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Protecting Inventors' Intellectual Property Rights in Biotechnology

Terence J. Centner and Fred C. White

Institutional devices encouraging biotechnological innovation may not be providing adequate returns or protection for inventors. This article identifies an optimal degree of patent protection and employs sensitivity analysis to link demand and supply characteristics and investment productivity. Four contemporary policy issues are identified to provide a foundation for future research.

Key words: biotechnology, invention, patents, plant variety protection.

To encourage innovation, governments of most developed countries have adopted a patent system that rewards inventors through the establishment and protection of intellectual property rights in new inventions. United States federal legislation governing inventors' property rights contains special provisions for plant inventions. The limited protection available under some of the legislation raises the question whether U.S. law provides adequate encouragement for biotechnological discoveries of living organisms.¹ More specifically, are existing infringement provisions sufficient to protect asexual and sexual plant discoveries, is additional protection needed for asexual plant parts, would it be advantageous to relax the requirements of the general patent law for living matter, or could additional legislation for multicellular animal inventions foster greater innovation?

Several authors have recently investigated issues concerning the nature and function of invention incentives and the use of patents in protecting property rights. Wright summarizes

the extensive literature on the economics of patents and discusses some shortcomings concerning specific institutional devices. DeBrock addresses the issue of an optimal patent life incorporating the problem of rivalry whereby there are duplicative costs in the form of expenditures by persons who are unsuccessful in being the first to obtain patent protection. Earlier research by Kamien and Schwartz; Scherer; and Kitch also contributes to an understanding of invention incentives.

A good descriptive analysis of institutional devices available to protect property rights relating to biotechnological discoveries in living organisms has been provided by Cooper; Bagwill; Plant; Schlosser; and Williams. This literature provides keen insights into research incentives, although recent judicial decisions modify some of the assessments. However, the literature confers little consideration of alternative types and degrees of property rights protection or the adequacy of protection afforded by existing legislation.

The objective of this article is to examine the adequacy of the United States' intellectual property legislation for encouraging innovation in living subject matter, with an emphasis on products of biotechnology as applied to commercial agriculture. The analysis commences with the identification of the institutional devices for protecting intellectual property interests. A model is developed and sensitivity analysis is used to prescribe the socially optimal level of patent protection. The analysis leads to the conclusion that the cur-

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¹ New living organisms may arise from biotechnological inventions involving changes in cell or protoplast structure, plant regeneration, somatic hybridization, hybridoma production, recombinant DNA, embryo transfers and rescues, gene insertion, and growth regulators and hormones. Although in its broadest sense biotechnology refers to the use of living organisms in industrial or technical processes and products, the definition employed in this article is more narrow and refers to the above-referenced new techniques.

rent allowable property rights coverage is inadequate. In response to this analysis, information from the model and distinctions in the various institutional devices are examined through a discussion of four policy issues: (a) protection against infringement, (b) description and enablement requirements, (c) non-obviousness requirement, and (d) developing an animal patent statute. Enhanced infringement protection, relaxed description and enablement requirements, a moderated interpretation of obviousness, and a new animal patent statute are suggested as options for encouraging invention. These issues also constitute topics that various firms and interest groups may place on future legislative agendas in an attempt to garner increased property rights protection.

Institutional Framework

The United States' institutional framework to encourage beneficial biotechnological discoveries is grounded upon a constitutional provision granting Congress the power to enact legislation to "promote the Progress of Science and the useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries" (U.S. Constitution). Both state and federal governments have enacted laws that operate to encourage scientific discovery and new ideas through the establishment of intellectual property rights. The promotion and protection of intellectual property rights embodied in these devices is believed to be an important factor in scientific achievements.

Patents and certificates of plant variety protection offer the most viable institutional devices for protecting intellectual property interests and compensating inventors of biotechnological discoveries. A patent establishes proprietary rights by providing for the exclusive control over making, using, and selling the subject material for a period of 17 years. Congress has enacted the Patent Act (PA) for patenting novel, useful, and nonobvious qualifying subject matter and the Plant Patent Act (PPA) for patenting asexually reproduced plants (U.S. Code, tit. 35). In addition, the Plant Variety Protection Act (PVPA) enables inventors of self-pollinating plants to apply for certificates of plant variety protection that pro-

vide patent-like protection for 18 years (U.S. Code, tit. 7).²

Choice of Protection

In some cases, inventors have some flexibility to choose from among the statutes for protection of a new invention. A recent Patent and Trademark Office administrative decision, *Ex parte Hibberd*, allows inventors a choice of selecting between two statutes, the PA and the PPA or the PA and the PVPA, for protecting their discoveries. Thus, the *Hibberd* decision opened the doors in the U.S. for patenting seed-propagated plants under the PA.

