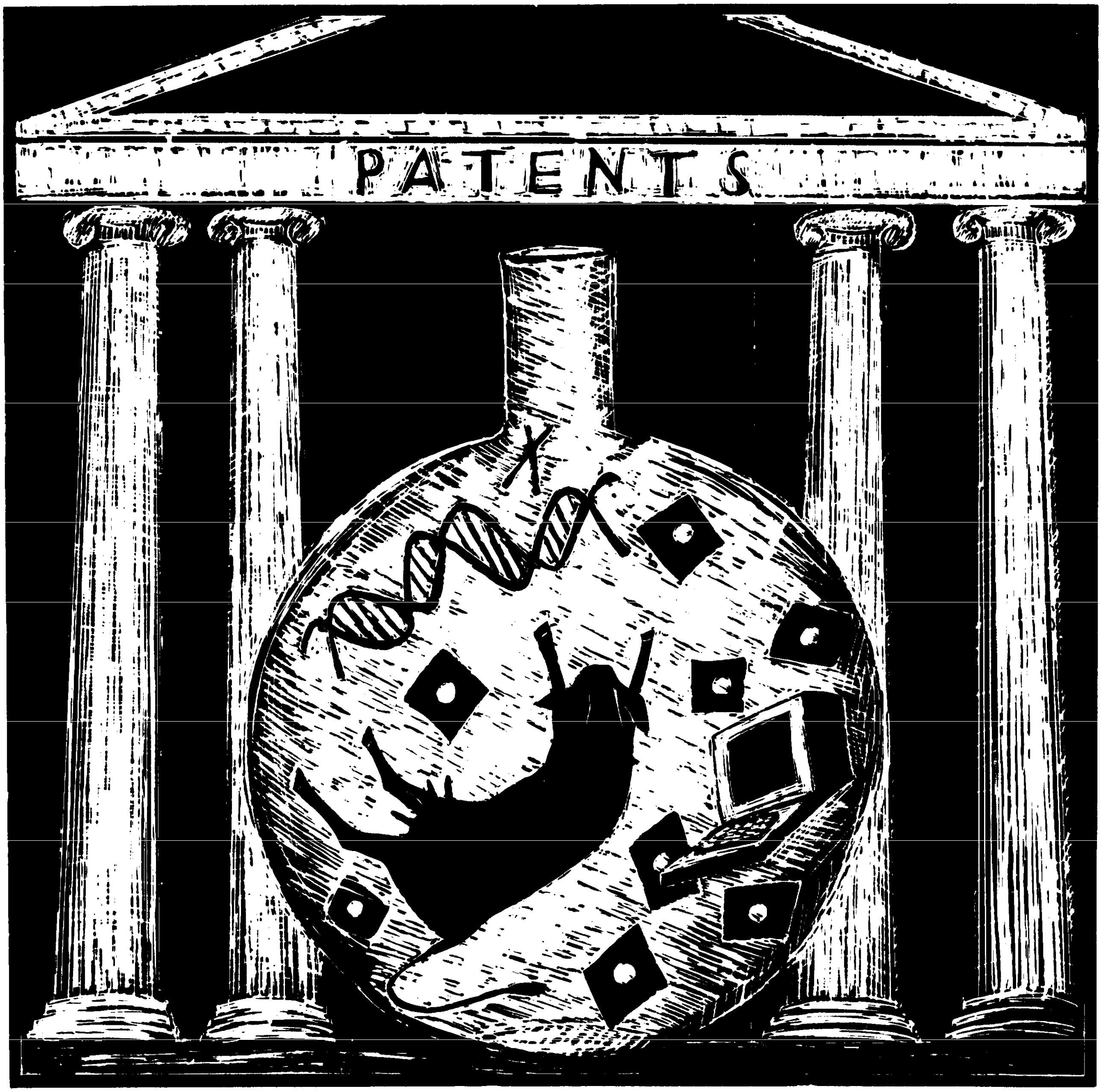


Photo credit: Claudia Tantillo

ing their investments in intellectual property, while, at the same time, stimulating the development of additional innovations and inventions. Although patenting seems the most direct and least cumbersome method of satisfying both objectives simultaneously, there are other means that have sometimes been employed or preferred. Chief among these have been secrecy and contractual arrangements.

