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An Agricultural Law Research Article

Owning the Secret of Life: Biotechnology and Property Rights Revisited

Part II

by

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acquisition of Delta.[226] What is it about the Terminator Seed that makes it so objectionable? Many of the objections to the terminator technology seem to surround the implications of private ownership of it. The Terminator Seed gives its owner automatic and extraordinary self-enforcing patent protection beyond that provided by any patent statute. Generally, a patent grants its owner, for a limited time only, the right to exclude others from making, using, and selling patented products without the consent of the owner.[227] However, because of agency costs and post contractual opportunism by licensees, enforcing patent rights is not always guaranteed. The terminator technology is a brilliant commercial response to patent enforcement problems because it comes with a built-in biological patent enforcement mechanism.[228] Indeed, the terminator technology creates its own biological patent system with the *perfect* and *perpetual self-help* enforcement of property rights. Because the Terminator Seed sterilizes its off-spring, the patent owner is assured that farmers and licensees who obtain seeds from the owner will not be able to cheat on the terms of the contract by breeding seeds without consent. But the biological self-enforcing protections are not limited in time as they are the case of patents. Thus, even after the patent protection has expired, the owner of the Terminator Seed can effectively and perpetually exclude farmers from improving the seeds.[229] This type of potential negative impact has led some critics of the terminator technology to describe it as *socially pathological*.[230]

For about 12,000 years, farmers all over the world have been developing non-proprietary techniques of producing, selecting, and retaining seeds.[231] Seed breeding techniques were shared and passed down from generation to generation thereby facilitating the development of new seed varieties. The Terminator Seed is seen as a threat to this ancient know-how and tradition.[232] As the Terminator Seed

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226. *Id.*

227. To obtain a utility patent, one must meet the requirements of novelty, nonobviousness, and utility. *See* 35 U.S.C.A. §§ 101 (West 2000) ("Whoever invents or discovers and new and useful process, art or method, and includes a new use of a known process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."); 102 (West 2000) (establishing the conditions under which an invention would not meet the novelty requirement); 103 (West 2000) (focusing on the requirement of nonobviousness). *See generally* Donald S. Chisum & Michael A. Jacobs, Understanding Intellectual Property Law § 2E (1996) (discussing the basic rights of patentee). *See also* 1,2 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW (1999) (examining in detail the nature, scope and level protection given to biotechnological patents).

228. *See* Kluger, *supra* note 222 (arguing that from a marketing perspective, the Terminator technology is brilliant).

229. The limitations and restrictions put on farmers has been described in various unkind terms. For instance, described as "immoral" and "'. . . really a vicious anti-farmer technology. Using genetic engineering to break that chain of seed that has always fed us just for a corporation's profit is wrong.'" *See* Nixon, *supra* note 221. It has also been described as biological warfare on farmers and food security. *See* Steinbrecher & Mooney, *supra* note 221.

230. Kluger, *supra* note 222. It has also been called the "neutron bomb" of agriculture. *See* Steinbrecher & Mooney, *supra* note 221.

231. Steinbrecher & Mooney, *supra* note 221. *See also* Hope Shand & Pat Mooney, *Terminator Seed Threatens an End to Farming,* EARTH ISLAND JOURNAL, Fall 1998.

232. Nixon, *supra* note 221 (expressing concern over the break in the seed chain).

technology gains acceptance in the farming community, seed breeding will be the exclusive domain of a highly concentrated group of seed companies and their scientists, who may affectionately be called *lab rats.*[233] Farmers who use the Terminator Seed will be unable to develop and maintain independent seed breeding techniques of their own. Traditional seed breeding techniques accumulated over centuries might all but disappear. Biodiversity in seeds maintained, in part, through traditional low tech breeding techniques will also be threatened. Diversity in seed plasma and genetic material, so essential to seed development, would tend to suffer. One may ask, what societal benefits may be found in a technology which seeks to reduce, terminate, or eliminate the acquisition or expansion of knowledge in an activity so ancient and so vital to human existence? The terminator technology implicitly suggests that *lab rats* know best what is good for society and they alone should be allowed to control the development of seeds. One cannot doubt that scientists have certain specific knowledge that ordinary farmers do not have, but that cannot support a policy of denying the world of the contribution of millions of people in the development of new seed breeding ideas within different environmental conditions. A policy that puts a higher premium on modern high tech biotechnological ideas at the expense of traditional techniques might be unwise. *What then is the cost of the Terminator Seed?*

One of the concerns expressed by critics of the Terminator Seed is that seed production will fall into the hands of an ever decreasing number of global enterprises that might restrict output to enhance prices or select seeds for production based purely on their profitability and not the needs of society.[234] This concern is reinforced by the fear that the terminator technology might be used as a platform for expanding its application in combination with other proprietary technologies such as Roundup-Ready, herbicide-tolerant, or insect-resistant genetically engineered techniques.[235] For instance, the expansion of the application of the terminator technology to rice and wheat could have serious implications because they constitute about 75% of the staple of the world's poor.[236] Farmers would be eliminated from the ancient practice of seed breeding and would not even be able to retain part of their harvest for future use. They would have to depend on seed manufacturers for their annual or seasonal seed needs. Thus, the food needs of large segments of the world's population will be controlled in the laboratories of a few de-personalized

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233. The problems of patenting genetically modified seeds have been the subject of commentary. *See, e.g.,* Anthony DePalma, *The 'Slippery Slope' of Patenting Farmers' Crops,* N.Y. TIMES, May 24, 2000, at A4 (expressing concern over the potential impact of patenting plant genes held a select number of companies and universities on Mexican farmers. These farmers developed about 20,000 varieties of maize for hundreds of years but could now be excluded because they shared their traditional techniques with researchers); Henry Tricks and Andrea Mandel-Campbell, *Mexico's Farming Habits under Pressure from Transgenics,* FIN. TIMES, Oct. 12, 1999, at 8 (explaining concern that genetically engineered seeds constitute genetic imperialism).

234. The suggestion of monopoly over seed production and sales is alluded in many of the reports on the Terminator Seed technology. *See* Kluger, *supra* note 222; Steinbrecher & Mooney, *supra* note 221.

235. *See Sowing Seeds of Discontent, supra* note 224.

236. *Id.*

global seed enterprises. With upstream supply side monopolies and downstream demand side competitive markets, one can only image what pricing policies would be adopted by global seed monopolies.

With the potential for cross-pollination, the expansion of the Terminator Seed into other types of seed such as rice and wheat would create an even greater risk to farmers using traditional farming techniques.[237] An increasing number of seed varieties would be exposed to and converted by the terminator technology. Such an expansion of the Terminator Seed technology would tend to create monopoly conditions for seed manufacturers. The risks presented by monopoly or oligopoly in other areas of the economy might be distinguished from those in biotechnology. As stated above, biotechnology is devoted to the fundamental issues of life and living and an abuse of power in it is likely to have a much wider and deeper impact on society than the concentration of power in other industries. Take the case of staple seeds being controlled by a few global seed producers concerned about the return to shareholders, earnings per share, and consequently the market price of shares; what production decisions would be made if they completely dominate the global seed market?

Obviously, if the goal of assigning property rights is happiness, the assignment of property rights in biotechnology presents a serious threat to the achievement of overall happiness of society. The attainment of happiness might require an aggressive regulatory regime or demand circumscribing property rights in some biotechnological inventions. In the case of the Terminator Seed, denying patent protection might be insufficient to address the concerns of its negative impact if the invention can nevertheless be used. With equal and free access to all, nothing prevents the widespread use of the Terminator Seed technology by all seed breeders in all seeds, patented and non-patented. Thus, denying patentability might have the undesirable effect of magnifying the negative impact of the technology on society. The solution might then lie in not only denying patent protection but also in making the Terminator Seed technology illegal, or by prohibiting its use.

iii. Monsanto and the Case of the Escaped Seed

The full implications of private ownership of the terminator technology can be fully appreciated by examining another seed dispute in which Monsanto is deeply involved. Monsanto brought a patent infringement suit against a Canadian farmer, Percy Schmeiser.[238] While the facts of the case are still in dispute, Monsanto is

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237. The risk to cross pollination was admitted by a Terminator Seed scientist at Delta and Pine Land Company. He also noted that the risk of genetic cross pollination in some plants is so high that the Terminator Seed technology is recommended for them. *See* Nixon *supra* note 221.

238. There are several newspaper reports of the law suit by Monsanto against Percy Schmeiser. *See generally* Karl A. Thiel, *Seeds in the Wind: For Monsanto, Patent Protection Stirs Controversy,* BIOSPACE (visited July 6, 2000) <http://www. biospace/articles/120699_print.cfm> (discussing the legal battle between Monsanto and Schmeiser in Canadian court); Dave Margoshes, *Saskatchewan Farmer Battles Monsanto, Sues Them Back,*

claiming that a large proportion of the defendant's canola crop contains Monsanto's patented genetically engineered Roundup-Ready gene, found only in Monsanto's Roundup-Ready canola seed.[239] The Roundup-Ready seed was designed to make canola plants resistant to Monsanto's Roundup herbicide.[240] Generally, farmers buy their seeds from seed producers such as Monsanto. However, in the case of the Roundup-Ready canola seed, Monsanto chose to maintain control over the seed through a lease agreement in which Monsanto, at all times, retained ownership of the seed and its technology.[241] Control was maintained through the following terms in the lease agreement: the farmers (1) must plant all seeds leased in the exact acreage agreed upon, (2) cannot hold back seeds for next year's needs nor engage in seed breeding, and (3) must lease from Monsanto each year's planting needs for the duration of the contract.[242] The defendant, Schmeister, is not one of Monsanto's seed lessees so it must then be determined how the Roundup-Ready canola seeds found their way onto his farm.

Notwithstanding that the facts are still in dispute, the case presents several significant legal and policy questions to be resolved. Two of the policy issues raised relate to patent policy and the ownership of genetically engineered naturally self-replicating organisms. While these issues could be examined in the section addressing patent policy below, they will be discussed here because of their importance to the traditional concept of utility.

At the outset, it should be noted that Monsanto held the patent in the popular Roundup herbicide used by farmers and home gardeners to control weeds. Just as the Roundup patent was about to expire, Monsanto developed the genetically engineered Roundup-Ready seed which had embedded in it a gene that made plants resistant to Monsanto's Roundup herbicide.[243] The new herbicide-tolerant seed gave the old expiring patent a new lease on life on a new platform with a new method of use. The new patent allows Monsanto to retain its competitive edge against potential producers of generic Roundup herbicide when the patent expires. While

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VANCOUVER SUN, Aug. 18, 1999 (explaining the nature of Monsanto's seed business in Canada and the suit against Schmeiser); Martin O'Malley, Percy Versus Monsanto (visited Nov. 11, 2000) <http://cbc.ca/news/viewpoint/columns/omalley/martin 880825.html> (copy on file with the *McGeorge Law Review*).

239. *See* O'Malley, *supra* note 238.

240. *See* Thiel, *supra* note 238, at 1.

241. Leasing of seeds rather selling them, appears to be a common practice among seed producers. While there are reports of such leases it is difficult to determine the exact legal character of such lease agreements without an examination of those agreements. For a discussion of the lease agreements between Monsanto and the farmers, see Margoshes, *supra* note 238, at 2 (describing a contracting format whereby Monsanto "sells" the seed to farmers but retains rights to the DNA in the seed). According to another report, farmers using Monsanto's seed must agree to sell the seed back to Monsanto and buy seeds again in the following year. *See About Percy Schmeiser v. Monsanto,* GENTECH ARCHIVE (visited July 6, 2000) <http://www.gene.ch/gentech/1999/oct/msg00187.html at 2>. These agreements have properly been called leases. *See* Jeff Singer, *David Countersues Goliath; Saskatchewan Farmer Percy Schmeiser Sues Monsanto Co.,* ALTERNATIVES JOURNAL, Jan. 1, 2000, at 2.

242. Control was maintained not only through the contract but also through a network of paid informants. *See* Margoshes, *supra* note 238, at 2-3.

243. Singer, *supra* note 241, at 2 (suggesting that Monsanto's patent on Roundup was about to expire).

theoretically the Roundup technology would be in the public domain, the new patent introduced a new and complementary method of use likely to create an entry barrier. Farmers may be reluctant to try generic Roundup herbicide if they associate the efficacy of the Roundup-Ready technology with Monsanto's brand of Roundup herbicide. The degree of complementarity of the old and new patents would invite tying agreements, actual or *de facto*. Indeed, there is no guarantee that Monsanto would not engineer technical complementarity between the Roundup-Ready seed and its brand of Roundup to maintain its edge in that technology.