The superior property rights protection of the PA as opposed to the PVPA is expected to lead private industry to patent new plant varieties rather than file for certificates of plant variety protection. However, many discoveries, especially products of "traditional" plant breeding, will not qualify under the PA and thus are likely to be protected under the PVPA (Diepenbrock; Elliott). This development tends to disrupt the international plant variety protection system established under the Union for the Protection of New Varieties of Plants (UPOV).³ The superior property rights available under the PA interfere with the free marketing of varieties developed from protected varieties and weaken the application of UPOV.⁴ *Hibberd's* acknowledgement that an inventor may have a choice of selecting a statute for the protection of property rights in man-made living organisms means that inventors will want to weigh the positive and negative features of the statutes before selecting the protection most amenable to their invention.

Distinguishing Provisions

Distinct statutory provisions and doctrines embodied in the PA, the PPA, and the PVPA

² For a discussion of these acts, see Cooper.

³ This international system is adhered to by Belgium, Denmark, France, Germany-Federal Republic, Hungary, Ireland, Israel, Italy, Japan, the Netherlands, New Zealand, South Africa, Spain, Sweden, Switzerland, the United Kingdom, and the United States as of July 1, 1983 (UPOV Publication). Conflicts between UPOV's plant variety protection and patent protection have crystallized into a controversial problem (Straus). The UPOV Convention is disrupted by the fact that a majority of nations do not adhere to its provisions.

⁴ Recognition that patent law offers greater property rights protection has weakened UPOV by the fact that nonsignatories are declining to initial the Convention (Straus).

disclose important differences in qualifications for protection and the scope of protection of inventors' property rights. These include description and enablement requirements, the nonobviousness requirement, and the equivalency doctrine.

The description requirement of the PA mandates a description that adequately describes the invention so that others may recognize the subject matter. This may be too exacting for biotechnological inventions of living organisms. The PPA relaxes the description requirement. The PVPA as a registration statute does not involve major problems with a description requirement. The enablement provision of the PA requires the patent application to present sufficient information to enable a person of ordinary skill in the pertinent art to make and use the invention. Unduly extensive experimentation to practice the invention means that the patent disclosure is not enabling, which thereby precludes the issuance of letters patent.⁵ The enablement requirement of the PA may be overly demanding for living organisms.

The nonobviousness requirement of the PA precludes the issuance of letters patent for any invention that is found to be obvious. In the recent case of *Ex parte Allen*, the patent examiner and the administrative tribunal found the creation of polyploidy in Pacific *Crassostrea gigas* oysters involving the use of hydrostatic pressure was obvious from published research on polyploidy of a different species of oyster using chemical treatment and thus precluded a patent. The examiner reached this decision even though the published procedure involved a different process and failed to produce polyploidy on the Pacific *C. gigas* oyster. Neither the PPA nor the PVPA embody this requirement.

Another doctrine, the equivalency doctrine, is embedded in the PA but not the PPA or the PVPA. This doctrine involves the scope of "claiming." If an unauthorized composition of matter is substantially similar to an existing patent, the patent holder has a "claim" and may maintain an infringement action. The

equivalency doctrine thereby operates to preclude others from using minor or inconsequential alterations to patented products as a basis for claiming a new product.

Such distinctions among the statutory provisions raise policy issues concerning enhanced property rights protection, which are discussed after the development of a model and sensitivity analysis.

Property Rights

Through patents, the government grants exclusive control of the rights to make, use, and sell products resulting from scientific discoveries as a means of encouraging scientific discoveries, as well as making the information open to public inspection. Patent laws are premised upon the theory that society benefits from the prompt disclosure of inventions, since others can then proceed to refine the discovery or use it for further innovations. In order to compensate scientific inventors for the disclosure of their invention, patent law grants inventors a negative right to exclude others from making, using, or selling the claimed invention for a specified period of time. A negative property right in patent law provides a framework for financial remuneration in the case of infringement. An additional feature of the patent system is that any invention drawing upon patented inventions will require permission of the patent owners before the invention can be marketed without fear of an infringement action.

Numerous examples can be cited of how failure to protect the property rights associated with a discovery has adversely affected the release and, hence, adoption of important discoveries. Burge alleges that the absence of patent protection precluded manufacturers from commercializing Sir Alexander Fleming's invention of penicillin for several years. The proposed manufacturer of a malaria vaccine was unwilling to manufacture the vaccine without establishing property rights (Plant).