Companies opting for secrecy rely on trade secrets and seek to conceal crucial details or key processes from competitors. This enables a recovery of investments in intellectual property; however, further innovation by other inventors is in the form of imitation (which does not compensate the inventor), as opposed to patent enablement (which does).

Companies relying on **contractual arrangements can** negotiate agreements with users of their products or processes in such ways that will permit recovery of investments. Negotiations carry substantial risks of disclosure, however, that could threaten the recovery of such investments. Furthermore, because users may intentionally or negligently breach a confidential agreement, inventors may be reluctant to contract with parties who do not have "deep pockets." The likely consequences of the use of patenting v. trade secrets or contractual arrangements are considered below.

Four distinct animal classes that might be affected by one or another method of intellectual property protection are 1) disease models, 2) production of pharmaceuticals, 3) poultry, and 4) livestock (figure 7-l).

Impacts on Inventors

Class 1—High-value disease **model** animals present a situation in which secrecy does not seem a useful approach. The precise genetic changes incorporated into the transgenic animal, as well as the method of inducing the changes and other relevant biological data, are all likely to be crucial to those who wish to devise studies or tests using the animals. Such information is also important to the interpretation and understanding of test results. Secrecy also stands contrary to historical traditions of openness and free exchange in academic research.

Contractual arrangements may offer an alternative to patenting. The number of major research institutions or corporations likely to use such animals is limited and the likely users can be identified. Violations of either contractual agreements or patent law are likely to be detected since the public confidence essential to acceptance of test results or data would entail disclosure of essential details about the animals used. However, a system relying on individual contractual arrangements between inventors/innovators and users would likely be more complex and variable than that entailed by existing patent law, though it could bring the advantage of flexibility.

Class 2—High-value animals, such as those used in pharmaceutical production, could be protected by a system of trade secrets. Relatively small herds of transgenic animals (e.g., 100 head of dairy cattle) could be used to produce significant supplies of human pharmaceuticals, such as tPA or other compounds for treating heart attack victims or blood clotting factor VIII for treating some forms of hemophilia. Existing arrangements between companies and the U.S. Food and Drug Administration might suffice for ensuring product safety while guarding against the disclosure of confidential business information. Contracts might also be adaptable to such arrangements. Patenting and licensing

Figure 7-l-Four Classes of Animals Potentially Affected by Intellectual Property

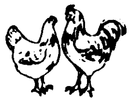
Class 1 – Disease Models

Animals used in biomedical research, such as the so-called "Harvard Mouse," U.S. patent 4,736,866.

Class 2- Production of Pharmaceuticals

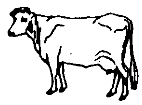
In the **early stages of** research, small animals (e.g. mice) are the subjects of Ihis type of research. If successful, this research will later be conducted on larger, milk-producing animals (e.g. cattle) for the production of pharmaceuticals used by humans.

Class 3- Low Value, Rapidly Reproducing



Poultry is an example of this class.

Class 4- Low Value, Slowly Reproducing



Cattle and other red meat **animals are examples of** this class.

SOURCE: Office of Technology Assessment, 19S9.

arrangements could serve the same ends, however, without diverting valuable resources from production efforts to trade secret protection or contract enforcement. It seems likely that neither trade secrets nor contracts would be as effective in stimulating innovation as the disclosure required for patents.

High-value animals used as breeding stock could probably be protected effectively either by patents or by today's practice of close monitoring and control under a system of contracts or trade secrets.

Class 3—Low-value, high reproductive rate animals, such as poultry, probably cannot be protected effectively by a system of trade secrets, The large number of different contract farms and turnover among personnel involved would make enforcement of secrecy a huge task. The relatively smaller numbers of integrators and processors might make contractual arrangements practical and there are precedents. However, it seems that a smoothly functioning patent system would serve equally well, obviating many of the problems that might follow from high turnover rates of valuable personnel in competitive market sectors.