Presumably, the Roundup-Ready seed technology has met all the technical requirements for patentability.[244] However, the question may still be raised whether patent policy is advanced when a patentee is allowed to extend the life of the patent by new and improved methods of exploiting technology that has enjoyed a full term of patent protection and should now be in the public domain. With the potential for technical complementarity, extending the patent protection of the Roundup herbicide technology was another brilliant business strategy with questionable policy and social implications. The strategy gave Monsanto the opportunity to maintain a stranglehold on the Roundup technology beyond what was contemplated by the first patent. One may ask, *how many bites at the apple are allowed?*

The patent infringement claim of Monsanto raises equally significant questions about the nature and scope of patent rights in genetically modified organisms. In response to the patent infringement claim, the defendant has maintained that he neither planted nor authorized the plantation of the canola seeds on his farm.[245] He however offered two theories of how the genetically modified seeds might have gotten onto his farm. First, he claimed that his canola crop was contaminated and polluted through cross pollination from neighboring Roundup-Ready canola farms.[246] Based on this theory, the defendant countersued Monsanto for damages arising from the pollution of his farm.[247] The defendant's second theory is also connected with some act of nature. According to him, the Roundup-Ready seeds were blown by the wind and spread either from neighboring farms or from the roads littered with spillover seeds during transportation.[248] Whether the seeds arrived in the winds or through some other force of nature, the defendant insisted that he played no part in it and should not be found to have infringed upon the patent. Implicit in the defendant's argument is the notion that the word "*infringe*" is an

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244. To obtain a utility patent, one must meet the requirements of novelty, nonobviousness, and utility. *See* 35 U.S.C.A. §§ 101 (West 2000) ("Whoever invents or discovers a new and useful process, art or method, and includes a new use of a known process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."), 102 (West 2000) (focusing on the requirement of nonobviousness).

245. *See* Thiel, *supra* note 238, at 1; Margoshes, *supra* note 238, at 1.

246. Thiel, *supra* note 238; Margoshes, *supra* note 238. The issue of cross pollination is not trivial as it reported that the Roundup Ready canola seed can indeed spread through cross pollination. *See* Singer, *supra* note 241, at 2.

247. Margoshes, *supra* note 238.

248. *Id.* at 3.

active verb which requires some volitional act on the part of the defendant. An act of nature is neither an act of the defendant nor an act attributable to him.

Suggesting what appears to be a strict liability approach, Monsanto has argued that patent infringement should be based upon the mere fact that Roundup resistant crops were found on the defendant's farm.[249] Should Monsanto's position be maintained, it would have serious implications not only on the issue of patent infringement but also on the question of ownership of the alleged infringing crop. Unlike mechanical patents, genetically engineered seeds are self-replicating and can migrate and spread through cross-pollination.[250] It is doubtful whether any patent policy would be advanced by finding infringement when the source of the infringement is a naturally occurring process. Besides, the defendant whose farm has been contaminated through cross-pollination is in a difficult position. He might not be able, nor should he be compelled, to stop the spread of the patented seed technology onto his farm.

Beyond the question of patent infringement is the larger issue of ownership of the alleged infringing crop before and after the harvest. According to the reported terms of the lease agreement between Monsanto and the farmers, Monsanto retained property rights in the seeds.[251] The question is whether Monsanto retains ownership as the canola seeds were carried across fields into neighboring farms. If Monsanto owns the escaped seeds does it follow that Monsanto also owns the crops that grow from these seeds? It is reported that, as part of the infringement action, Monsanto is asserting property rights over the canola plants and the crop upon harvest.[252] The answer to the question of ownership is neither obvious nor dictated by the logic of the initial ownership of the seeds. The implications of Monsanto's claims can best be explained by the following hypothetical scenario suggested by the defendant: "What if a farmer has a scrub bull? . . . And his neighbour's got a herd of purebred registered cows? Through negligence, the bull gets over the fence and impregnates his neighbour's cows. Now the guy with the scrub bull says those calves are his. The cows too! Same thing eh?"[253]

The defendant's hypothetical raises the important question of the ownership of the calves contaminated by the scrub bull. The patented Roundup-Ready seed might be seen by some farmers as an inferior product similar to a scrub bull. Such a position might be held by organic farmers who hold genetically modified foods and crops in very low esteem. To them, cross pollination and contamination of their crop would be a total disaster with more widespread implications than the case of the scrub bull. In the case of the scrub bull, the contamination is of the calves, not the high quality cows. The next generation of calves can be controlled for quality by

249. Thiel, *supra* note 238, at 1.
250. Singer, *supra* note 241, at 2; Nixon, *supra* note 221, at 3.
251. *Supra* note 241.
252. O'Malley, *supra* note 238, at 4.
253. *Id.*

selecting a high quality purebred bull. However, in the case of cross-pollination, the contamination affects the seed which is the source of future generation of seeds. The farmer cannot hold back any seeds for future use nor can he alter the quality of the seed during the next farming season short of abandoning the contaminated seed. If ownership of the contaminated crop is assigned to the patentee as suggested by Monsanto, that might be viewed as adding insult to injury in that the farmer, in addition to having his farm contaminated, would also lose his crop to the patent holder.

The case might be a lot more complicated if the bull were genetically engineered with very specific designer qualities and characteristics and through the negligence of its owner impregnated the neighbor's cows thereby transferring the patented genetic qualities and characteristics to the calves. Suppose that there is no contamination as the calves are of higher quality and have a higher market value than ordinary calves. Who would own the calves, the owner of the bull or the owner of the cows? If ownership is denied to the owner of the bull, might the owner of the cows not be unjustly enriched for receiving the value added by the bull without incurring any associated cost? Or, might it not be argued that the calves are the product of cross breeding between the genetically engineered bull and ordinary cows in which case the resulting calves are a different species of calves not the subject of patent protection? One can provide other hypothetical circumstances that would further complicate the question of ownership under similar circumstances. However, that would be unnecessary since the complexities of assigning property rights to self-replicating genetically engineered living matter and organisms have been sufficiently demonstrated.

The discussion above suggests that measured against traditional utilitarian views, the issues raised in the dispute over the escaped seeds demand much more careful analysis of instrumentalist policy objectives. The assignment of any property rights must take into account the potential for the negative impact to be created by holders of such rights. The welfare of society might well demand a different approach to the treatment of the fruits of biotechnology than the urge towards privatizing rights in them.

However, in contradistinction to the case of the escaped seeds, cross-pollination introduces a different set of complex legal issues. Suppose, as the defendant claims, his farm was cross-pollinated by a Roundup-Ready crop. Does the genetic makeup of the defendant's crop change after the cross-pollination or after the seeds have been formed? This is a scientific fact that can be determined through research. If cross-pollination changes the genetic makeup of the plants, does ownership change at that point or after the seed has been formed? Cross-pollination is a naturally occurring phenomenon and if the patented gene in the Roundup-Ready crop spreads naturally, as it ought to, should the patentee claim ownership of the affected crop? But if the gene can spread naturally, should the patent have been granted in the first place?

The issues of ownership become equally complicated in the case of interbreeding where the patented seeds spread naturally into other varieties without any human intervention. Granting ownership to the patentee would raise significant policy implications. In the first place, interbreeding might be seen as the natural production of something unique, new, unpatented, and therefore not owned by anyone. If the patented organism cannot be controlled or can escape and spread naturally through interbreeding the product should be viewed as part of the commons. Moreover, if ownership is granted to the patentee, a single genetically engineered seed could be used to acquire unprecedented widespread property rights in new breeds of seed neither earned nor clearly sanctioned by patent policy. Thus, a single genetically enhanced seed could be an instrument for the acquisition of monopoly power over all types of seeds including those used in subsistence farming in many parts of the world.

3. Summary

If the central tenet of traditional utilitarian philosophy is that property rights should be assigned in such a way as to promote happiness, that goal is not necessarily attainable in the case of biotechnological inventions. As demonstrated in this section, biotechnology is a complex, multifaceted discipline that generates a variety of significant fundamental ideas in science and technology. Many of the innovations in biotechnology stand to have a tremendous impact on life, living, the quality of life, the ecological balance, and on culture, politics and economics. Given the potential for such widespread impact, the assignment of property rights to promote happiness must then be sensitive to the multi-variate and differential social, political and economic impact. A monolithic policy of assigning property rights to private individuals in ideas that go to life itself threatens the goal of promoting general happiness because private decisions concerning the use, access, and exploitation of property rights in ideas may have objectives other than promoting happiness or general welfare.

Moreover, as demonstrated above, the central focus of biotechnology is not so much the end product as it is the control over the pathways to the end product. Privatizing the pathways to the products of life might not be the best way to promote happiness. Besides, in specific cases privatizing biotechnological inventions present a serious risk to social welfare and happiness. In particular, the assignment of property rights in biotechnological advances in seed breeding deserve special attention. Private ownership of genetically engineered technology for seeds such as the infamous Terminator Seed creates numerous risks to a human society still dependent on food for sustenance. Private ownership might depress and suppress the continued development of centuries of knowledge acquired through traditional seed breeding techniques, create intolerable dependency on a few global producers of seeds, and threaten biodiversity. It is seriously doubtful if a property regime that

presents these risks would, as a general rule, promote happiness and general welfare as envisioned by traditional utilitarian thought.

E. Economic Utilitarianism

Disappointed with the general looseness and measurement difficulties presented by traditional utilitarian theories of property, economists sought to offer a much more rigorous utility-based, instrumentalist conception of property.[254] They argue that property rights are created to serve a variety of concrete societal objectives. In a broader sense, some argue that private ownership of productive resources provide the bedrock foundation upon which the edifice of capitalism is built.[255] Accordingly, the object of private property is the nourishment of capitalism and its supporting ideology.

At a less general and comprehensive level, economic utilitarians view property as an instrument for achieving some concrete societal objectives. The primary function of property, arguably, is the creation of incentives for the efficient use and enjoyment of scarce resources.[256] According to economists, common ownership of property generally imposes a cost on individuals and society with respect to the use and enjoyment of such property. Common ownership creates a disincentive for conservation and efficient use, encourages overaccumulation and hoarding, and leads ultimately to the depletion of common scarce resources; such a phenomenon has been described as "The Tragedy of the Commons."[257] Private property is therefore seen as a solution to this tragedy since it creates an incentive for minimizing the cost and externalities associated with common ownership.[258] Private property rights are also seen as an incentive for the efficient utilization of scarce productive resources. According to Posner, the efficient use of scarce productive resources requires exclusivity and transferability.[259] He argued that if ownership connotes unqualified power to exclude others from a scarce resource that is freely transferable, property rights would maximize value.[260] Value meant the maximum

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254. PROPERTY RIGHTS, *supra* note 9, at 67.

255. It has been recently argued by Lester Thurow that capitalism will not work unless the assignment of property rights are clear. In particular, the protection of ideas lies at the center of the modern knowledge based economies. *See* BUILDING WEALTH, *supra* note 1, at 116-19.

256. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 30-32 (3d. ed. 1986); Harold Demsetz, *Toward A Theory of Property Rights*, 57 AMERICAN ECON. REV. 347, 348 (1966) (explaining the primary function of property as creating incentives for internalization of externalities).

257. The tragedy of the commons was first advanced by Garret Hardin to address the problems of over population and the management of scarce resources. Hardin associated common ownership with several ills: over use, waste, no incentive to conserve, and the eventual destruction of common property. For a discussion of the problems of common ownership, *see* Garret Hardin, *The Tradegy of the Commons*, 162 SCIENCE 1243 (1968). The problems of common ownership had been raised two years earlier by Demsetz using as an example, the fur trade in North America. Demsetz, *supra* note 256, at 350-53.

258. Demsetz, *supra* note 256, at 348; Hardin, *supra* note 258, at 1245.

259. POSNER, *supra* note 256, at 32.

260. *Id.*

price the resource would fetch in an open-market voluntary transaction.[261] Thus, the ultimate goal of the assignment of such property rights would be the maximization of value. In more specific terms, economists argue that property rights would also encourage allocative efficiencies and distributive equities. The achievement of these goals are conditional on very strict technical conditions of Pareto optimality that will not be pursued here.[262]

The general incentive justifications for the existence of property rights noted above have been extended to the protection of ideas. Accordingly, it is maintained that protecting ideas as property would create two distinct incentives: the incentive to discover or invent and the incentive to disclose inventions and new ideas.[263] According to the incentive to invent theory, without some protection given to ideas as property, there would be no incentive to invent or discover new ideas, resulting in the discovery of too few ideas.[264] To the extent that inventions are freely appropriable by any one not faced with the cost of inventing, competitors and free riders, would be able to copy new inventions and enter the market with underpriced products.[265] The inventor would be unable to recover the cost of the investment and would certainly be discouraged from repeating that process with another invention. To remedy the situation, a regime of trade secrets would emerge and predominate, making new ideas less accessible and costly to discover.[266] Moreover, because research and development activity is highly risky and expensive, there would be under investment in the creation of new ideas or investments would be biased towards ideas requiring lower preparatory investments.[267] Besides, without some guarantee that free riders and competitors can be excluded from new inventions, there would be little incentive for inventions of great social value.[268]

The incentive to invent justification is not free from controversy. According to critics, the incentive to invent might be undermined if granting property rights in inventions results in monopolies restricting access and new inventions. Moreover, the incentive to invent might distort the very economic efficiency it seeks to achieve by encouraging inefficient allocation of productive resources toward speedy inventions with little social value that would nevertheless facilitate the race to patent office. The potential distortions would include the financial burdens imposed on

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261. PROPERTY RIGHTS, *supra* note 9, at 68; POSNER, *supra* note 256, at 11, 31.

262. For a discussion of Pareto optimality conditions and efficiency, see JULES COLEMAN, MARKETS, MORALS AND THE LAW (1988); *see also* Kojo Yelpaala, *Towards the Theory of an Organic Contract*, 57-70 (2001) (forthcoming Mellen Press) (*on file with author*).