An innovating firm may not capture the maximum potential benefits from innovation for a number of reasons. First, the government may not grant exclusive control to the firm. For example, an exception allows patented materials to be used for experimental use. In addition, exclusive control is not possible for those biotechnology discoveries which cannot meet the requirements for patenting under cur-

⁵ In *Ex parte Forman*, the judicial tribunal declined to find a living vaccine to be enabling in the absence of direct control over the various mating and transconjugation procedures set forth in the specification and the absence of a deposit. Other inventors have had to appeal the findings of patent examiners in order to surmount the "undue experimentation" hurdle. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*

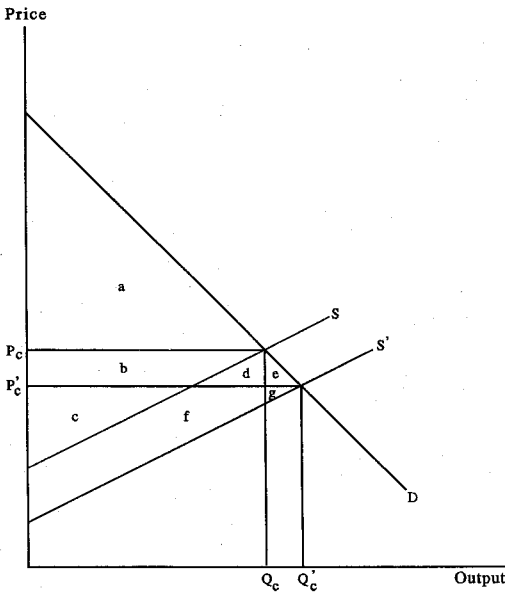


Figure 1. Economic rents associated with innovation and exclusive control

rent law. Second, the innovating firm's expenses of securing a patent or of ensuring the enforcement of property rights under a patent may outweigh the benefits. In such cases, an innovative firm may not acquire a patent and/or may not ensure the enforcement of an existing patent. Finally, other firms may legally and/or illegally infringe on the rights of a firm that has a patent, which reduces the benefits from the patent. Under the PVPA, a crop exception for farmers reduces the benefits to owners of certificates of plant variety protection.

Conceptual Framework

The economic impact of useful discoveries in biotechnology can be measured by (a) changes in consumer surplus, (b) changes in economic rents to producers, (c) changes in economic rents to input suppliers and/or market intermediaries, and (d) the social cost of displaced labor, if applicable. Some of these components may be positive, while others may be negative. From a public perspective, the greater the expected net benefits, the more desirable the investment in research, *ceteris paribus*. From the perspective of a private entrepreneur, those benefits that can be internalized, accruing to the inventor, are most important. The mag-

nitude of the benefits that accrue to the inventor is directly related to the inventor's control of making, using, and selling the discovery. A grant of exclusive rights to an inventor maximizes the inventor's benefits for given levels of exclusivity and enforceability.

Economic returns to investment in innovation can be described under certainty using the industry supply and demand curves depicted in figure 1. Assuming static analysis and a fixed demand for a given product (e.g., corn), the demand curve is D , and the initial supply curve is S . Under competitive equilibrium, the price initially would be P_c . Consumer surplus is area a and producer surplus is area $b + c$. Assume that innovation has improved the quality of one of the inputs used in the production process, such as an improved variety of seed being used in crop production. As a result of the innovation, the supply curve shifts to S' , resulting in a new lower price of P'_c and a larger output of Q'_c . Consumer surplus would increase by the area $b + d + e$, which is obviously a positive change for consumers. Changes in producer surplus would be area $f + g$ minus area b , which could be positive, zero, or negative depending upon the elasticity of demand, the elasticity of supply, and the nature of the shift in the supply curve.

In a perfectly competitive environment, the innovating supply firm would not be able to capture the increased economic surplus resulting from the innovation (assuming the absence of trade secrets). If competing input suppliers could also supply the same improved input without incurring investment in innovation, the innovating firm would not have an incentive to innovate. In order to compensate firms for investing in innovation, the government offers patent protection for qualified innovations.

It is assumed that patent protection would allow the innovating input supplier to charge a higher price in order to receive a royalty on its run-of-the-mill or ordinary innovation. The run-of-the-mill or ordinary innovation is described as one for which the final equilibrium is assumed to be back at the preinvention equilibrium price, P_c , and the preinvention equilibrium quantity, Q_c . (Arrow; Nordhaus).⁶ The innovating input supplier is assumed to cap-

⁶ For unique innovations, the quantity could be restricted to a lower level than the preinvention equilibrium. Although the possibility of unique innovations are recognized, no further analysis of this type of innovation is undertaken in this study.

ture the net addition to producer surplus represented by area $d + f$. In this situation, there is a deadweight loss of area $e + g$. With patent protection, the level of economic surplus that accrues to consumers and producers after innovation is the same as before. The additional economic surplus generated from the innovation accrues to the innovating firm.