Class 4—Low-value, low-reproductive rate animals like cattle or other red meat animals constitute the most complicated case. Low reproductive rates mean technological innovations to the animals themselves (as opposed to processes for raising or processing) will be relatively slow to disseminate (although embryo transfer technologies may speed the process). These market subsectors typically operate with low net margins, meaning changes that might substantially increase production costs will not be adopted quickly unless they bring a commensurate increase in returns. The large numbers of individuals involved, in terms of farms, shippers, and processors, as well as animals, are additional complicating factors. Secrecy does not seem feasible because of cost and logistics, and contracts seem only slightly more practical. The large numbers of individual animals and the extended and complex paths they follow to market mean significant difficulties would be associated with any effort to recoup patent royalties linked to individual animals.

One economic analysis (6) suggests that "everything else held constant, small firms benefit more from patents than large ones due to the penchant of small firms to license technology and the impediment such firms face when attempting to enter production with limited capital and managerial reserves. " Others point out that larger firms patent more often and further note that licenses could be granted from trade secrets as well as patents. In either case, it is possible that much of the relevant activity could be covered by negotiation of a relatively small number of contracts (5).

Impacts on Users/Producers (Licensees)

The likely impacts of animal patents on different users or producers will vary with the type of transgenic animal involved and the structure of the market sectors associated with them. The discussion in this section follows the same breakdown of transgenic animals into separate classes as presented above.

Class 1— Disease models serve a specialized function in the esoteric realm of biomedical research. Such research now uses many different animal disease models. The availability of patenting for transgenic animals may lead to more of these models relying on transgenic animals in the future. Patenting may result in researchers paying higher prices for such animals or finding their reproduction rights limited or restricted. In many cases, however, the existence of new, patented animals may cut the time needed for studies to generate data of statistical significance. It has been estimated that the first animal patented, the so called "Harvard Mouse," may lead to some tests for chemical carcinogenicity being compressed from 3 years to 3 months in duration (9) (box 7-A). If this is realistic, net costs for experimental animals as well as the total number of animals used in such studies could drop dramatically in spite of substantial increases in the cost of individual animals used.

It should also be noted that precedent exists for patent holders to make such animals available to researchers free or at minimal cost, sometimes for costs of shipping and handling alone, or otherwise on a not-for-profit basis. There is, however, no compelling reason that such arrangements should either be universal or necessarily continue where they now exist.

Box 7-A—The Marketing of Oncomouse

U.S. patent 4,736,866 for transgenic nonhuman mammals was issued by PTO on April 12, 1988. Seven months later, on November 15, the E.I. DuPont de Nemours & Co. of Wilmington, DE announced that it would commence sale of "Oncomouse" in early *1989.*

Oncomouse (so named because it carries activated human cancer genes) was developed at Harvard University. DuPont was a major sponsor of the research and owns exclusive rights to the patent. The first oncomice will sell for $50-$100, five to ten times the price of an ordinary laboratory mouse. It is unknown how large the initial market for the mice will be. DuPont will handle the orders for the mice, which will be bred by Charles River Biotechnical Services (a Bausch and Lomb Company) in Massachusetts.

SOURCE: Office of Technology Assessment, 1989.

Class 2—Animals producing pharmaceutical products, in contrast to the other three classes of animals discussed here, in many respects constitute a new industry. It stands to displace only a portion of its primary competitor, microbial fermentation. Because of the strong possibility of protection via means other than patents (e.g., trade secrets or contractual arrangements) it is by no means clear that patents on the animals will always be sought even where possible. Therefore. it seems likely that the availability or unavailability of such patents need not have any major disrupting impact on users, as the markets will develop in accord with whichever practice obtains.

Classes 3 and 4—If (poultry and livestock) are patented, it seems that patent holders might attempt to collect royalties from users. Collection could be a complex process; it is not clear whether developers would seek to recoup the entire cost of development from initial sales. Yet, because of the self-replicating abilities of animals, once sold the invention will effectively enter into common public use whether or not royalties or registration fees are paid. One difficulty is monitoring a patented animal. If the royalty on such an animal is high, it creates an incentive to divert animals, semen, and eggs by those possessing the animal. For example, fruit trees have long been patented, but royalties collected for superior varieties have remained modest (10).

