
Regulation and Economic Concerns for Canada's Biotechnology Industry

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INTRODUCTION

Biotechnology is a growing and important industry in most developed countries. The possibilities for commercial gain from biotechnology are thought to be enormous. Post modern economies are based on new ideas rather than natural resources such as, land, labor, capital, or strategic location (for example, the old silk trail). New ideas require investment to develop of new products and processes, that will create wealth of nations in the twenty-first century.

To create this wealth, institutional arrangements that lower the cost of investing in biotechnology research and development will be needed. For example, firms want to be certain their inventions will be protected from predators at a low cost. Without such protection, investors may move their investments elsewhere. Another important cost is related to the licensing of new products. In the business of new ideas, time is important because competitors will be close behind. Thus firms want a regulatory process that is quick and careful. Finally, access to world markets is important because no domestic market is large enough to absorb the cost of developing these new products. Therefore, access to foreign markets is an important issue in determining where firms will invest their money.

This new investment opportunity is largely contained in the private sector. Governments are supplying only regulations, along with some training and basic research, while the private sector supplies the capital and management. While this division of responsibility concerns some, the future biotechnology industry will be driven by private capital attempting to earn a return for private investors.

This paper will address the two issues of regulation and economics. First, the impact of regulations of biotechnology from a domestic and trade perspective will be examined. Second, the domestic market conditions for new products will be looked at, followed by discussion of some of the potentials and impacts these new products will have on Canadian agriculture. Obviously, the surface can only be scratched because these are complex issues.

THEORETICAL ISSUES

The economics of regulation is a well-developed field of study. The early work in this field was done by George Stigler, who linked the economic performance of an economy to the existing regulatory environment. In this paper, a short description of a model of regulation is provided by Ulrich, Furtan, and Schmitz (1987).

If agricultural products are created through the use of two technologies (with or without biotechnology), it can be assumed that the consumer will view them as two different products. The production possibilities curve (Figure 1) depicts the trade-off that occurs in the level of production of the two different products. If the regulations block the amount of biotechnology the economy produces and the relative prices for the two products is R_0 , the production of only one product occurs at X_1 . If the regulators allow both products to be sold, then production occurs at Z_1 along R_1 . Clearly, the level of welfare in the economy has gone up because consumers can now purchase the type of product they prefer.

Over time, technology change will shift the frontier from X_1Y_1 to X_1Y_2 and the optimal production point will move from Z_1 to Z_2 , holding the relative prices constant. By blocking the introduction of biotechnology products, the agricultural sector loses more over time. If the relative prices change from R_2 to R_3 , then the production of biotechnology products drops but the sector is still better off at point X_1 .

REGULATION IN THE BIOTECHNOLOGY INDUSTRY

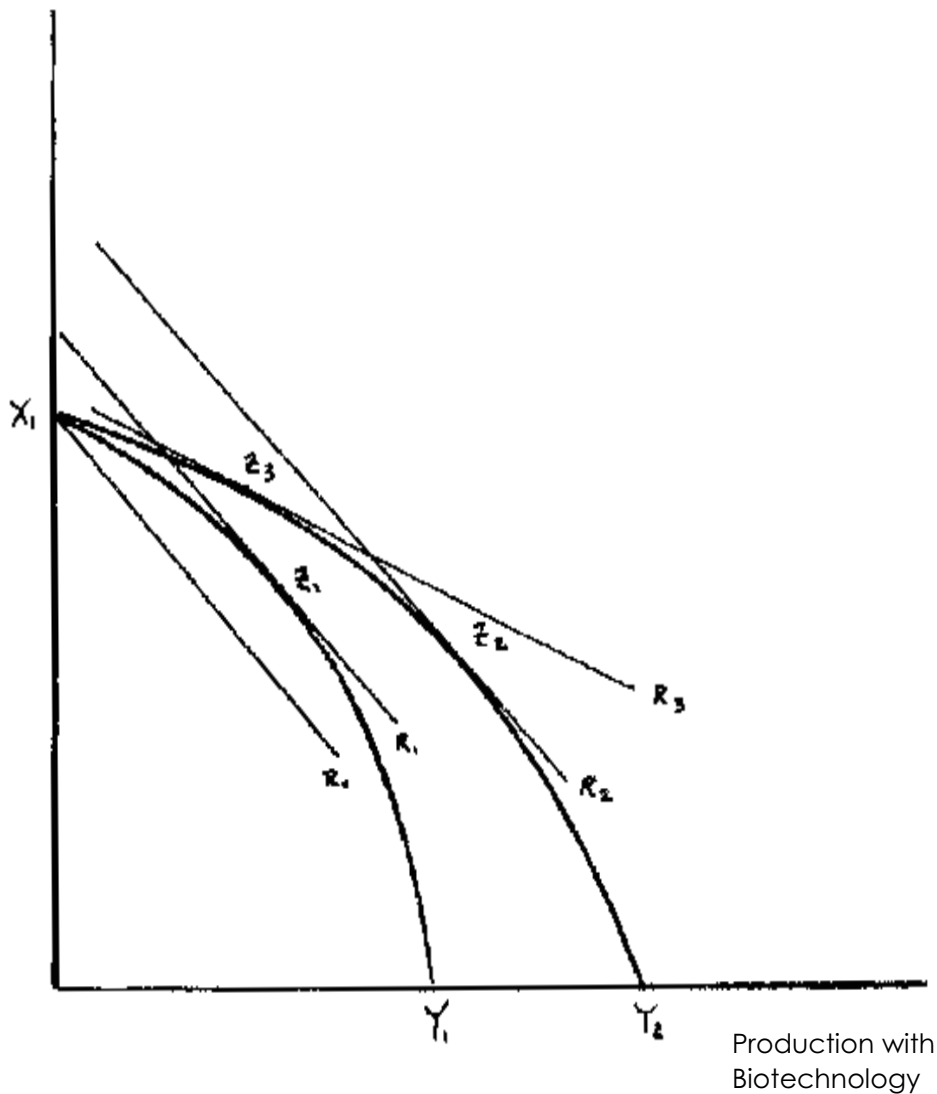
Regulation of agricultural biotechnology and related products is under the review of the federal government.¹ At least three departments are involved: Agriculture and Agri-Food Canada, Health Canada, and Environment Canada.