Failure to qualify for a patent or infringement from competitors would reduce private returns to innovation. Some of the returns from innovation not captured by the innovator would accrue to consumers and some to competitors. The proportion of the benefits accruing to competitors would depend on their market power.

The actual degree of patent protection for any particular innovation may vary depending upon whether the innovation qualifies for protection and upon the level of protection provided for by the patent law. Referring to figure 1, the final equilibrium may be somewhere between the two extremes of preinvention and postinvention equilibriums depending upon the degree of patent protection provided for the innovation. As the price approaches the preinvention equilibrium, P_0 , more of the benefits would accrue to the innovating firm, but the deadweight loss would increase. Conversely, as the price approaches the postinvention equilibrium, P_1 , less of the benefits would accrue to the innovating firm, and society would experience a smaller deadweight loss. However, without patent protection there would be inadequate incentives to innovate.

Optimal Patent Protection

Current legislation includes three patent laws with each having approximately the same length of patent life. However, the level of patent protection varies considerably among these laws. This section describes a model of the optimal degree of patent protection rather than optimal patent life as a basis to understand differences in patent laws.

An increase in the degree of patent protection tends to increase the profits of an individual inventor. However, accompanying deadweight loss may result in a reduction of aggregate social welfare. This trade-off between inventor profits and economic surplus indicates that society's optimal level of patent protection could be identified given relevant

criteria (Nordhaus; Scherer; DeBrock). The solution to the problem would be a Nash equilibrium that reflects maximum economic surplus attainable for society given profit-maximizing actions of inventors.

The Model

Consider a situation in which initial industry supply and demand curves are given:

$$\begin{aligned} (1a) \quad & P = D(Q); \\ (1b) \quad & P = S(Q, I); \end{aligned}$$

where P is price, Q is quantity, and I is investment in research and development (R & D). The supply curve can be shifted down and outward by investment in R & D which reduces marginal costs. With complete patent protection, it is assumed that the inventor could extract the additional producer surplus resulting from innovation. Following Nordhaus, it is assumed that a run-of-the-mill innovation and complete patent protection would result in the same price and quantity as under the competitive equilibrium.

However, it may be economically efficient from society's viewpoint to grant only partial protection, i.e., to allow firms to recoup only a portion of the maximum potential royalties resulting from patenting. For this purpose, a patent protection parameter, λ , is defined as the proportion of maximum potential royalties that accrue to the innovating firm. Values for λ are determined by the government and can range from zero for no royalties to one for maximum potential royalties. For any level of patent protection, revenue (R) is assumed to be an increasing concave function of investment (I), inferring $R_I > 0$ and $R_{II} < 0$. The cost of production (C) is assumed to be related to investment as $C_I > 0$ and $C_{II} \geq 0$. The firm will maximize profits from investment in R & D as follows:

$$(2a) \quad \pi = R(I, \lambda) - C(I) - I,$$

where π is profit; R is revenue; I is investment in R & D; λ is the patent protection parameter, $0 \leq \lambda \leq 1$; and C is cost of production. Computing the total differential of the profit function with respect to changes in I and λ and setting $d\pi = 0$ defines the slope of an isoprofit curve as follows:

$$(2b) \quad \frac{dI}{d\lambda} = \frac{-R_\lambda}{R_I - (C_I + 1)}.$$

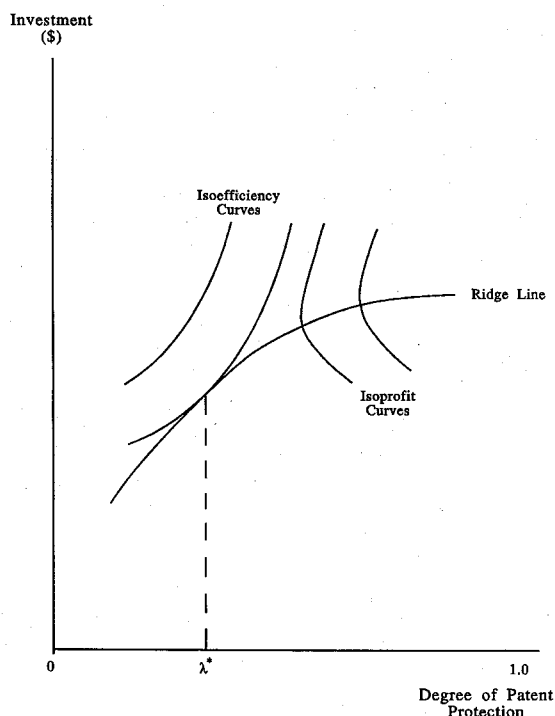


Figure 2. Optimal patent protection derived from isoprofit and isoefficiency curves