With broilers there are relatively few integrators who hold title to the birds. Genetically engineered chickens could be sold to the integrator's hatchery supply operations. Monitoring these few, large, easily identifiable operations would be fairly straightforward. Egg producing operations are more involved due to the larger number of primary customers. The relatively small number of hatcheries through which the industry operates, however, makes it seem likely that royalty collection arrangements could remain tractable. Existing breeders are likely to become involved with any patented poultry, if not as owners of the patents, then as incorporators of the licensed traits into production birds and distribution of stock to hatcheries.

The pork subsector also seems to be relatively open to adopting royalty collection measures. Large farrow-to-finish operations are essentially self-contained. Through either contract production or other contractual arrangements it may be feasible to collect royalties, for example, on all hogs shipped to packers. Additional stipulations might restrict sales to packers only, thereby reducing the probability of improper diversions. Large existing breeders would likely become involved in the commercialization, multiplication, and distribution of patented pigs. It is not clear that patenting would bring any major reorganizations in this subsector.

Smaller operations, however. might well be affected. The numerous farms specializing in feeder pig production or finishing would be more difficult for a patent holder to monitor. With increasing production by very large operations, a tendency may emerge to provide patented animals preferentially to the larger operations. The existence of animal patents might, then, increase some of the existing pressures toward concentration in pork production.

Incorporating royalty collection into the beef and dairy cattle subsectors would be far more complicated. Calving throughout the year on the numerous farms involved would make royalty collection a difficult and expensive process as applied to dairy cattle. Incorporating royalty collection into the beef sector would be even more involved. The geographical separation of calf production and cattle feeding, the numerous producers, and the variety of breeds involved would all combine to make monitoring a monumental problem. For these reasons, contracts calling for one-time payment of royalties or registration fees could make logistical sense, providing the patented animal made economic sense in these typically low-margin operations.

At this early stage it seems that royalty collection on patented cattle would be forbiddingly difficult and complex without fundamental change in the structure and organization of the beef and dairy subsectors. It is not clear how this might be accomplished, and the size and structure of the markets make this seem most unlikely (box 7-B). Sheep present similar problems, except that as a much smaller subsector it would theoretically be more easy to adapt. Whatever the eventual arrangement, royalties on dairy or beef cattle would appear to be far less easily collected than with either poultry or hogs. Because of this, an economically viable development in cattle will probably require a much higher-improvement in production efficiency, than that needed in either poultry or hogs, if royalty collection is the only means to recoup the cost to developers of innovations. Such dramatic increases in production efficiency are likely to be difficult to accomplish since cattle are biologically the least efficient converters of feed grain to meat.

Incorporating patented animals into existing production methods will be driven by economics. If a patented animal is engineered to carry a new trait, and if the trait reduces costs by 10 cents per pound, then the farmer could perhaps pay as much as (but never more than) the equivalent of 10 cents per pound more for the patented animal. At prices above that threshold it would be more economical to continue using the nonpatented animal. Thus, as long as traditional breeds remain available they will provide caps on how much can be charged for patented alternatives. The continued existence of traditional breeds does not seem threatened except possibly with poultry, where pure stocks are closely held by a few firms (1).

Box 7-B—Royalty Collection

Once a patent is granted, the patent holder has the right to keep others from making, using, or selling the invention during the 17-year patent term. It is common practice for a patent holder to permit others to use art invention upon payment of a royalty or licensing fee. In the absence of an agreement with a patent holder, a person who makes, uses, or sells the invention is liable to the patent holder for infringement.

Royalty collection is one element of the debate on the patenting of animals that has engendered public debate and legislation. Some argue that the ability of a patent holder to collect royalties on an invention is a basic right under the U.S. patent system. Others argue that the collection of royalties for various classes of patented animals will be burdensome if not impossible. During the 100th Congress, the House of Representatives passed H.R. 4970, the Transgenic Animal Patent Reform Act, which said, in part:

> It **shall not be an act of infringement for** a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.