263. Kenneth W. Dam, *Intellectual Property in an Age of Software and Biotechnology, in* CHICAGO LECTURES IN LAW AND ECONOMICS 113, 114-16 (Eric A. Posner, ed., 2000).

264. *Id.* at 115; POSNER, *supra* note 256, at 36.

265. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1025 (1989); POSNER, *supra* note 256, at 36.

266. POSNER, *supra* note 256, at 36.

267. *Id.*

268. Eisenberg, *supra* note 265, at 1025.

new invention and attempts to invent around existing patents.[269] These criticisms of the incentive to invent are certainly applicable to the biotechnology industry.

Posner raises a much more basic objection to the creation of property rights in ideas. According to Posner, ideas, unlike tangible objects, have no physical locus and suffer from identification problems. In time, they tend to be diffused, thereby making it difficult to identify the source of specific ideas embodied in products. Assigning rights to any particular individual as the source of an idea found in a product is therefore difficult.[270] Apart from the illusiveness of ideas, there is some tension between open access to ideas for the advancement of humanity and the idea of exclusivity embodied in the concept of property. As pointed out by Kenneth Dam, that tension has to be resolved by balancing the needs of society against those of the inventor.[271] A balance between exclusivity and access may require certain limitations and restrictions on property rights in ideas. How the balance is struck is particularly important in the case of biotechnology where the line between basic knowledge and inventions is often thin.

1. Economic Utilitarianism and Property in Biotechnology

As one might expect, economic utilitarian theories of property focus on efficiency as the object and purpose of property rights. However, given the nature, scope and the declared mission of the biotechnology industry, the extent to which economic efficiency should dominate the issue of creating property rights in biotechnological inventions and discoveries is in serious doubt. It may be recalled that the central and directed mission of the biotechnology industry is to decode, understand, and manipulate the basic building blocks of life which have remained unchanged throughout evolution.[272] This mission raises significant issues of ethics, religion, morality, and policy considerations that go beyond the question of identifying ideas, private ownership, and economic efficiency. For instance, through mimicking nature, scientists have developed techniques of genetic engineering that have resulted in the cloning of animals, transgenic cloning of organs, and the mass production of proteins which play a critical role in the chemistry of life.[273] Improvements in the science and technology of cloning might eventually lead to the science of cloning or creating human beings afresh. The possession of such technology raises questions beyond economic efficiency.

The implications of biotechnology also go beyond cloning. Genetic manipulation of living organisms at the cellular level provides various opportunities for altering the genetic makeup of any living organism including human beings.

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269. *Id.* at 1025-30 (discussing various studies and arguments on the incentive to invent theory).
270. POSNER, *supra* note 256, at 37.
271. Dam, *supra* note 263, at 115.
272. Davis, *supra* note 31, at 314.
273. *Id.*

With this technology it would be possible to design babies with specific intellectual, physical, and other characteristics.[274] The successful mapping of the Human Genome that provides the sequencing of the entire human genome opens another chapter in the study of human biology, medicine and other related subjects.[275] If the past is any indication of the future, one would expect other breakthrough advances resulting from the Human Genome Project. Thus, the biological sciences and biomedical technology hold a great promise for the discovery of the cures to debilitating diseases such as cancer and Alzheimer's.

The activities mentioned above require significant amounts of risky investment of large amounts of financial and human resources. Legitimate questions are raised about the returns of such investments, if they are to be continued. However, the question is not so much the size of investment nor the nature of the risk as it is a basic philosophical and moral question. The question is whether certain scientific advances might be so important to life, living, and human, social, economic, and political environment that they should be excluded from the regime of private property notwithstanding the significant private investment cost involved.[276] The policy considerations required here are not new; they were confronted by the ancient Romans in their classification of property and continue to influence the choices made by modern societies even today.[277] In that regard, might private ownership of some inventions be denied when such ownership would pose a threat to the social, political, and religious values of society? Consider the discovery of an anti-aging pill. How might the private owner of that technology exploit it and for what purposes? Imagine what the history of the world might have been if such a pill was available in Hitler's Germany, Stalin's Soviet Union, Mao's China, or Titos' Jugoslavia as private property based on a pharmaceutical invention.[278] While the political and social problems are not solely those of private property rights, they nevertheless would be accentuated by private ownership.[279] Furthermore, take the

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274. *See generally* Lemonick, *supra* note 13.

275. *Supra* note 128 and accompanying text.

276. For a general discussion of the ethical issues in patenting genes, see Barbara Looney, *Should Genes Be Patented? The Gene Patenting Controvesry: Ethical, and Policy Foundations of an International Agreement*, 26 LAW & POL'Y INT'L BUS. 231 (1994).

277. *See infra* Part III.B.

278. The race to develop an anti-aging pill seems to have reached a promising stage and the discussion has now shifted to the economic, social and political implications of such a pill. The impact of a successful development of anti aging pill has described as being equivalent to "Big bang explosion" as many things would flow from that. People will live longer, over population will be a real issue and the struggle to stay alive might lead to chaos, or the technology will be controlled by a few people at the expense of all the others. If the technology is not made generally available, it might be exploited to maximize profits that could mean only the affluent markets would be exploited. We already face a situation where proletariat diseases are often not the subject of research and development by pharmaceutical companies. That pattern could be repeated in the case of the marketing of an anti-aging pill. For a discussion of the potential impact of the anti-aging pill, see David Stipp, *The Hunt for the Youth Pill*, FORTUNE, Oct. 11, 1999, at 199-200.

279. It is unclear whether the owner of an anti-aging technology would make it available to all nor is it whether governments would not influence its use for political purposes.

case of the cure for cancer. Lester Thurow has recently argued that no society will permit monopoly rights in the cure for cancer. According to him, democratic societies cherish egalitarian values so much that they would want lifesaving technologies to be generally available to all, rich and poor alike.[280] The goal of egalitarian access might be achieved through making all lifesaving technologies non-proprietary or acquiring those rights from their private owner under the eminent domain doctrine. Irrespective of the policy instrument used, the judgment would have been made that such technology better serves the interest of society by being non-proprietary.

Biotechnology also presents peculiar difficulties to the economic theories of property. If the goal of the assignment of property rights is to encourage the efficient utilization of scarce resources, the ownership of biotechnological discoveries and inventions might undermine that efficiency objective. As previously noted, the goal of biotechnological inventions is not so much the control over products as it is the control over the pathways to products. The number of pathways to be controlled is almost infinite and if each one is separately owned, certain problems would arise. Take for example the sand on the beach. *If every grain of sand is owned by a different person, the concept of the beach would be in serious jeopardy.* It would be difficult to organize transactions to assemble all the grains of sand to form the beach. Serious problems of hold-up and hold-out might frustrate that effort. To the extent that intransigence and total lack of cooperation serve the subjective needs of some owners, the concept of the beach would remain an abstraction not realizable in reality. Thus, the beach would never exist and whatever benefits the beach could bring to *beach bums* and the rest of society would be lost. Similarly, the ownership of every pathway, every new discovery, and every invention by an infinite number of individuals with the right to exclude all others would not only present serious problems aptly described as "The Tragedy of the Anticommons"[281] but would also undermine the concept of property rights.

The proliferation of owners of an ever-increasing number of strands and pathways of biotechnological inventions can be found in patents granted for anonymous gene fragments, expressed sequence tags (ESTs) and new DNA sequences including gene fragments.[282] The proliferation of property rights can also be found in patents for receptors used in screening potential pharmaceutical products at the preclinical stage. An increase in the number of Research Through Licence

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280. Lester C. Thurow, *Poaching Patents,* CALIFORNIA LAWYER, Nov. 1999, at 23.

281. Heller & Eisenberg, *supra* note 1, at 698.

282. The proliferation of patents in gene fragments is alleged to have been instigated by the National Institute of Health when it filed a patent application for 347 gene fragments. Questions were raised about the wisdom of the application and the property rights implications. Currently pending before the U.S. Patent and Trademark Office are applications containing 18,500 sequences. *See* Dale B. McDonald, *Who Owns Nature,* FARM INDUSTRY NEWS, Mar. 1, 1999. For an excellent and thorough explanation of the nature, public policy analysis, and suggestions on how ESTs migh be treated, see Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags,* 85 IOWA L. REV. 735 (2000).

Agreements (RTLAs) whereby inventors hold rights in downstream discoveries represent another manifestation of the anticommons phenomenon.[283]

The heterogeneity of interests held by an ever-increasing number of inventors in different strands and gene fragments and sequences present the same type of transactional problems raised in the case of different owners of the grains of sand on the beach. Each isolated fragment or gene sequence may have no socially-useful property value, but assembling all necessary pieces would be a daunting bargaining task with significant transaction costs.[284] The hold-up and hold-out problem would emerge again and any efficient gains that might have been contemplated by the grant of each individual patent would be frustrated. Thus, the phenomenon of the tragedy of the anticommons suggests that the proliferation of property rights in biotechnology might, in fact, undermine the concept of private ownership. Ironically, a return to common ownership might be more efficient than the private ownership suggested by Hardin in his article, "The Tragedy of the Commons."

The anticommons problem might be addressed with patent pooling and other arrangements designed to facilitate access and use of widely dispersed fragments of patents.[285] However, these techniques still require some voluntary cooperation of owners which cannot always be guaranteed because of the hold-up and other transaction cost problems discussed above.[286] The tragedy of the anticommons appears to be a systemic problem and if it is, the solution might lie in an overhaul of the entire system rather than tinkering with it at the margins.

The proliferation of property rights in biotechnological inventions and discoveries poses other problems for society. The social and political institutions of humanity are built on knowledge and the free and unfettered access to ideas that are disseminated at home, in schools, in colleges and within other institutions. Free access to ideas fosters egalitarian principles and democratic values as knowledge tends to bridge the gap between people. Free and unencumbered access to basic ideas in science, literature, mathematics, and other disciplines also plays a significant role in the way in which any society raises, educates, and prepares its young to play the role of useful citizens. The proliferation of property rights in general, and in biotechnology in particular, threatens the attainment of these goals of society. The line between basic ideas that are in the public domain and those considered innovative enough to be owned as property is already very thin and is getting even thinner.[287] As more and more marginal innovative ideas become

283. Heller & Eisenberg, *supra* note 1, at 699; DAM, *supra* note 17, at 8.

284. Heller & Eisenberg, *supra* note 1, at 699.

285. *Id.* at 700.

286. It has been argued by Dam that the anticommons problem is merely a serious possibility which does not warrant as much attention as the risk of insufficient patent protection. *See* DAM, *supra* note 17, at 10. However, it is apparent from the discussion in this Article that Hellen and Eisenberg have uncovered a serious problem, the depths of which seems to have been missed Dam's comment. Thus, the solutions (patent pooling, cross-licensing, etc.) suggested by Dam seem more optimistic than the problem might warrant. *Id.* at 11.

287. *See* DAM, *supra* note 17, at 6.

proprietary, an increasing number of ideas that should be in the public domain would be privately owned. With the multiplicity of pathways available in biotechnology, property rights in those pathways, their supporting research data and information would limit access and undermine the educational needs of society. The impact of such denial of access is likely to be severe on academic institutions that thrive on openness.[288] For them, free and unencumbered access to research results, information, and data facilitates the development and deepening of fundamental concepts and the falsification and objectification of new ideas. A regime of property that denies access to such information and data to academic institutions will hamper the intellectual mission of such institutions.[289]

Again, the question is whether the solution lies in a systems reconstruction or in mere tinkering with the system, such as an experimental use exception to patent protection.[290] *Dancing around the fire may contain it but does not extinguish it.*

2. *Summary*

It is apparent from our discussion above that biotechnological inventions present significant difficulties in the application of traditional utilitarian theories of property. The idea that property rights might be assigned to achieve happiness is not susceptible to easy application in the case of biotechnological inventions. Even though biotechnological inventions hold incredible promise for the good of humankind, they also present new and unfathomable fears in many segments of society. There is concern that whatever benefits might arise from biotechnology inventions might eventually be destroyed by an irreversible negative impact, not just on humanity but also on the environment and the social and political structure of society. These fears seem to loom so large that one wonders whether the utilitarian goal of happiness is achievable through the assignment of property rights. The discussion above seems to suggest that privatizing the rights in biotechnological inventions should not be undertaken without a careful analysis of the potential negative impact on the goal of happiness.

V. TOWARD A HIERARCHY OF NORMS IN PATENT POLICY

A. *Historical Overview of Patent Policy*

In 1941, Professor Walton Hamilton of Yale University Law School submitted a monograph report entitled, Patents and Free Enterprise, to the Temporary Economic Committee created by Congress to investigate the concentration of

288. *See id.* at 3.

289. *Id.*

290. *See* Heller & Eisenberg, *supra* note 1, at 1018.

economic power.[291] After a thorough historical analysis of the subject, he concluded that the U.S. patent system had, by 1941, departed from its original mission directed by the Framers of the U.S. Constitution.[292] Like other institutions burdened with the future in their instructed charge, the patent system necessarily had to adapt to changing circumstances to survive. No patent system could afford to be stuck in the past if it was to serve the evolving needs of the country. Therefore, as Professor Hamilton put it, the quarrel was not with the departure from the instructed path, but rather with the fact that the departure was not guided by any conscious policy.[293] In response to the tumultuous development and growth of industry, the patent system, in practice, had deviated significantly from the text of the relevant statutes that had remained relatively unchanged over time.