The denominator of this expression is zero at maximum profit conditions ($MR = MC$), so the isoprofit curve is vertically sloped when profit is maximized. Connecting optimal investment levels for various levels of patent protection yields a ridge line or private reaction function as shown in figure 2.

Net economic surplus is assumed to be measured by:

$$(3) \quad W = S_c(I, \lambda) + S_p(I, \lambda) - I,$$

where W is net economic surplus, S_c is consumer surplus, and S_p is producer surplus. Computing the total differential of the net economic surplus function with respect to changes in I and λ and setting $dW = 0$ defines the slope of an isoefficiency curve. The highest level of surplus attainable is defined by the tangency between the ridge line of the inventor and the isoefficiency curve for society (see fig. 2). This tangency identifies the optimal degree of patent protection.

Sensitivity Analysis

In this section an operational model involving a hypothetical innovating supplier is devel-

oped and analyzed to measure the influence of supply and demand characteristics on optimal patent protection. The stochastic nature of the research output effect is recognized but considered explicitly only through a sensitivity analysis using alternative effects. Linear industry supply and demand curves are assumed with investment entering the model as follows:

$$(1a') \quad \text{Demand: } P = a + bQ.$$

$$(1b') \quad \text{Supply: } P = c + dQ + gI^{1/2}.$$

Alternative values for the coefficients a , b , c , d , and g will be considered. The quantity traded, Q_λ , is assumed to be established within the range of the preinvention equilibrium quantity (Q_c) and the postinvention equilibrium quantity (Q_c').

$$(4) \quad Q_\lambda = \lambda Q_c + (1 - \lambda)Q_c',$$

where λ is the patent protection parameter determining the degree of patent protection. The market price, P_λ , is determined from the quantity traded, Q_λ . Equations (1a') and (1b') can be used to determine Q_c when I is zero and Q_c' when I is nonzero. Using this approach, the quantity traded is:

$$(4') \quad Q_\lambda = \frac{c - a + (1 - \lambda)gI^{1/2}}{b - d}.$$

The innovative supply firm's revenue is assumed to be only a fraction of the additional producer surplus, depending upon the patent protection parameter, λ . The cost of the innovative firm is assumed to be given by investment in R & D. Hence, the profit for the innovating supply firm is given by:

$$(2') \quad \pi = \lambda \Delta S_p(I, \lambda) - I,$$

where $\Delta S_p(I, \lambda)$ is change in producer surplus.

In determining maximum profit conditions, the preinvention producer surplus is assumed to be unaffected by investment in R & D. From the first-order conditions for maximum profit for a given level of patent protection, the optimal level of investment, I^* , is given by the following:

$$(5) \quad I^* = \frac{\left\{ \begin{aligned} &(b - d)(a - c) + [(a - c)^2 \\ &+ (2b - d)(c - a)](1 - \lambda) \end{aligned} \right\}^2}{2(b - d)^2/g + [2g(b - d) + (d - 2b)g(1 - \lambda)](1 - \lambda)}.$$

The complete model is based on equations (1a') and (1b') which depict the market supply

Table 1. Optimal Patent Protection under Alternative Supply and Demand Relationships

	Price Elasticity of		Investment Productivity g	Optimal Levels of		Optimal Investment with Maximum Patent Protection $I^* (\lambda = 1)$
	Demand ϵ_d	Supply ϵ_s		Patent Protection λ^*	Investment I^*	
Base Scenario	-1.0	1.0	-.010	0.94	23,660	25,000
Alternative ϵ_d	-0.2	1.0	-.010	1.00	25,000	25,000
	-2.0	1.0	-.010	0.78	22,020	25,000
Alternative ϵ_s	-1.0	0.2	-.010	0.78	23,350	25,000
	-1.0	2.0	-.010	0.93	22,920	25,000
Alternative g	-1.0	1.0	-.005	0.98	6,130	6,250
	-1.0	1.0	-.015	0.81	47,810	56,250

and demand characteristics, equation (2') which depicts the profit equation for the innovating supply firm and its derivative, and equation (3) which depicts net social welfare. The innovating supply firm maximizes profits by selecting the optimal level of investment for a given and known level of patent protection. Net economic surplus is maximized by selecting the optimal patent protection parameter.