However, the bill held that it would be an act of infringement:

> **for a person to sell the germ cells, semen, or embryos of a patented transgenic farm** animal.

Several opinions and proposals have been advocated during congressional consideration of the royalty issue. These include:

- the creation of broad-based exemptions for **various users (e.g.. farmers);**
- the creation of limited exemptions if certain conditions are met (e.g., farms operating as single family enterprises, limited gross receipts, total acreage, number of animals);
- limiting royalty collection to a specified number of generations of a patented animal;
- the creation of a tribunal, based on the Copyright Royalty Tribunal, to set rates and distribute funds for certain classes of patented animals;
- a prohibition on animal patents, which would remove any royalty issue from the patenting context; and
- no action by the Congress, thereby relying on existing patent infringement provisions for patented animals.

SOURCE: Office of Technology Assessment, 1989.

Impacts on Consumers

Class 1—Disease model laboratory animals will be distributed to a limited number of consumers, i.e., researchers. Even if patented animals are not distributed freely in this sector, the cost impact of patented animals is likely to be a small part of the total cost of health care. As research leads to products that approach commercialization, increased activity by private firms might be anticipated. In terms of final costs, as noted above, if new models developed are less costly or more efficient than existing models or lead to more effective treatment and prevention methods the net effect could be lower costs for individuals.

Class 2—Pharmaceutical production work in this area is primarily directed towards finding more economical or effective methods of producing currently available products. This effort should result in a decline in costs to consumers. There is no reason to expect that the existence of such products will increase concentration in the pharmaceutical sector. Indeed, the entry of new firms may well take place as is suggested by the experience with biotechnology companies and pharmaceutical firms to date.

Classes 3 ***and 4—The*** poultry and livestock sectors operate now as competitive industries, which suggests that the benefits of cost-reducing technological developments could, in the long term. be passed on to consumers. However, if royalties equal the cost saving associated with the new genes, then the farmer's cost of production is the same as before and the consumer gets none of the cost savings of the new technology. The consumer arguably does not care whether the price they pay is for royalties or the old inputs (10). Benefits to producers are most likely to accrue to successful early adopters of innovations. What is not clear is how patented animals might contribute to anticompetitive pressures. If they cause anticompetitive market pressures to increase, other avenues are available for redress (e.g., antitrust or antimerger law).

SUMMARY

The largest economic sectors likely to be influenced by an increase in animal patents are the different markets for agricultural livestock and possibly some sectors of the pharmaceutical industry. The principal agricultural markets involve poultry, dairy, and red meat. These markets are organized quite differently and are subject to different degrees of economic concentration. Poultry is most concentrated (though still diffuse by other industry standards, e.g., automobiles) with the dairy and red meat sectors being much more diffuse. Different economic forces are important in the several markets as well. Federal price supports are of major importance in the dairy market, while the market for poultry is more open and competitive.

The existence of animal patents and the degree they are employed in the different markets may introduce some new economic relationships. It is not now clear that these are likely to have any substantially adverse effects on the major markets or existing market forces. The same types of pressures that have driven economic choices in the past are likely to continue to dictate them in the future—if an innovation increases costs (e.g., if a patented animal costs more than the unpatented alternative), it is unlikely to be adopted unless it increases outputs or product values commensurately. It therefore seems that although cost savings can be anticipated to follow from animal patenting in some areas (e.g., pharmaceutical production or drug testing) innovations due to patented animals are likely to advance more slowly in low margin operations such as the raising of beef cattle.

In some cases, efficient alternatives to protection of intellectual property protection via patents are feasible. Trade secrets or contractual arrangements might serve well where the animals involved have a high intrinsic value and are limited in number, e.g., animals used for pharmaceutical production or for breeding stock. When faced with the complexity of the markets for pork or beef production, however, such alternatives are clearly less practical, although the same complexity complicates any scheme for enforcement or royalty collection associated with patenting.

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