Certain risks are generally associated with significant deviations between the law in practice and its underlining statutory scheme.[294] The deviation might be indicative of a usurpation of the legislative powers of Congress being manifested in judicial activism. In a Constitutional framework, such as that of the United States, where the separation of powers is well entrenched, the usurpation of the powers of Congress by the judiciary might constitute a serious threat to the checks and balances enshrined in the Constitution by the Framers. The deviation might also suggest the mere employment of creative interpretative techniques designed to avoid absurd results. But creative interpretative techniques employed over a long period of time might suggest an abdication by Congress of its legislative responsibilities. At least, it might be argued that the unresponsiveness of Congress to the evolving needs of the patent system invites judicial activism. A third risk is the erosion of general public respect for statutes. When the law in practice deviates so significantly from the controlling statutory scheme, judges, lawyers, and ordinary people might conclude that statutes do not matter. In all of these cases, the risks created could be minimized if Congress intervened with necessary and timely reformative policies and statutes. Concerned about the impact of a drifting system, Professor Hamilton called for a conscious policy giving the patent system its appropriate place in the national economy.[295]

Over half a century after the Hamilton report, the U.S. patent system may again be described as dislocated and being "out of sync" with the vibrant and explosive advances in science and technology, particularly in the biotechnology industry. The reasons for the dislocation and the degree of the misfit are both numerous and systemic. First, it appears that the patent system, designed over a century ago, has

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291. PATENTS AND FREE ENTERPRISE, INVESTIGATION OF CONCENTRATION OF ECONOMIC POWER, TEMPORARY NATIONAL ECONOMIC COMMITTEE (Monograph No. 31 1941) [hereinafter PATENTS AND FREE ENTERPRISE].

292. *Id.* at 145.

293. *Id.*

294. *See generally* PATENTS AND FREE ENTERPRISE, *supra* note 291 (discussing the different problems that arise with a patent system that deviates from its statutory framework.).

295. *Id.*

been overtaken by the depth and complexity in human ingenuity. The incredible expansion and deepening of knowledge in modern science and technology, especially in biotechnology, has resulted in inventive activities of such variety and complexity that could not have been contemplated by the designers of the old patent system.[296] In particular, the discovery of DNA and the resulting inventive advances in genetic engineering involving living organisms raise several moral, ethical, cultural, religious, and socio-economic issues beyond what could have been contemplated by the policymakers tens of decades earlier.[297] The reasons for the inadequacy of the old patent system have been aptly described by Thurow in the following terms: "Designed more than a hundred years ago to meet the simpler needs of an economy based on natural resources and mechanical devices, our system of intellectual property rights are an undifferentiated one-size-fits-all system."[298]

Certainly, a system designed for mechanical devices would be most unsuited to the new era of inventions and discoveries involving new life forms, living organisms, gene sequences, intra-species, and transgenic cloning of living organisms including human beings.[299] The fundamental policy issues raised by inventions and discoveries in the biotechnology industry are not only different, but also challenge the core premises of the patent system itself. One might say that trying to fit these new and complex scientific discoveries and inventions within the framework of the old monolithic patent policy is like *putting new wine into old bottles.* Little wonder then that there has been such an uproar over the patenting of genes, gene sequences, and other biotechnological inventions and discoveries.[300] Besides, a system that was aimed at mechanical devices might still be inadequate even with respect to modern inventions of an inorganic nature. For instance, the nature and pace of advances in computer hardware and software seem to make the old patent system obsolete.[301] The policy and legislative response to the dislocation in the patent system lies not in tinkering with it at the margins but in overhauling its basic framework.

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296. *Supra* notes 21-24 and accompanying text.

297. *Supra* notes 15-16 and accompanying text.

298. Thurow, *Poaching Patents, supra* note 195, at 23.

299. *Supra* note 6 and accompanying text.

300. The objections to biotechnological patents have been broadly based. Some objections are made because biotechnological inventions permit humans to play God, others are centered round issues of human rights and the ban on slavery. For a general discussion of the objections in the U.S., Canada, and the E.U., see Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals,* 5 HEALTH L.J. 147 (1997) (providing different types of objections to the patenting of animals, humans, and other biotechnological inventions). Public outcry against biotechnological patents led to the holding of hearings by the U.S. Congress. *See Patents and the Constitution: Transgenic Animals: Hearings Before the Sub-Committee on Courts, Civil Liberties and the Administration of Justice of the House Committee on the Judiciary,* 100th Congress, 1st Sess. (1998); Sellers, *Patenting Non-Natural Occurring Man-made Life: A Practical Look at the Economic, Environmental and Ethical Challenges Facing "Animal Patents"*, 47 ARK. L. REV. 269 (1994).

301. *See generally O.P.M. Files for Bankruptcy Protection, 1981 Facts on File,* Apr. 10, 1981 (discussing the inability of a computer leasing company to help keep its clients up to date with the latest computer technology); Stuart Cheifet, *All Things Considered,* NPR Radio Broadcast, Feb. 12, 1996 (complaining about the rate of obsolescence of computers and software).

A second and equally important reason for the misfit can be found in the policy issues raised by biotechnological inventions and discoveries. Unlike mechanical inventions, genetic engineering involves new life forms, living organisms, cloning, and existence itself and, for that matter, raises a wide range of fundamental questions including those of ethics, morality, theology, culture and economics, to mention a few. Indeed, as discussed in earlier sections of this Article, the existing patent system is terribly unsuited for addressing the new complex issues of patentability and ownership of inventions involving human life forms, intra-species and trans-genic cloning techniques. Neither the policy nor the statutory framework were designed to resolve the significant and fundamental moral, ethical and other concerns generated by biotechnological inventions. It is therefore doubtful whether the designers of the old patent framework ever intended that it be used to support the creation of rights in certain inventions that give inventors potentially awesome "God-like" powers.

Stating that the conditions in biotechnology are screaming for reform would not be an exaggeration—the question is whether Congress will respond. Most observers will agree that a patent system that lacks the structural flexibility necessary for adjustments and distinctions to be made between different categories of inventions is deficient. To remedy such deficiency, Congress might design a new patent system that is sensitive and responsive to the variety of complex and fundamental policy issues presented by the inventions in biotechnology.

Third, it should be noted that the systemic problem discussed so far is not in any way limited to biological life sciences; it also extends to other life sciences and living organisms other than mammals. The significance of the fundamental ethical, moral and other policy considerations discussed above are not lessened by the fact that the inventions concerned involve genetically modified seeds, foods, or plants. Such inventions not only hold an uncertain promise but also present certain risks to the concentration of economic power and to the destruction of the sources of knowledge and ideas developed and maintained for thousands of years. The interest of society in the development and maintenance of human knowledge might be undermined when the patent system permits or encourages the acquisition and maintenance of rights in ideas that would produce the risk of such drastic consequences.[302] Thus, even in the case of genetically modified organisms, the patent system needs to be transformed to meet the needs of society outlined above.

Finally, other manifestations of the unresponsiveness of the patent system to the new and evolving inventive activities can be found in the imbalance between the right of exclusion and the access of the general public to new ideas. The proliferation of property rights in ideas described by Heller and Eisenberg as *anticommons* pose significant problems for access to even basic ideas.[303] We have

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302. *Supra* notes 221-53 and accompanying text (discussing the potential impact of the Terminator Seed technology and Roundup Ready canola seed dispute between Monsanto and the Canadian farmer).

303. Heller & Eisenberg, *supra* note 1, at 698.

referred to such a pattern of ownership as akin to private ownership of the grains of sand on the beach by countless individuals. A patent policy that permits such a result probably undermines more than it supports the concept of property in ideas. The reason for such a subversive outcome may lie, in part, in the reliance on an old and outmoded balancing of interests system.

Policies constructed for a world of mechanical devices and simple inventions do not raise the same issues of access as do inventions that are intertwined with basic knowledge or that implicate life, existence, and survival. As maintained by Dam, the line between basic research and applied research is thin.[304] As an increasing number of basic ideas enter the private property regime, the domain of public property in ideas will continually shrink. It is generally maintained that there is some tension between the notion of access to ideas and the incentive to invent.[305] Patent policies designed to strike a balance between these two competing interests decades ago would not necessarily fit the policy choices of today. The nature and impact of biotechnological inventions and discoveries are different from those relating to the invention of the combustion engine and other mechanical devices. To ensure that the effects of the anticommons phenomenon are minimized and to create a better balance between the incentive to invent and the public right to access ideas, a new patent policy is necessary.

B. Survey of Current Patent Policy

Any revision of the patent policy must start with the unimpeachable authority of Congress granted by the Constitution. Seldom is the delegation of powers to Congress by the Constitution so explicitly and briefly stated and the exercise of those powers so directly instructed as those relating to the promotion of science and the useful arts. In Article I of the U.S. Constitution, the Framers stated very briefly that "Congress shall have the power 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 writings and discoveries."[306] The exact contours of the delegated powers cannot easily be ascertained outside the words used by the Framers. For, all the critical terms and phrases were undefined, and any attempt to discover their meaning from supplementary sources and debates at the Constitutional Convention would be unrewarding. The clause was adopted without struggle, formal debate, or opposing pamphlets from which one could deduce the intent of the Framers.[307]

Notwithstanding the absence of definitions, it is believed that the power granted to Congress to promote science and the useful arts was sufficiently explicit and

304. DAM, *supra* note 17.
305. POSNER, *supra* note 256, Eisenberg, *supra* note 265.
306. U.S. CONST. art. I, § 8, cl. 8.
307. PATENT AND FREE ENTERPRISE , *supra* note 291.

broad[308] to meet the needs of an evolving society. The question therefore is how that power might be exercised in the case of biotechnology. First, it must be noted that the Framers did not command Congress to promote science or the useful arts; nor did they decree that Congress cannot discourage or prohibit specific scientific investigations or advances. The Framers merely empowered Congress to promote science if, in its infinite wisdom, Congress chose to do so. Second, in the event that Congress chose to exercise its powers under this clause it had to promote science and the useful arts in the manner prescribed by the Constitution for the ultimate benefit of society. Third, the grant of powers allows Congress to grant patent protection or to provide some other form of limited duration exclusive rights to inventors. However, it does not forbid Congress from decreeing a bounty, purchasing inventions, or contriving some other arrangement.[309] The policy options available to Congress for addressing the complex issues raised by the biotechnology inventions are therefore many. How Congress exercises those choices would require a careful analysis of the issues raised in this Article.

However, the policy choices of Congress in dealing with the biotechnology explosion are further complicated by the specific instructions of the Framers to *promote* science and the useful arts. The term "promote" suggests that the objectives of Congress, in a general sense, had to be directed at encouraging the advancement of science and the useful arts; but does it also demand that the results of scientific investigation encouraged be positive? Has Congress properly exercised its powers to promote science if the results would have a significant negative impact on society or the environment but the invention itself opens up new possibilities? Is it consistent with the Constitutional directive to promote science for the ultimate good of society if the patent system protects scientific discoveries that create monopolies in areas of vital importance to human existence, or pose a serious threat to the ecology or the human social, economic and political society as we know it? Should the advance in science take precedence over the survival of society and its value system? All of these questions are relevant in the determination of patentable subject matter in biotechnology.

One of the first policy considerations to be undertaken by Congress is the issue of the patentability of biotechnological inventions. As noted throughout this Article, biotechnology raises fundamental questions of morality, theology, politics and economics and on how human society is organized. Creating exclusive rights in discoveries and inventions involving the human body, in new life forms, and in the technology for cloning living organisms within or across species, raises innumerable questions of policy. Also, according property protection to ideas on the transgenic manipulation of life forms, seeds, and plants and, in particular, in the entire human

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308. Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) (Court noted that grant of power to Congress by the Constitution to legislate was broad).

309. PATENTS AND FREE ENTERPRISE, *supra* note 291.

gene sequence recently successfully mapped, further raises issues that cannot be adequately addressed by the existing general patent policy.

The need for a systemic transformation of the criteria for patentability was raised before the U.S. Supreme Court in the case of *Diamond v. Chakrabarty*.[310] In *Chakrabarty*, the Court was asked to determine whether human-made genetically engineered bacterium and micro-organisms were patentable under section 101 of the U.S. patent statute. Many objections to the patent were raised and the Court summarized them in these words:

> To buttress his argument, the petitioner, with the support of amicus, points to grave risks that may be generated by research endeavors such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."[311]

Notwithstanding the gruesome parade of horribles, the Court limited itself to the narrow task of constructing section 101 of the patent statute passed by Congress in exercise of the powers granted it under the Constitution. Its interpretive exercise was, however, to be guided not by the wisdom, or lack thereof, of the statute at hand, but rather by what Congress meant by the words it used in section 101.[312] The Court found the language of section 101 to be broad enough to cover the patentability of genetically engineered bacterium and micro-organisms.

In coming to the conclusion that micro-organisms and genetically engineered bacteria were patentable, the Court was mindful of the concerns raised by the opponents to the patent. It, however, saw the issue as one relating to the competence of the Court to develop the criteria of patentability. It remarked:

> What is more important is that *we are without competence to entertain these arguments*—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of

310. 447 U.S. 303 (1980).
311. *Id.* at 316.
312. *Id.* at 318.

> investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[313]

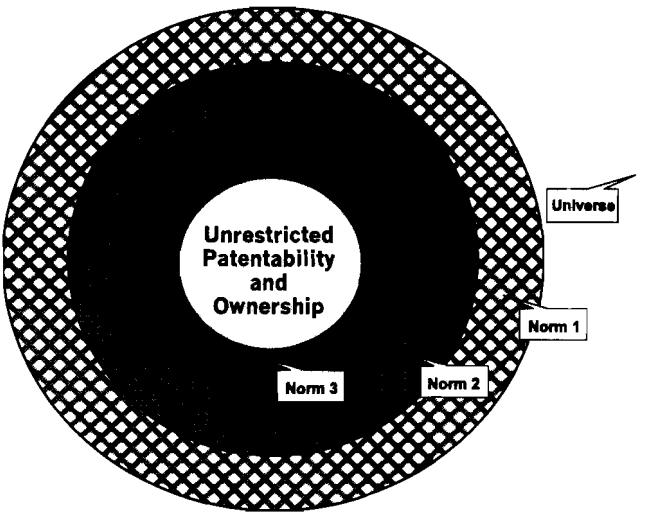
Given the Constitutional delegation of powers to the Congress on this matter, the Court was probably right in its conclusion that any change in the nature or scope of patentable subject matter lies within the province of the legislative branch of government and not the Court. How then might Congress approach its task of constructing a new patent regime for biotechnology?

C. Hierarchy of Norms for Patentability

Any attempt to construct a new regime for biotechnological inventions must proceed from the lessons taught to us from history about the nature, classification, and policy justifications for property. That history teaches that property rights have always been less than absolute, a bundle of different coexisting rights, and capable of accommodating various interests simultaneously. We also learn from history that certain things were excluded from the property regime not because they could not be subjected to the control and dominion of people, but because they played such a vital role to human life and the social, economic and political organization of society. History also teaches that the concept of property has always been driven by instrumentalist objectives. Property is an instrument for achieving certain goals of society. So what is included or excluded from the property regime is generally controlled by the goals of society at hand. In addition, any search for a new regime for biotechnology must take into account the application of the broader concept of property to ideas. It must also confront the fundamental issues of morality, ethics, religion, and other socio-economic and cultural considerations implicated by inventions involving life forms, living organisms, and the potential for creating human life *de novo*. To address all of the relevant issues, the following hierarchy of norms, as presented in Figure 2, presents a guide for developing a patent policy that is responsive to the complexities of the biotechnology industry.

313. *Id.* at 317 (emphasis added).

Figure 2: Universe of Ideas in Biotechnology



Universe: Universe of ideas in biotechnology.

Norm 1: That which cannot be owned is not patentable.
Norm 2: That which can be owned may nevertheless not be patentable.
(a) Specific exclusion.
(b) Exclusion through patentability criteria.
Norm 3: That which is patentable may nevertheless not be patented on public policy grounds.

1. Norm 1: That Which Cannot Be Owned Is Not Patentable

The first norm presents the broadest and most inclusive patent policy that could be adopted because it defines the limits of patentable subject matter against the backdrop of the limits of property rights. It confronts the issue of whether certain ideas might be excluded from the property regime and must not be the subject of legislation to the contrary. Thus, even if the legislative powers of Congress are not so specifically limited by the Constitution, Congress might nevertheless refrain from putting specific categories of ideas inside the property regime. It may be recalled that the Constitution of the United States is not mandatory, but merely hortatory or permissive in the protection of ideas. In other words, Congress might adopt a policy that certain ideas, inventions, and discoveries are of such a nature that they cannot be the subject of private ownership and, on that account, are not patentable. Under this norm, the exclusion of an idea from the property regime has much more severe implications than is usually associated with non-patentability. Ideas, inventions and discoveries excluded from the property regime would also be excluded from the regime of trade secrets. In other words, *that which cannot be owned cannot be the subject of an enforceable secrecy agreement.* Thus, biotechnological inventions that cannot be the subject of property rights will always be in the public domain for the benefit of humanity.

Obviously, this norm puts a premium on total and unimpeded access to certain ideas in whatever form they come. One may then ask: what is it about these ideas that they must be excluded from the regime of private property? Such ideas or inventions may be critical to human existence, form part of the general patrimony of humanity, or are the source of basic knowledge for all societies. Congress may also consider such ideas as serving some fundamental societal interest that would be undermined by private ownership. To facilitate the adoption and implementation of this norm, Congress would develop a positive list of inventions and discoveries that can neither be owned nor patented. Such a list might include the discovery of certain basic ideas in science and mathematics including the functioning of nature and its genetic structure. Discoveries and inventions on the human body, including gene sequences, such as the human genome sequence would also fall into this category. In addition, inventions and discoveries that go to the very existence of humanity, human life forms, and living organisms would qualify for exclusion from the property regime and patentability. Furthermore, techniques for the cloning of life forms including human life and genetic manipulation of seeds and seed breeding would also be candidates for exclusion from ownership and patentability.

The primary focus of this norm is not the regulation of research and scientific investigation. Nonetheless, Congress might consider the possibility of creating a category of inventive activities that could be excluded from scientific investigation or experimentation. One such category might be the cloning of human beings or the creation of human life forms *de novo*.[314] A policy that positively and deliberately restricts the acquisition of knowledge in any field is a serious limitation on the intellectual growth of humanity and therefore should not even be contemplated unless the actual threat to society is obvious and serious. Even when the conditions demand restrictive measures, those measures can only be adopted after a careful balancing of the risks and benefits. Congress might conclude that the risks associated with cloning or creating human beings, on balance, outweigh any benefits that can be generated. For instance, the inventor would acquire the attributes of "God" with awesome powers. Not only might such inventions and discoveries dislocate the entire human belief system, but it might also pose a threat to the very existence of human social, economic, and political organization. Perhaps human social and political organizations need transformation, but it is uncertain whether such a transformation can take place smoothly without some human belief system. Besides, one is not sure of how a human "Inventor God" might exercise the power that comes with the ability to create human life form.

In conclusion, because the policy and legislative agenda contemplated by this norm raises several significant issues and suggest new pathways, it demands national debate and Congressional hearings before implementation. A national

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314. The debate that has erupted regarding cloning suggests that it might be an example of the kind of activities that could be controlled.

discourse over the type and nature of ideas that must be excluded from the property regime and patent system would invite views from, and debate among, different interested groups. A Congressional hearing would present a forum where the full implications of the policy will be discussed. In such debates, or hearings, the views of experts and interest groups will inform the process and enrich the outcome. Should Congress adopt this approach, we might start to bring some coherence and clarity to policy and legislation on the issue of intellectual property.

2. *Norm 2: That Which Can Be Owned May Nevertheless Not Be Patentable*

The focus of the second norm is to define, in a broad sense, ideas that can be the subject matter of private property. The operating general premise of this is that an idea that can be owned may also be the subject matter of an enforceable secrecy agreement and patent protection. However, specific inventions and discoveries may be put in the public domain based on a deliberate policy to achieve certain objectives. Under this norm, inventive ideas and discoveries can be put into the public domain in one of two ways: (1) through specific exclusion, or (2) through patentability criteria. We shall examine these categories below.

a. Specific Exclusion

In the case of specific exclusion, certain inventions and discoveries might be specifically excluded from the patent regime for various reasons. The inventions in question may serve some positive societal objectives or that they pose a significant risk of negative impact on society. The inventions may also be excluded because they hold an incalculable and uncertain promise of social, economic, and cultural dislocation. Whether the impetus for the exclusion is the positive or negative impact of the invention in question, achieving different important policy objectives might be the goal.

The policy objective might be to make such inventive ideas available to all because of the importance of inventions or discoveries to society, or because Congress believes that exclusive rights in them might lead to undesirable monopolies. Any discovery of the cure to cancer and Alzheimer's disease could be proprietary. However, the importance of such a discovery to human health and the goal of democratic societies to foster egalitarian access to the best cures for the worst diseases might lead to their exclusion from patentability.[315] The development of new techniques in medical treatment including genetically engineered processes such as gene-therapy and the cloning of organs might also fall into this category.[316]

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315. THUROW, BUILDING WEALTH, *supra* note 1.

316. Cloning of organs is a controversial subject and may well be regulated by other legislative processes other than through the patent system.

The development of certain new seeds, plants, and animal varieties, to the extent they are not covered by Norm 1, might also be excluded from the patent regime based on a policy judgment that they would best serve society in the public domain rather than in the hands of private owners.

On the other hand, the use of the norm might be guided by the potential negative impact of an invention or discovery on society or the environment. Such a policy approach might be driven by fear and the parade of horribles alluded to by the U.S. Supreme Court in the *Chakrabarty* case.[317] If an invention has a known or an uncertain negative impact on life, living, nature, or the ecological balance that has evolved over millions of years, Congress might take the view that it should not be actively encouraged with a reward of exclusive rights even if it is for a limited duration. Of course, the fears might be unwarranted after the fact, but policy makers might feel that an overly protective policy is better in the case of uncertainty because *it is always better to be safe than to be sorry.*

A policy of specific exclusion of certain inventions from the patent regime permits Congress to encourage controversial research while retaining ultimate control over the issue of access and use of the results. A research activity may have the potential of producing patentable results with multiple uses or applications. Some of these uses and applications may pose certain unacceptable risks and others may have beneficial impacts on society. Instead of prohibiting the scientific investigation as discussed under Norm 1, Congress might encourage the research activity but limit patentability to certain applications but not to others. Take the case of the technology for mass destruction; a policy could be adopted to outlaw its development. However, the policy choice might not be that clear in the case of the development of robotic fighting human machines with organic computer brain power similar to that of humans. The robots might have vision, the ability to communicate, take and give orders, and engage in tactical and strategic maneuvers. The technology itself may have other useful purposes. Intelligent robots might be used in space exploration, to manage and control nuclear accidents and waste cleanup, fight fires, engage deep sea exploration or rescue, or other activities too dangerous for human beings. However, the technology could also be used for other more controversial purposes. Its use to create a robotic fighting machine might lead to the creation of a robotic army with human characteristics, and that would be no laughing matter for any society. Because of the risks that might be posed by such a technology, Congress might choose to regulate its use rather than prohibit the investigation of the scientific basis for it.

Finally, there is the question of inventions currently protected by the patent regime which nevertheless would have qualified for exclusion from the patent regime under this norm either because they would better serve the interest of society in the public domain or because they, after the fact, pose some unacceptable risk to

317. 447 U.S. 303, 316 (1980).

society. With respect to inventions that prove to be not useful to society, the patents might be revoked under the utility doctrine or the patents be might subject to eminent domain or inverse condemnation.[318] In the case of inventions that would better serve society in the public domain, the government could exercise its eminent domain powers to acquire such inventions and put in the public domain.[319] However, there might be some inventions that would fall into the category of things that are not patentable because they could not be owned under Norm 1 above. For those inventions, in addition to the concepts of inverse condemnation or eminent domain, it might be useful to consider the use of the public trust doctrine to revoke any private ownership rights that the patent regime might have created.[320]

b. Exclusion Through Patentability Criteria

Patent regimes are generally governed by a system of patentability criteria which, to a large extent, control the subject matter of patents. Patentability criteria define the nature and scope of what is and what is not patentable. Where, however, the inventive activities are dynamic and constantly evolving, the patentability criteria may easily become obsolete and not responsive to new inventions. Such is the case of the biotechnology industry.

As mentioned above, the current U.S. patent regime was designed substantially for a simpler economy dominated by inventive activities dealing with mechanical and simpler devices.[321] It was not designed to provide adequate guidance, if any, to discoveries and inventions dealing with living organisms, new life forms, genetic

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318. *See generally* KLK Inc. v. U.S. Dep't of the Interior, 35 F.3d 454 (1994) (stating that "Inverse Condemnation is a shorthand description of the manner in which a landowner recovers just compensation for a taking of his property when condemnation proceedings have not been instituted."); Grant, *A Revolutionary Vie of the Seventh Amendment and the Just Compensation Clause*, 91 Nw. U. L. REV. 144, 191-205 (1996).

319. *See generally In re* Ohio Turnpike Comm'n, 131 N.E. 2d 397 (1955) (defining eminent domain as the power of the sovereign to take without the owner's consent for public use); Wescott v. State Highway Comm'n, 138 S.E. 2d 133 (1964); Rose v. State, 123 P.2d 505 (1942) (claiming that the eminent domain power is a fundamental power of sovereigns founded on the law of necessity); Tomasek v. State, 248 P.2d 703 (1952); State *ex rel.* Eastvold v. Superior court of State, 269 P.2d 560; Grover Irrigation and Land Co. v. Lovell Ditch, 131 P.43; Joseph L. Sax, *Takings and the Police Power*, 74 YALE L.J. 36 (1964) (discussing federal takings jurisprudence).

320. The basic argument of this article is not based on the public trust doctrine nor is it developed on that principle. To do so would have required a thorough and careful analysis of the concept to determine its limits and degree of applicability. The argument of this article is differently and independently premised. However, the public trust doctrine might provide another instrument for addressing the power of the state to create property rights in biotechnological inventions. For a discussion of the public trust doctrine, see *Virginia Matthews v. Stanley C. Van Ness*, 471 A. 2d 355 (1984) (where the court described the concept of the public trust doctrine as imposing some limits on the power of the sovereign over certain types of property rights and derivatively creating rights for the general public over private property acquired from the sovereign. The court traced the origins of the concept to Roman law which put certain things out of the reach of private ownership based on natural law); for a seminal article discussing the nature, origins, and scope of the public trust doctrine as applied in the natural resource arena, see Joseph L. Sax, *The Public Trust Doctrine in Natural Resource Law: Effective Judicial Intervention*, 63 MICH. L. REV. 471 (1970).