Initially, assume that the hypothetical supply firm has \$1 million in sales at a price of \$1 per unit with no investment in R & D. Under this base scenario, the elasticities of demand and supply are assumed to be -1 and 1, respectively, with no investment; and g , the coefficient on productivity of investment, is assumed to be -.01. In this case the optimal degree of patent protection would be 94% with an optimal investment of \$23,660 (table 1). If the firm had patent protection resulting in preinvention competitive pricing, the optimal investment would be \$25,000.

Results from three other selected scenarios are reported in table 1. Optimal patent protection would be 100% for an elasticity of demand of -.2 and 78% for an elasticity of demand of -2.0. Optimal patent protection would be 78% for an elasticity of supply of .2 and 93% for an elasticity of supply of 2.0. A change in the productivity of research, as measured by the coefficient g , has a relatively large impact on both the optimal degree of patent protection and the optimal level of research investment. For $g = -.005$, the optimal patent protection would be 98% compared to 81% for $g = -.015$. It is recognized that the research effect (g) is stochastic, and these results indicate that this type of uncertainty can be important in determining the optimal degree of patent protection. These results indicate that

the optimal degree of patent protection is dependent on supply and demand characteristics in addition to productivity of investment.

A similar model also was applied to selected U.S. commodities for alternative levels of research productivity. This analysis might conceivably be addressed at any one of several vertically related markets. For example, the innovation considered might be an improved variety of seed corn. The analysis could be directed to either the input market or the output market with similar results (Just, Hueth, and Schmitz). The output market is selected for analysis in this study because of the availability of supply and demand parameters.

International trade is accounted for in this model by using long-run general equilibrium price elasticities, which would reflect both exports and imports. With this formulation, consumer surplus includes both domestic and foreign consumer surplus. For the cases in which a commodity is both imported and produced domestically, it is assumed that the patent allows the innovating firm to capture a share of only the increased domestic producer surplus. However, both domestic and foreign producer surpluses are accounted for in measuring aggregate economic surplus.

The results for the optimal degree of U.S. patent protection for selected commodities are reported in table 2. A high degree of patent protection ($\lambda > .95$) would be appropriate for economically important commodities with low elasticities of demand such as beef, dairy, and hogs. Under similar conditions of research productivity, corn ideally would be given a higher degree of patent protection than wheat because of corn's inelastic demand. Although wool accounts for the smallest amount of cash receipts of any commodity considered, its in-

Table 2. Optimal Patent Protection for Selected U.S. Commodities

Commodity	Supply Elasticity ^a	Demand Elasticity ^a	Prices ^b (\$)	1985		Optimal Patent Protection for Alternative Levels of Research Productivity		
				Cash Receipts (\$ bil.) ^b	Imports to Cash Receipts Ratio ^c	Low (g = -.005)	Medium (g = -.01)	High (g = -.015)
Wheat	.5	-3.0	3.20	7.9	.00	0.76	0.58	0.37
Rice	.6	-2.2	7.85	0.9	.00	0.87	0.86	1.00
Corn	.4	-.75	2.49	16.0	.00	0.94	0.78	0.62
Sorghum	.4	-1.45	3.98	1.9	.00	0.95	0.95	0.94
Barley	.7	-1.4	2.10	1.0	.00	0.97	0.96	0.91
Oats	.7	-3.7	1.41	0.3	.00	0.96	0.93	0.70
Cotton	.5	-.5	0.56	3.8	.00	0.86	0.64	0.48
Soybeans	.6	-3.0	5.42	10.8	.00	0.98	0.75	0.58
Tobacco	.5	-1.5	1.60	2.7	.40	1.00	1.00	0.99
Peanuts	.3	-1.5	0.23	1.0	.00	0.33	0.13	0.10
Sugar	.4	-.2	1.54	1.5	.61	1.00	1.00	1.00
Potatoes	.5	-.5	3.91	1.6	.00	0.95	0.95	0.99
Beef	.6	-1.0	54.57	28.8	.04	1.00	1.00	1.00
Dairy	.5	-.65	12.73	18.1	.04	1.00	1.00	1.00
Hogs	.6	-.6	43.88	8.9	.09	0.99	0.96	1.00
Eggs	.8	-.43	0.57	3.3	.00	0.91	0.76	0.61
Wool	.2	-.8	0.63	0.1	.35	0.97	1.00	1.00

^a Source: B. L. Gardner.^b Source: U.S. Department of Agriculture, Economic Research Service.^c Source: U.S. Department of Agriculture, *Agricultural Statistics 1986*.

elastic demand and supply and relatively large imports call for a high degree of patent protection. A high degree of patent protection would be appropriate for sugar and tobacco because competition from imports is high for these commodities. While it may not be feasible in policy making to distinguish between small differences in λ such as .05, many of the differences reported in table 2 appear to be economically important. These results are instructive pointing out that differences in economic characteristics of the market call for differences in the optimal degree of patent protection.