¹Source: Ulrich, A., W.H. Furtan, A. Schmitz, 1987. The cost of a licencing system regulation: an example from Canadian prairie agriculture. *Journal of Political Economy* 95

Figure 1

Economic Impacts of Blocking Biotechnology in Agricultural Production (Ulrich, et al., 1987)

Production
with no
Biotechnology



The principal department in charge of agricultural biotechnology is Agriculture and Agri-Food Canada, which regulates issues such as transgenic plants under the Seeds Act, microbial products such as animal feeds under the Feeds Act, microbial growth supplements under the Fertilizers Act, microbial pest control products under the Pest Controls Product Act, and veterinary vaccines and biologics under the Health of Animals Act. The Biotechnology Strategies and Coordination Office is under the direction of Agriculture and Agri-Food Canada and is responsible for importation and phytosanitary measures under the Plant Protection Act and the Health of Animals Act. It is also responsible for food safety and standards and prevention of fraud under the Canadian Agricultural Products Act. While this system is similar to that in the United States, and is consistent with the European Economic Community's premarket clearance, it still leaves the Canadian industry with a fragmented system.

Environment Canada is involved, as well, in the regulatory process. It is the responsibility of this department to set environmental assessment standards for food products. This is done in consultation with Agriculture and Agri-Food Canada but Environment Canada is responsible under the Canadian Environmental Protection Act for making certain that new food products resulting from biotechnology are safe.

Health Canada is concerned with food safety issues and particularly new food products using biotechnology. The formal regulatory process administered by Health Canada comes under the Food and Drug Act, but the policy that is in place has not yet been approved by the government of Canada. Anyone wishing to introduce a novel food must notify the Health Department 90 days in advance of marketing the product. The department is then given 98 days to request more information.

The Novel Food Regulations are clearly aimed at addressing consumer's concerns over food safety. They specify that before a novel food can be marketed in Canada the firm must notify Health Canada of the intention to do so 90 days in advance. A novel food is defined as

- a substance that has previously not been used in Canada or will result from a process that has not previously been used for food in Canada;
- an existing food that has been modified by genetic manipulation and exhibits one or more characteristics that were previously not identified in that food or food that results from production by genetically manipulated organisms exhibiting such new characteristics;
- food containing microorganisms that have previously not been used as food or to process food; and
- food that is substantially modified from the traditional product or is manufactured by a process that has been substantially modified from the traditional process.

An example is bovine somatotropin (BST), which is given to dairy cattle. Under this regulation, BST is a novel food and must therefore be examined by both Agriculture and Agri-Food Canada and Health Canada. Clearly, there is an overlap of jurisdiction, as well as a difference of opinion as to what is acceptable and safe.

From an economic perspective, this regulation is expensive for firms that introduce new products. Using an economic framework, this slowdown of technology and the extra cost make investment in Canada more expensive and more risky.

INTELLECTUAL PROPERTY RIGHTS

The area of intellectual property rights has grown in importance as countries recognize that the postmodern economy is built on ideas rather than on resources or population. For companies to invest and create wealth, they must be able to capture some of the wealth. If they are not able to capture wealth, they will have no incentive to invest. There are many reasons why companies may not be able to capture wealth, such as the nature of the good produced (public vs. private), market and institutional failures, and information problems. Institutional problems, such as having others steal your invention, can be corrected through legislative changes that provide affordable protection for innovators. This is why the issue of property rights is an important legislative concern and is a form of market failure. Countries disagree on how best to handle this issue. Some feel that by protecting innovations, rich countries will be able to advance their economies while poor countries will not be able to afford the investments. These people call for larger public investments in agricultural research. Others argue that private research is the most efficient way to allocate resources to much of the agriculture sector and this can be achieved only by protecting property rights, including intellectual property. Given the reduction in government budgets and the shrinking political power of agriculture, the latter group is the most likely to win the day for now.