321. THUROW, *supra* note 1, at ch. 6.

engineering, and all the other activities that the biotechnology industry has become so accustomed to lately. Subjecting the inventive activities of the new industry to the old rules of patentability is what we described above as putting new wine into old bottles. To the extent that the old patentability criteria do not contain sufficient built-in flexibility with checks and balances governing the range of ideas that should be included or excluded from the patent system, a reform is imperative. A manifestation of the need for reform and the degree of disconnect between the patentability criteria and the needs of the biotechnology industry may be gleaned from the U.S. Supreme Court decision in the *Chakrabarty* case.[322] The Court pointed out that there might well be cause for adopting new patentability criteria in the case of biotechnological inventions but concluded that it was the task for Congress.[323] And the facilitation of that task is what this section is aimed at.

There are several goals and objectives that Congress might seek to achieve in any redefinition of patentability criteria. First, there is a need to draw a brighter line between basic research and applied research. It is claimed that in biotechnology research, scientists are merely mimicking nature and not necessarily inventing anything new.[324] Accordingly, genetic engineering is seen as the mere application of what nature has taught to us. The goal of Congress would be to resolve this debate by adopting patentability criteria that are informed by the current state of scientific knowledge.

A second goal of Congress would be to address the questions raised about the desirability and practice of patenting information, data, and research results generated during biotechnological innovation. Redefining the criteria for patentability would also permit Congress to address the issue of access of the general public to basic scientific knowledge, ideas, information, and data. The adoption of new patentability also permits Congress to confront the problem of the proliferation of patents that, individually, are not socially useful but create the anticommons phenomenon.[325] Moreover, one of the major threats to scientific research in universities and other research institutions can be addressed in the new patentability criteria. As pointed out by Dam, the idea that research results, data, and information can be patented poses serious problems for academic institutions that rely on the free flow of information to carry out the mission of teaching, falsifying new ideas and expanding basic and fundamental ideas upon which inventors rely. While Eisenberg has argued for an experimental use exception, addressing the problem at the systemic level would provide a better solution.[326]

Finally, it should be noted that redefining the criteria for patentability might not seem that radical, but it has the potential for a significant negative impact on the

322. 447 U.S. 303, 316 (1980).
323. *Id.* at 317.
324. Davis, *supra* note 31, at 308.
325. Heller & Eisenberg, *supra* note 1.
326. Eisenberg, *supra* note 265.

proliferation of new forms of patents that seem to threaten the ability of economic agents to act in a free enterprise system. The current patent system permits the patenting of various new information formats that results in a concrete tangible result.[327] If this process continues, the proliferation of patents could cripple the very system it was designed to promote. New patentability criteria could set limits that remove the risk of anticommons or the phenomenon of every grain of sand on the beach being individually owned.

However, redefining the nature and scope of patentable subject matter might be an inadequate approach to the explosion and major advances in the biotechnology industry. Like the European Union, Congress might develop a new patent system uniquely tailored to the needs of the biotechnology industry. An industry specific policy would provide the basic essential structure consistent with the major advances in that industry and its peculiar needs. A biotechnology patent system would also facilitate the policy choices advocated above and permit Congress to avoid the problems associated with the current one-size-fits-all policy.

3. *Norm 3: That Which Is Patentable May Nevertheless Not Be Patented on the Grounds of Morality or Public Policy*

The policy framework set out above permits Congress to develop different legislative responses to many categories of the fundamental policy issues raised by biotechnological inventions. While many of those issues relate to ethics, morality, and fundamental public policy, the suggested choices presuppose some *prior* knowledge of the nature, scope, and potential impact of future biotechnological inventions on society. However, no legislature or policy maker can have full knowledge of the nature and potential impact of *all* future inventions. Therefore, notwithstanding all attempts to control the patenting of biotechnological inventions to minimize any negative effects on society, some future inventions might nevertheless pose substantial risk to basic morals, ethics, and fundamental public policy. Norm 3 is designed to give patent policy and legislation some flexibility and ultimate control over what is patented. Thus, even when such inventions might satisfy all the technical requirements of patentability, the patent could still be denied on the grounds of morality or public policy. A public policy exception to patents in general, and to biotechnological patents in particular, would allow the Patent and Trademark Office to reject patents for inventions that not only offend morality and public policy but also would undermine the policies behind any of the prohibited categories discussed above.

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327. *See* State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368 (Fed Cir. 1998) (holding that data can be patentable subject matter as long as they can produce useful, concrete, and tangible results); AT&T Corp. v. Excel Communications, Inc. 172 F.3d 1352 (Fed Cir. 1999) (applying the *State Street* process claim rationale to mathematical algorithm to produce a useful, concrete and tangible results without preempting other uses).

a. Historical Overview of Public Policy

The public policy exception to patents is not a new phenomenon in the World. It is claimed to have existed in the Statute of Monopolies of 1623 in the United Kingdom.[328] This seventeenth century policy appears to have found expression in many modern patent systems which explicitly provide for a morality or public policy exception to patents. An example of a modern patent system that contains the public policy exception is the European Patent Convention (EPC).[329] Article 53(a) of the EPC does not permit the granting of a patent if the *publication* or *exploitation* of the invention would be contrary to "ordre public" or morality.[330] Similarly, the United Kingdom Patent Act of 1977 provides that a patent shall not be granted if the *publication* or *exploitation* of the invention would be generally expected to encourage offensive, immoral, or antisocial behavior.[331] The United Kingdom statute appears to have adopted language similar to that of the EPC so as to comply with and give effect to the EPC. The public policy exception is also captured in the European Directive on the Legal Protection of Biotechnological Inventions (Biotechnology Directive).[332] Under Article 6 of the Biotechnology Directive, "[i]nventions shall be considered unpatentable where their *commercial exploitation* would be contrary to ordre public or morality."[333] It is obvious that there are similarities and differences in the language used in all three instruments. Both the EPC and the United Kingdom Patent Act seem to focus on the publication and exploitation as separate and distinct sources of offending conduct. As such, they seem to provide a broader public policy exception than does the Biotechnology Directive. The former takes the view that the mere publication of an invention might offend some moral code or public policy even if the invention is not exploited. The Biotechnology Directive, on the other hand, seems only concerned with the *commercial exploitation* as the source of offending conduct. Note however, that commercial exploitation is more limited than exploitation in general, since all exploitations need not be commercial. Combining this limitation with the exclusion

328. *See* Peter Drahos, *Biotechnology Patents, Markets and Morality,* 21 EUR. INTELL. PROP. REV. 441 (1999).

329. CONVENTION ON THE GRANT OF EUROPEAN PATENTS (EUROPEAN PATENT CONVENTION) (European Patent Office, 10th ed. 2000).

330. *Id.* Article 53 of the Convention states that European patents shall not be granted in respect of:

"(a) Inventions the *publication or exploitation* of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all the Contracting States;" (emphasis added).

331. Patents Act, 1977, ch. 37 § 1 (Eng.)

332. DIRECTIVE 98/44/ EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions (O.J. L 213, 30/07/1998 p. 0013-0021) [hereinafter Biotechnology Directive].

333. *Id.* Article 6 (1) of the Biotechnology Directive fully states: "Inventions shall be considered unpatentable where their *commercial exploitation* would be contrary to ordre public or morality; however, exploitations shall not be deemed to be so contrary merely because it is prohibited by law or regulation." *Id.*

of the publication exception makes the Biotechnology Directive much more limited than the EPC and the United Kingdom Patent Act.

Arguably the Biotechnology Directive excluded publication because the drafters did not see any morality or public policy issues raised by the mere publication of biotechnological inventions. However, the difference in language between the Biotechnology Directive and the other instruments might have been induced by the desire of the European Union to comply with its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).[334] As a general matter, what practical impact the differences in language would have on a patent system that must seek and maintain consistency between national patent regimes, the ECP, and the Biotechnological Directive is yet uncertain.[335]

There is even a broader acceptance of the public policy exception to patents in the TRIPs Agreement adopted in 1994. Article 27 (2) of TRIPs permits member states to exclude an invention from patentability if doing so is "necessary to protect *ordre public* or morality."[336] Article 27(2) states as follows:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. [337]

The acceptance of the public policy or morality exception under TRIPs by its member states signifies the endorsement of that principle by a large number of states albeit in a limited form. Since TRIPs is only enabling, any perceived limitations

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334. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization Annex 1C, LAW & PRACTICE OF THE WORLD TRADE ORGANIZATION 383 (Joseph F. Dennih, ed., 2000) [hereinafter TRIPs]. Since the Biotechnology Directive came after the entering force of TRIPs, it is only logical that the directive would have tried to comply with TRIPs. TRIPs does not compel the use of the public policy exception. It only requires that the exception be used in a certain way if a member decides to adopt it.

335. The problems that may arise from the differences in the language may be complicated further by the way in which various patent authorities interpret the public policy exception. *See* Amanda Warren, *A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by "Dolly"*, 20 EUR. INTELL. PROP. REV., 445 (1998) (discussing the difficulties presented in achieving uniformity and consistency in the use of the public policy and morality exception when different tests are employed by patent authorities); *see also* Margaret Llewelyn, *The Legal Protection of Biotechnological Inventions: An Alternative Approach*, 19 EUR. INTELL. PROP. REV. 115, 121-23 (1997) (comparing the morality and public policy exception under the EPC and the Draft Biotechnological Directive); Sigrid Sterckx, *Some Ethically Problematic Aspects of the Proposal for a Directive on the Legal Protection of Biotechnological Inventions*, 20 EUR. INTELL. PROP. REV. 123 (1998) (commenting on the ethical issues raised in the first draft of the Biotechnological Directive with respect to the human body, genes, gene sequences, etc.).

336. TRIPs, *supra* note 334, at 398.

337. *Id.*

suggested by the use of the term *commercial exploitation* as opposed to *publication and exploitation* might be handled, in good faith, by signatory states through their domestic legislation. It is important to note, however, that Article 27(2) opens the door for the development of the public policy concept internationally.

b. Public Policy in United States

Unlike the United Kingdom or the European Union, the United States patent statute does not contain an explicit public policy exception. However, the public policy exception is not foreign to U.S. patent law. In the 1817 case of *Lowell v. Lewis*,[338] Justice Story was called upon to decide whether a patent was invalid under the Patent Act of 1793 for not being a "useful invention."[339] In view of the fact that the statute contained no explicit public policy exception, the issue was raised in terms of the usefulness of the invention. Relying on the "utility" concept, Justice Story held that a patent would be invalid if it was "frivolous or injurious to the well-being, good policy, or sound morals of society."[340] In spite of the generality and seeming timelessness of the language used by Justice Story, it is doubtful whether a public policy exception extracted from a statute lacking specific statutory mandate over 150 years ago should control issues of patentability today.[341] Certainly the moral compass of Eighteenth century United States has experienced significant shifts between the 1793 Patent Statute and the current 1952 Patent Act. Within that time period, the atom was split giving impetus to the development of the atomic bomb; the theory of relativity was discovered; the technology for transportation went from horse and buggy to jet airlines; and penicillin was discovered, just to mention a few. The moral and ethical issues raised by these monumental scientific and technological advances were certainly different from those that existed in the early days of the Republic. The moral and ethical issues have, since 1952, been further complicated by the discovery of DNA and the resulting explosion in the advances in biotechnological research. How then could Justice Story's formulation be controlling today without some adjustment? The need for an explicit public policy exception is further demonstrated of the decision by the U.S. Supreme Court in *Diamond v. Chakrabarty*[342] that genetically engineered bacteria and micro-organisms are patentable[343] and the proliferation of biotechnological patents that followed.