Patent Policy Issues

The distinct statutory provisions and doctrines embodied in the Patent Act, Plant Patent Act, and the Plant Variety Protection Act create distinguishable categories for inventions and infringement protection. The results reported in table 2 indicate that some differences in coverage are warranted. However, the coverage under the current statutes does not appear to be justified by some combinations of supply, demand, and investment productivity measures. In particular, although the current prop-

erty rights protection for animal innovations is clearly less than the coverage for crops because of the absence of provisions comparable to the PPA and the PVPA, the empirical analysis indicates greater protection is needed for livestock. Furthermore, there is currently a similar degree of coverage for such crops as grains, but the empirical analysis indicates that differences in coverage may be warranted from the supply and demand parameters. Potatoes are excluded from protection under the PPA, but the empirical results indicate that the optimal degree of patent protection is relatively high.⁷ These disparities in coverage as well as other policy issues suggest that additional consideration of property rights protection is warranted.

The economic model presented above provides a rationale for the existence of differences in optimal patent protection for various commodities. Existing legislation provides for differences in patent protection, but the degree of patent protection currently provided may not be optimal. The following sections will attempt to identify situations in which current

⁷ Although potatoes may be patented under the PA, problems with meeting the description and enablement requirements and with assuming the responsibility of defending the validity of a utility patent may cause the PA to be inapposite for protection.

patent protection is not optimal and to suggest alternatives for modifying patent protection. Such alternatives are suggested as operationally feasible strategies for modifying the degree of patent protection.

Protection Against Infringement

Five infringement limitations of the PPA and the PVPA operate to diminish the property rights protection of these statutes when compared to the PA. First, although inventors may have the choice of applying for a utility patent, the rigid description and enablement requirements may pose additional problems in obtaining property rights protection. The ability to meet description and enablement requirements was not a factor in the economic model for differentiating patent protection. From an economic perspective, limiting benefits for an innovation that does not meet description and enablement requirements is not justified. Hence, there is a basis for addressing these infringement issues and establishing enhanced property rights protection through legislative changes related to the PPA and the PVPA.

Second, the doctrine of equivalency embodied in general patent law may offer broad protection for patents granted under the PA, while inventors' proprietary property rights receive less protection if the innovation is patented or certified under the PPA or the PVPA. Not only do the PPA and the PVPA require definitive proof of use of the patented subject matter, but the registration requirements of these acts only provide limited infringement protection.

The third and fourth limitations are embodied in the provisions of the PVPA. An exemption for experimental use allows researchers to use and reproduce the protected variety thereby decreasing the scope of property rights protection. A crop exception allows crop farmers to save, use, and sell certified seed in certain situations without compensating the inventor.

A fifth infringement limitation is the interpretation of the PPA to apply only to entire plants as opposed to plant parts. This interpretation has resulted in cut flowers reproduced from patented plant varieties in foreign countries being imported into the U.S. without payment of royalties.

Infringement limitations embodied in the proof of derivation requirement of the PPA have been considered by the Plant Patent

Committee of the Patent, Trademark, and Copyright section of the American Bar Association. The Committee has proposed that the PPA infringement requirement "be based upon a comparison of the depiction and description of the variety as set forth in the patent to the characteristics of the accused plant . . ." (Cooper, section 8.15). The Committee's proposal not only removes the derivation requirement but may operate to extend the protection of the PPA by incorporating an examination requirement. A similar amendment to the PVPA could broaden the infringement protection for plants certified under that statute. An alternative approach would be to amend the PPA or the PVPA to incorporate an examination standard or some type of equivalency requirement. As explained in the conceptual framework, broader protection under the PPA or the PVPA would tend to increase market power of innovators and, hence, increase the returns to innovation.

Description and Enablement Requirements

Problems with meeting the description and enabling requirements of the PA may restrict the qualification of some inventions for patent protection. Two major policy options exist to extend patent protection to a broader range of biotechnological discoveries. First, the rigid description and enablement requirements could be relaxed for living organisms to allow more materials to qualify for patents under the PA. However, a significant limitation accompanies this option. If the patented materials are not adequately identified, the enforcement of infringement actions and the judicial resolution of patent disputes will be more difficult.