In the case of agricultural biotechnology, there are two ways that new material can be protected and private investment facilitated: through patents and plant breeders' rights. Canadian law treats these two issues differently and, in the case of patents, differently than the United States.

To get an invention patented in Canada, four criteria must be met. The first is to demonstrate that the invention is new and has not been done before. Second, the invention must be proven to have some commercial value and not be trivial. Third, the invention must fall or fit into a predetermined category. Finally, it must demonstrate some progress or advancement. Once these criteria are met, an application can be made under the Patent Act to the commissioner of patents for Canada.

In a recent paper Churchill (1996), pointed out that Canada has not fully come to grips with its policy on the patenting of living material. Currently, this is an important difference between Canada and the United States, and it will be seen as a cost to investors in Canada when compared to the United States. This represents a large transaction cost in Canada and will lower the level of investment made in Canada in the area of agriculture biotechnology.

A second method to protect some biotechnology products and processes is the Plant Breeder's Rights Act. This act protects plants through the process of granting breeder's rights to certain varieties by restricting others from using the varieties without the payment of royalties. The term *plant variety* is defined to mean "any cultivar, breeding line, or hybrid of a prescribed category of plant that can be cultivated" (Churchill). The new variety must be stable, distinguishable from other varieties, and homogenous. While useful, this act provides only limited protection to intellectual property.

The final point that needs to be made is that there is a gradual consolidation of regulation on intellectual property protection in developed countries. Clearly, firms will go where they have the greatest chance of profit, and if a country taxes firms by failing to protect investments, they will move to more acceptable climes. This problem is forcing some countries such as Canada (that wish to attract this type of investment) to align their regulatory systems with those of the United States and the European Community. Canadian farmers also stand to lose competitiveness if new technology is not made available to them at the same time it is made available to their competitors.

INTERNATIONAL TRADE AND MARKET ACCESS

There are two issues of concern around market access and international trade. The first is consumer acceptance. There is no incentive to produce a product that consumers will not buy because of perceived (or other) concerns over safety. Second, there are rules that affect the trade of agricultural biotechnology products. Both of these concerns must be dealt with by firms that plan to introduce new products into the marketplace.

If farmers produce a product that some consumers will not purchase, it must be segregated from other similar products. The case in point is transgenic canola, which is acceptable in the Canadian, American, and Japanese markets but not the European market. This segregation must be done in such a way as to meet the standards of the market; that is, consumers want to be certain of the origin of the products they are consuming. Segregation of products is expensive, and its cost may block the introduction of new food products. Mayer (1996) examined this question and showed that the cost advantages of transgenic canola are such that farmers will grow the new varieties even with the cost of segregation. She estimated that Canadian prairie farmers would benefit in the order of \$441 million annually if transgenic canola is accepted in all markets and \$215 million annually if only Japan blocked the new product.

She also showed that the lack of market access can completely block the introduction of transgenic canola.

Since producers are growing transgenic canola, they must assume that consumers will purchase the product once it is on the shelf. A recent survey of consumers in the United States and Europe reported that 73 percent of those in America would purchase food derived from transgenic crops while only 15 percent in Europe would do so, if they had the choice (Wadman, 1996). This suggests that agricultural biotechnology is going to have a more difficult time gaining market access in Europe than in America. The situation in the Canadian market is not altogether clear; we have accepted transgenic canola but not BST.

The rules for trade in agricultural biotechnology products are set by the World Trade Organization (WTO). There is a recognition internationally that technology is outpacing the existing legal regimes in most countries. Also, most agree that investment dollars will flow to those countries that provide protection for intellectual property. Given these concerns, the WTO has set minimum standards for the protection of agricultural biotechnology products and trade in such products.

The WTO rules include: (1) love thy neighbors equally and not less than thyself, that is, rules for domestic firms must also be made available to others; (2) patent rules must be transparent, that is, individual firms must be able to find out exactly what the rules are and how they are applied; (3) the patent rules must be enforced by the home country; (4) any product or process is patentable for 20 years from time of filing; (5) there must be compulsory licensing of patents so that technology is available to other firms; and (6) the patenting of life forms is excluded.

The WTO has also set rules regarding trade in genetically altered feeds and foods. The sanitary and phytosanitary standards require that the importation of new foods be based on the following four criteria: scientific basis, risk assessment, acceptable risk, and national treatment. While these rules sound good, there still is no agreement on how they will be applied. For example, whose scientific evidence or opinion will be accepted, and what is acceptable risk? The debate over the safety of certain growth hormones in cattle feed is an issue that some say is real and others say is just a poorly disguised trade barrier. This still leaves market access very much open to question.

CONCLUSIONS

Agricultural biotechnology holds many promises for the future as a major investment opportunity. For Canada to compete with other major players, the costs of doing business in Canada in terms of regulation must be lowered and the appropriate institutional arrangements in place to protect intellectual property must be put in place. Market access remains a concern, but it can best be tackled through education and work with other trading nations through the WTO.

Canadian farmers need to be concerned with developments in the field of biotechnology. As they will be using and producing the products, their economic livelihood depends on the orderly regulation of this sector. To be certain this occurs, they are going to have to be actively involved in the process.

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