In 1998, the U.S. PTO sought to address the issue of the public policy exception in a press release. Allegedly, the PTO received a patent application for a technique

338. 15 F. Cas. 1018 (C.C. Mass. 1817) (No. 8, 568).
339. The Patent Act, ch. 11, 1 Stat. 318 (1793) (cited in *Lowell v. Lewis*).
340. 15 F. Cas. at 1019.
341. THUROW, *supra* note 1, at 120.
342. 447 U.S. 303 (1980).
343. *Id.* at 318.

that combines human and animal embryo to produce a single animal-human embryo or "chimera." Apparently, the patent was filed by a cellular biologist to instigate a public debate over the appropriateness of patenting genetically engineered biological life forms and genetic components.[344] Confronted with the general public outcry against genetic engineering and the publicity generated by the animal-human embryo patent application, the PTO felt obliged to respond. It issued a press release in which it suggested that a patent might be denied on public policy grounds under the *Lowell v. Lewis* decision.[345] To achieve its objectives, the PTO indicated that it would review patent applications with an eye toward seeking compliance with the strict patentability requirements contained in the patent statute, including the requirement that inventions have "utility."[346]

Apparent from the actions of the PTO, there is a definite need for a much more deliberate and explicit policy for rejecting patent applications when inventions offend basic morality or fundamental public policy. The practice of extracting the public policy exception from the interpretation of the concept of "utility," while perhaps necessary, is an inadequate response to a major policy need. The concept of utility does not naturally or necessarily conjure up issues of morality or public policy in its use. Any reliance on it is likely to be strained, and can only provide a temporary solution to a serious and growing problem. It is therefore time for the U.S. Congress to address the need for the public policy exception with a new biotechnology patent regime that is sensitive to the interests and concerns discussed in this Article. Should Congress undertake to provide for an explicit public policy exception to patents, it could benefit from the experience of other countries that have addressed this issue in their domestic legislation. The difficulties and concerns emanating from the explosion of the biotechnology industry are not confined to single nations; they are of a universal character. National solutions and approaches to the public policy exception would be most effective if there is collaboration among nations on this issue.

c. Defining and Adopting the Public Policy Exception

However, adopting the public policy exception to patents is not without difficulties. As a concept, public policy is "vague, nebulous, intractable, and lacks meaningful and consistent contours that can guide its definition and application. Like a chameleon, it seems to be seriously influenced by its environment,

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344. *See* Thomas A. Magnani, *Biotechnology and Medical Devices: Patenting Lifeforms: Chimeras: The Patentability of Human Animal Chimeras,* 14 BERKELEY TECH. L.J. 443 (1999) (describing the nature of chimera inventions, and the legal, moral, and policy concerns raised by such patents); *see also* Jehanne Henry, *Biotech's Bad Boy,* CALIFORNIA LAWYER, Nov. 1999, at 53 (discussing the work of an activists lawyer representing the interest of those opposed to biotechnological inventions and in this case confronting the patentability of the human-animal chimera and legal issues raised by Dr. Newman's application).

345. *PTO Press Release*, 20 EUR. INTELL. PROP. REV. 119 (1998) (News Section National Reports).

346. *Id.*

surrounding circumstances, and the purposes for its use . . . It is like the ghost of Banquo which slips in when least expected."[347] In short, public policy provides a standard that is not only variable with purpose, but also within time and culture.[348] The experience of patent systems that have adopted the public policy exception suggests that determining the nature, content, and scope of the concept is both a difficult and universal task for all. Any attempt by Congress to adopt the public policy could benefit from a study of the experience of other patent systems and from the general use of the concept in the United States as well.

A useful place to start an examination of the nature and content of public policy as applied to patents is the European Patent Convention. Recall that Article 53(a) of the European Patent Convention provided a public policy exception with two prongs: morality or public policy.[349] Starting from a strict interpretive posture, the European Patent Office argues in the Guidelines that the exceptions to patentability should be narrowly construed.[350] Accordingly, the term *ordre public* is given its literal meaning, "public disorder" and only inventions that are "likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour" would be excluded from patentability.[351] The Guidelines offer as an example of an invention that might incite public disorder, the technology for a letter-bomb.[352] Such a narrow and literal meaning ascribed to the term *ordre public* distinguishes it from the more inclusive concept of public policy. Note also that the Guidelines do not explicitly define morality nor do they distinguish morality from *ordre public* though there is language suggestive of the difference. For instance, the statement that the Article 53(a) exception might be applicable if "it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable" seems more directed at morality than *ordre public*."[353]

The decided cases, on the other hand, seem to treat the two exceptions separately.[354] In the *Plant Genetic Systems* case, the Board of Appeals drew a clear distinction between *ordre public* and morality.[355] According to the Board, *ordre public* is generally understood as being applicable to inventions likely to threaten

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347. *See* Kojo Yelpaala, *Restraining the Unruly Horse: The Use of Public Policy in Arbitration, Interstate State and International Conflict of Laws in California,* 2 TRANSNAT'L LAW. 379, 380-81 (1989).

348. Robin Nott, *The Biotech Directive: Does Europe Need a New Draft*, 17 EUR. INTELL. PROP. REV. 563, 565 (1995) (discussing the morality prong of the public policy exception).

349. *Supra* note 330 and accompanying text.

350. *See* Guidelines for Examination in the European Patent Office, (European Patent Office, 2000), C-IV 3.

351. *Id.*

352. *Id.*

353. *Id.*

354. *See* Amanda Warren, *A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by "Dolly"*, 20 EUR. INTELL. PROP. REV. 445 (1998) (discussing the morality criteria applied by EPO in addressing the public policy exception under Article 53 (a)); EPO, *Case Law of the Boards of Appeal* (last modified Aug. 10, 1999) < http://www.european-patent-office-org/case_law/english/I_B_I.htm [hereinafter *EOP case law*] (providing a summary of the case law addressing the criteria and their application to various cases).

355. *Plant Genetic Systems NV (PGS)* [1995] EPOR 357, at 366.

public security and the physical integrity of individuals as part of society. The concept would also apply to inventions the exploitation of which might induce the breach of public peace or social order such as acts of terrorism. Finally, the Board argued that the concept of *ordre public* is also generally understood as excluding from patentability inventions that pose a serious risk to the environment.[356] It is apparent from the preceding discussion that not only does the concept of *ordre public* have multiple meanings but also that, in practice, it is applied to a wider range of circumstances than its literal translation might suggest.

Outside the patent system, public policy also has many meanings.[357] In the famous case of English case of *Egerton v. Brownlow*, Justice Baron Parke ascribed an ordinary meaning to public policy and described it as political expediency or that which is good for the common good of the community.[358] The nature of public policy has also been the subject of judicial commentary in the United States outside the patent system. According to Justice Story, "'Public Policy means anything which tends to undermine that sense of security for individual rights, whether of personal liberty or private property.'"[359] In the case of *Loucks v. Standard Oil*, Judge Cardozo defined public policy as embodying, "some fundamental principle of justice, some prevalent conception of good morals, [or] some deeply rooted tradition of the common weal."[360]

The definitions outlined above appear to share some basic characteristics in that they all seem to address the basic and fundamental value system of society, some conception of the general good, or right and wrong. To the extent that this characterization is accurate, these definitions have something in common with Justice Story's formulation of the public policy exception to patents in *Lowell v. Lewis*. He stated that to be patentable an invention must not be "frivolous or injurious to the well-being, good policy, or sound morals of society."[361] Like the other formulations of the public policy exception, the statement by Justice Story is necessarily general and not very helpful in specific situations without further guidance. To remedy that situation, Justice Story provided examples of inventions that would not be patentable on public policy grounds. According to him, "a new invention to poison people, or to promote debauchery, or to facilitate private assassinations, is not a patentable invention."[362] What might one learn from the

356. *Id.*; *see also Harvard/Onco-mouse* [1990] EPOR 501, 513 (where the Board of Appeals stated that in addition to the suffering of transgenic animals, considerations of the danger genetically manipulated animals might pose to the environment if released should be taken into account in determining patentability under Article 53(a) of the EPC).

357. Yelpaala, *supra* note 347, at 388-94 (discussing eight different ways of defining public policy within the context of conflict of laws).

358. 10 Eng. Rep. 359, 409, 4 H.L. Cas. 1 (1853).

359. Safeway Stores v. Retail Clerks Int'l Ass'n, 261 P. 2d 721, 726 (1953) (citing and adopting the definition of Story's work).

360. 120 N.E. 198, 202 (1918).

361. 15 F. Cas. at 1019.

362. *Id.*

examples given by Justice Story? What types of biotechnological inventions would arise to the level of moral repugnance and condemnation intimated by these examples and must be excluded from the patent regime? Would the application for a patent of the "chimera" fall into the category condemned by Justice Story? These are some of the questions Congress would have to answer in its approach to the public policy exception to patents, even if it were minded to apply Story's formulation of public policy.

It should be noted that much of the discussion of the public policy exception is cast in the negative. Public policy is invoked to stop the patenting of an invention that is abhorrent, unacceptable, morally repugnant or offends our deeply rooted value system. However, public policy has a positive side, which may play an important role in the case of biotechnology. It might be invoked for some good to rid the world of hunger, to feed starving children of the world or to make a medical breakthrough available to all humanity. In any such case, the patent application may be rejected on public policy grounds, not because the invention poses a threat to society or has any moral or ethical negatives, but because it holds so much promise for so much good that its best use to humanity would be in the public domain. Many advances in seed genetics and biomedical research would easily fall into the category of inventions and discoveries to which the positive use of public policy would be appropriate.

For a public policy exception to be useful, it would need to remain open-ended, but at the same time be guided by concrete examples and suggestions of biotechnological inventions that might run afoul of this exception. Congress might invite the informed opinion of the scientific community, social scientists, and those considered to be guardians of the moral, philosophical, and religious values of society. The views of the latter group might be perceptual but they will provide a useful and essential balance against the more objective opinions of scientists and social scientists in developing the concrete examples. The subsequent use of the public policy exception would be guided by the type of moral condemnation inherent in those examples. Of course, this is the approach suggested by Justice Story in *Lowell v. Lewis*; but it has also been used by other patent systems. For instance, Article 6 (2) of the Biotechnology Directive provides the following examples of inventions that are not patentable under its public policy exception: "(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man, animal, and also animal resulting from such processes."[363]

Congress might decide to take a different approach than that of the European Union or any other foreign patent system with the public policy exception. Whatever

363. Biotechnology Directive, *supra* note 332.

approach Congress adopts, a well-articulated public policy concept supported by a representative array of examples would be indispensable if the U.S. patent system is to avoid problems confronting the EPC in the use of the public policy exception.[364]

d. The Public Policy Exception and the Terminator Seed

The absence of a deliberate and well-articulated public policy exception to biotechnological inventions poses certain risks to the application of that concept based on an implicit reading of the patent statute. A good example of an invention that raises serious public concerns of a very fundamental nature, apparently missed by the PTO under the implicit reading of the U.S. patent statute, is the Terminator Seed technology.[365] Whether the PTO ever considered the public policy implications of the Terminator Seed technology when the application for the patent was made remains unclear. It is also unclear whether the PTO would revoke the patent under the public policy exception. What is clear, however, is that the validity of the Terminator Seed technology is doubtful under any reasonable definition of public policy. It is difficult to see how the PTO did not reject that patent on public policy grounds if, as the PTO believes, *Lowell v. Lewis* is still good law.

It may be recalled that the patented Terminator Seed technology produces a seed that sterilizes its offspring. As argued earlier, biotechnological inventions involving seed varieties might be excluded from the patent regime as a general policy because of the importance of that science to human needs for food and survival. If however, Congress, in its infinite wisdom, decided otherwise the question is whether the terminator technology should nevertheless be covered by the public policy exception as discussed above? We propose to examine that question below.

The express purpose for which Congress is empowered to enact patent laws is to promote science and the useful arts. Implicit, if not explicit, in the Framers' design was the expansion of human knowledge through the patent system. This fundamental objective of the Framers seems to be undermined if the *purpose or effect* of an invention is to stultify the ingenuity of millions of farmers and traditional seed breeders who have practiced that art openly and freely for thousands of years. Granted that the Terminator Seed technology does not compel anyone to use the Terminator Seed; that, however, should not be the basis for determining its patentability. An invention that has as its motive, explicit or implicit, the destruction of a source of human ingenuity, the spread of knowledge, and the ability to tinker with ideas in nature should not be patentable. An invention that would preclude the use of natural techniques to improve on the quality, variety, or other characteristics of seeds by large numbers of people seems nefarious and to undermine the very

364. *See* Warren, *supra* note 354, at 445-48.

365. *Supra* notes 228-230 and accompanying text discussing the Terminator Seed technology.

goals sought to be achieved under the patent regime by the Framers. The fact that Monsanto has indicated that it will not practice the invention only goes to confirm the seriousness of the danger the technology presents.[366] If Monsanto believes that the Terminator Seed technology should not be practiced then perhaps the patent should be revoked on public policy grounds.

There are other reasons why the Terminator Seed technology should not have been patentable under the public policy exception. With its own built-in biological patent protection, the actual patent protection extends beyond the statutory period for non-scientists. Besides, the invention creates the potential for absolute monopoly. The seed buyer must always return to the seed producer for its seasonal and other seed needs even after the patent has expired because the inventor can extend the protection indefinitely through self-help. An indefinite duration of protection would invite monopolistic output restrictions, price enhancement, and the abuse of dominant position. Moreover, the Terminator Seed technology has the potential for serious environmental damage. Through cross-pollination, the Terminator Seed technology could spread from farm to farm and into other varieties of seeds. Given that the Terminator Seed technology can be combined with ordinary non-patented seeds and with other genetically engineered technologies such as the herbicide-resistant plant technology, the spread of the Terminator Seed technology would be virtually unstoppable. Imagine the thousands of different varieties of maize in Mexico being exposed to the Terminator Seed technology from a few farms. With time the technology could threaten the bio-diversity of seeds in Mexico.[367]

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366. One should be careful about what to make of any statements by Monsanto on the issue of exploiting the Terminator technology. Monsanto apologized for its attitude and position on the technology but one should be careful about its genuineness. According to *Fortune*, Monsanto might have little choice in the matter. *See* David Stipp, *The Voice of Reason in the Global Food Fight*, FORTUNE, Feb. 21, 2000, at 164 (explaining that Monsanto had sought advice from Mr. Gordon Conway, a scholarly British ecologists who severely rebuked Monsanto and went public with his advice subsequently Monsanto followed with the apology); *see also* Michela Wrong, *Monsanto Apologises for 'Arrogance'*, FIN. TIMES, Oct. 7, 1999, at 9 (The Chairman of Monsanto, Mr. Robert Shapiro, stunned the audience of environmentalists in the United Kingdom with an apology for corporate arrogance); Nikki Tait, *Monsanto Pledge on Sterile Seeds*, FIN. TIMES, Oct. 5, 1999, at 1 (explaining and discussing the commitment of Monsanto not to commercialize the terminator technology). As part of its efforts to improve its public image Monsanto also announced that it would make the working draft of the genetic structure of rice readily available to all. This announcement was made in China and has been well received. *See* Michela Wrong, *Monsanto Opts to Work with the Grain*, FIN. TIMES, Apr. 11, 2000, at 11 (discussing the decision of the Monsanto to make the working draft of the genetic structure of rice available and the importance of such action as a model for other companies), Justin Gillis, *Monsanto to Donate Patents for Rice*, THE SACRAMENTO BEE, Aug. 4, 2000, at A6 (Monsanto has decided to make some of its patent rights in rice readily available to speed up the genetic modification of rice).