The second option concerns the establishment of a proprietary or public depository for patented multicellular asexual plants which would allow more discoveries to qualify for PA patents. The floriculture and ornamental horticulture industries, in particular, would benefit from this development. The projected response of monopolistic pricing to either or both of these options would increase returns to innovations thereby encouraging biotechnological scientific discoveries.

Nonobvious Requirement

The recent finding by a patent examiner in *Ex parte Allen* that a multicellular oyster was not

patentable raises the issue of obviousness. Under the PA, letters patent for a product-by-process claim can be issued only if the invention is nonobvious. If the *Allen's* exacting interpretation of nonobviousness is not reversed, it will limit the ability of inventors to secure patents and preclude inventors of biotechnological innovations from receiving benefits from their scientific discoveries. As indicated in the economic model, such a distinction in patent protection is not justified.

Developing an Animal Patent Statute

Scientists are expected to make new biotechnological discoveries for animal agriculture beyond the current advances in protein production, vaccines, gene insertion, and embryo transplants. Although current patent law may adequately protect inventors' property interests in existing inventions, the absence of special legislative provisions for animals comparable to the PPA or the PVPA raises the question of whether the PA can adequately protect property interests involving animal inventions. Results from the economic model indicated that a distinction in patent protection between plants and animals is not justified. Hence, greater patent protection than currently exists for animals is warranted.

The problems associated with the enablement provisions of the PA were disclosed in *In re Merat*. The Court of Customs and Patent Appeals found that the description for a new species of chicken in a patent application was inadequate, so no patent was issued. The development of new technology regarding animals suggests that a new statute, altering the enablement requirement so that the description of the animal need only be as complete as reasonably possible, may be desirable.

New statutory provisions extending patent coverage for animals might provide an exclusive patenting procedure for animals or could be supplementary to the existing provisions of the PA. One possibility would be to pattern the procedure after the PVPA which is administered by the U.S. Department of Agriculture and offers patent-like protection through certificates to protect new varieties. Such a statute would only offer limited protection since the PVPA does not incorporate an equivalency doctrine providing broad exclusionary rights. In addition, any legislative enactment should more fully define require-

ments for the characterization of a new organism.⁸ The development of new patent provisions facilitating protection for animals would impact inventors and consumers in a similar manner as the relaxation of description and enablement requirements; the encouragement of innovation and exclusivity might promote returns from investment through monopolistic pricing.

Concluding Comments

Public intrigue and the investment of venture capital in biotechnology firms have led to the growth of a significant private sector in genetic engineering research. Existing legislative provisions of the three patent and patent-like statutes encourage biotechnological innovation by providing a mechanism for the protection of some intellectual property. However, difficulties in securing patents for man-made living organisms and distinctions among infringement provisions suggest that inventors may be expected to seek legislative amendments to strengthen property rights in future discoveries.

The expansion of patent protection alters the assignment of property rights between private firms and the public. Adopting the premise that legislative changes should be founded upon enhanced social welfare rather than the maximization of profits or revenues, an optimal degree of patent protection occurs at the tangency of the ridge line of the inventor and the isoefficiency curve for society. This framework provides a standard against which the performance of patent laws can be measured. Through a sensitivity analysis, this article delineates a method to link optimal patent protection to demand and supply characteristics and investment productivity. The results from this model indicate that market conditions such as supply and demand characteristics and expected productivity of research investment influence the optimal degree of patent protection. Hence, there is an economic rationale for maintaining differences in patent protection.

A review of patent legislation revealed that there are major differences in patent protection. However, the actual differences do not

⁸ Cooper suggests incorporation of the term "novel variety," modified to cover animal breeds, be used to avoid the use of the undefined term "breed."

correspond to the theoretical differences indicated by the economic model. Many actual differences are based on whether or not an innovation meets the description and enablement requirements of the PA. There is not sufficient economic justification for this distinction. Hence, the protection under the PPA and the PVPA should be liberalized.

Enhanced infringement protection under the PPA and the PVPA, relaxed PA description and enablement requirements, a moderated interpretation of obviousness, and a new animal patent statute appear to offer operationally feasible alternatives for eliminating some of the nonoptimal differences in patent protection. Additional research on the optimal degree of patent protection of innovations is warranted. Such research might expand the analysis to account for various firms racing to develop similar innovations (Scotchmer and Green). The expected productivity effects of research could also be broadened so that uncertainty could be addressed. Finally, the deadweight loss might be measured differently using a social welfare function other than consumer and producer surplus.

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