367. The threat to the seed varieties in Mexico has been commented upon by journalists. *See, e.g.*, Anthony DePalma, *The 'Slippery Slope' of Patenting Farmers' Crops*, N.Y. TIMES, May 24, 2000, at A4 (discussing the risk to the about 20,000 varieties of maize in Mexico from patenting plant genes which will put the maize in the hands of private companies and universities which cannot always sort their research priorities); Henry Tricks & Andrea Mandel-Campbell, *Mexico's Farming Habits under Pressure from Transgenics*, FIN. TIMES, Oct. 12, 1999, at 8 (explaining that the 24,000 varieties of maize in the cradle of corn might be in jeopardy because the rich diversity of corn is under threat from imported genetically modified corn).

While the risks associated with the Terminator Seed technology are not the same or as dramatic as those associated with the technology for poisoning people or private assassinations, they nonetheless pose another type of risk to human survival and the environment. The potential impact of the Terminator Seed technology could be more severe, diffuse, and more pervasive than the technology for private assassinations. The user is more easily forewarned about the effects of a technology for private assassinations whereas the potential impact of the Terminator Seed technology is not that obvious to the user at the outset.

If the goal of the public policy exception is to protect society from the negative impact of inventions, it would serve that purpose very well if it is applied to revoke the Terminator Seed technology, and to prohibit its use.

VI. THE INCENTIVE TO INVENT AND THE EMPLOYMENT CONTRACT

Current intellectual discourse on the justifications for the patent system and the protection of ideas is that without such protection there would be too few new ideas invented or discovered.[368] The theory is that human ingenuity is best engaged if some potential private gain is dangled in front as the carrot for creative effort. Thus, the incentive to invent seems to focus on the individual as the center of government policy. The suggestion that the grant of a patent to the individual inventor would spur inventive activities is somewhat misleading. The patent system is designed to reward corporations and the management of inventive resources and only secondarily, the inventor.[369]

The idea of a starry-eyed, solo and rugged tinkerer burning the midnight oil in his attic to come up a spectacular invention is mostly illusionary, if not imaginary, particularly in the biotechnology industry.[370] The notion of an individual with an innovative biotechnological invention sketched out on a piece of brown paper is equally less likely. For sure, some individual inventive activity takes place but such individual genius does not easily find expression outside the biotechnology industry or outside elaborate facilities or laboratories which are expensive to establish and maintain.[371] Only corporations, universities, research foundations, and institutions that are sufficiently funded can support such activities and even then the cost can still be too high. The high cost and risk associated with biotechnology research has prompted the formation of alliances, networks, and collaborations among corporations to share the high cost of research and development.[372]

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368. POSNER, ECONOMIC ANALYSIS OF THE LAW, *supra* note 256.

369. The 1941 report by Professor Hamilton pointed out the important role of the corporations in the creation and maintenance of the patent system. That role has magnified given that the resources for inventive activities in biotechnology are mostly in the hands of corporations and other institutions.

370. PATENT AND FREE ENTERPRISE, *supra* note 291, at 153.

371. *Supra* note 264-271 and accompanying text.

372. Stuart, *supra* note 208.

No matter how complex or how well equipped a research institution might be, it would still need at least one individual to function. Corporations do not invent; people do. Machines do not invent; people do. Neither machines nor corporations are tinkerers, rather it is people who tinker. Thus, at the end of the day, any policy that is designed to create the incentive to invent might best be directed first at the tinkerer, the starry-eyed dreamer, or the bespectacled nerd and only secondarily at the corporation, the university, or the research institution.

The motivation to invent or discover is a complex one. Inventors might be motivated by peer pressure, fame, bragging rights, idle curiosity, financial rewards, or a host of other reasons. Designing a policy to capture any of these motivations is *not easy* but designing a policy that focuses on the funding sources: corporations, universities, and research institutions is also *too easy*. On the other hand, the policy might be aimed at the link between the starry-eyed tinkerer and the corporation or university which is the *employment contract*. If the goal of the policy is to generate as many inventive ideas as possible, it might be useful to investigate the question of whether the employment contract between the inventor and his employer serves that purpose.

Current policy makers appear to assume that inventors and scientists, as rational economic agents, would only accept terms and conditions of employment most beneficial to them. If they are satisfied with the employment contract they will be encouraged to be inventively productive. Policymakers also seems to assume that the employer will impose only those terms and conditions most conducive to inventive conduct. Both of these assumptions may be false.

First, is the issue of the unequal bargaining power between the parties. Most inventors have a weak bargaining position in relation to their corporate or other institutional employers. A disparity in bargaining power may influence the rewards and penalty terms of the contract and ultimately the incentive to invent. Second is the question of the mobility of scientists and researchers. While the employment contract may not prohibit mobility of employees the conditions for resigning may effectively put clamps on the inventive capability of departing employees.[373] Third, the type of secrecy agreements and termination conditions imposed on departing employees would have an impact on their inventive capacity. Finally, investigating the types of injunctive relief available to employers before the courts against departing employees would be useful. The more liberal the injunctive relief, the more restrictive the employment contract is likely to be of mobility and consequently of inventive activities. Thus, the employment contract might pose a greater burden on the incentive to invent than one might think. Whether this is the case, and if so to what extent, would become part of the task for Congress to investigate.

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373. Secrecy contracts and non-competition provisions might limit unnecessarily the inventiveness of a departing employee.

A. Summary

Given the importance of the biotechnology industry to many aspects of life and the need for greater access to new ideas, it might be time for Congress to reexamine the incentive to invent policy from a new and different direction. The goal of such a new policy is not to replace any incentives to corporations, universities, or research institutions but, rather to make the inventive individual its primary focus by confronting the conditions under which individual inventive activities take place.

VII. Rethinking the Policy of Access—The Usufruct to the Rescue?

Inherent in any patent system is the tension between the right of the public to have free and unimpeded access to all ideas and the right of inventors to exclude all others from patented ideas. The notion of creating property rights in things as fluid and ephemeral as ideas seems inconsistent with the essential role they play in the coherent and stable organization of human society. The tension is magnified the greater the number and rate at which ideas enter the patent regime as private property, even if for a limited duration of time. The problem of access is particularly serious in the case of the biotechnology industry because of the proliferation and multiplicity of patents. As discussed earlier, an ever increasing number of patents are issued covering various forms of genetic engineering, gene sequences, biomedical information, research results and their supporting data. These patents systematically decrease the pool of available knowledge in the public domain and, as the patent system continues to be permissive, the problem will be magnified.

There are several reasons why there is concern over the decreasing access to an increasing number of new discoveries and inventions in biotechnology. First, as pointed out by Dam, the line between basic and fundamental research and applied research is very thin.[374] A permissive patent system that allows patents for ideas that properly belong to the public domain is likely to impose an unreasonable burden on society's need for access to all ideas. Second, patenting research data, results and information seem to run contrary to the long established tradition of academic institutions having an open system of access to ideas. The tradition of openness facilitated the falsification of ideas and the propagation of knowledge.[375] Third, the proliferation of patents have also created a problem of access since the transaction cost of organizing a multitude of patented information to be useful would outweigh any potential benefits.[376] Finally, there is an undertone of nervousness that society is worse off with a permissive patent system. The view might be held that free

374. Dam, *supra* note 263.
375. *Id.*
376. Heller & Eisenberg, *supra* note 1.

access to ideas of any description at all times is part of the grant to humanity to use and teach its offspring for the good of mankind.

Given the existing patent system, various solutions to the problem of access have been suggested. Prominent among them is compulsory licensing under which others can practice a patented invention under certain statutory conditions and requirements. Compulsory licensing has been used by the United Kingdom to improve access to patents.[377] To alleviate the problem of access to researchers and those interested in scientific investigation an experimental use exception has also been suggested.[378] The solution to the lack of access might lie in patent pooling whereby all patents are put in a pool and made available to all within the pool or based on an agreement among the members of the pool.[379] Patent pooling might, however, pose other problems of access. The terms of the pooling agreement may admit only those with inventions or with inventions of certain characteristics. Moreover, patent pooling might raise serious antitrust questions. Yet another approach may be to put all inventions into a clearing house from which licenses can be obtained similar to what is found in the music industry. However, a clearing house for biotechnological inventions would also have to pass some anti-trust test and does not guarantee access.

This Article argues that a new regime of patents is necessary to address the needs and concerns of society over the biotechnological inventions. These suggested solutions, while relevant, seem to confront the issue of access by dancing around it. One solution Congress might consider that would guarantee an easier and wider range of access to patented ideas than those discussed above is to apply the *usufruct* to patents. That is, Congress might make the grant of biotechnology patents subject to the *usufruct.*

Claimed to have originated in Roman law, the usufruct is defined in the Justinian Code as the "right to use and enjoy the property of others without injuring its substance."[380] The right to enjoy the property includes the right to take the fruits from it.[381] Put differently, the right in the usufruct is in the material part of the thing which cannot be consumed or destroyed in the very fact of use.[382] Should the use and enjoyment of the usufruct compromise the material existence of it, the usufruct ceases to exist.[383] The existence of the usufruct and the rights and duties of those affected by it are dependent on various technical conditions that cannot be pursued here. The task at hand is merely to introduce the concept as a solution to the problem of access to patented ideas.

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377. Case 19184 Pharmon BV v. Hoechst AG, 1985 ECJ Celex Lexis 3183.

378. Eisenberg, *Experimental Use*, *supra* note 265.

379. Heller & Eisenberg, *supra* note 1.

380. S.P. Scott, Corpus Juris Givilis, Title IV 227 (1973).

381. *See* WILLIAM A. HUNTER, ROMAN LAW 224 (1994 Reprint), PRINCIPLES OF ROMAN LAW, *supra* note 64, at 356.

382. HUNTER, *supra* note 381, at 226; PRINCIPLES OF ROMAN LAW, *supra* note 64, at 356.

383. HUNTER, *supra* note 381, at 226; PRINCIPLES OF ROMAN LAW, *supra* note 64, at 356.

From its ancient origins, the usufruct migrated into civil law systems including that of the State of Louisiana[384] and also seeped into the common law in the form servitudes, and other burdens on property. Elegant as its Roman law origins might be, the usufruct seems to have evolved independently in non-western collectivist societies with the emphasis on developing techniques for managing access to common property, communal resources, or private property. Because these societies have had extensive experience with the usufruct, in addressing needs similar to those confronted by the current intellectual property regime, an investigation of the concept and its evolution in those societies might shed some light on its possible use in the intellectual property regime of the United States. One region of the world where the usufruct has evolved and has become well entrenched in the property regime is Africa. In particular, the usufruct appears to have existed in the land tenure systems of African societies for time immemorial. Its importance in the customary property regime of Africa was explained by the Privy Council in the famous case of *Amodu Tijani v. The Secretary, Southern Nigeria.*[385] Speaking for the Privy Council, Viscount Haldane described the usufruct as:

> "a mere qualification of or burden on the radical or final title of the sovereign where that exists. In such cases the *title of the sovereign is a pure legal estate, to which the beneficial rights may or may not be attached. But the estate is qualified by a right of beneficial user* which may not assume definite forms analogous to estates. . . ."[386]

According to Viscount Haldane, the African usufruct was influenced by some elements of the law of trust. The holder of the legal title could enjoy the property but could not exclude other members of the community with the beneficial interest from using and enjoying it. The usufruct was most prominently used in communal property. As was further explained by the Privy Council, the community has "the possessory title to the common enjoyment of a usufruct, with customs under which its individual members are admitted to enjoyment, and even to a right of transmitting the individual enjoyment as members by assignment inter vivos or by succession."[387]

The concept of the usufruct, as explained by the Privy Council, affected the entire concept of property in African societies.[388] Unlike the Blackstonian power theory of property, with its focus on absolute and despotic dominion over a thing

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384. The Civil Code of Louisiana in Article 535 states: "Usufruct is a real right of limited duration on the property of another. The features of the right vary with the nature of things subject to it as consumable or non-consumables." *See* A. N. YIANNOPOULOS, LOUISIANA CIVIL LAW TREATISE. 10 (1989).

385. Amodo Tijani v. Secretary, Southern Algeria, 2 A.C. 399 (Court of Appeal 1921).

386. *Id.* at 403 (emphasis added).

387. *Id.* at 404.

388. An example of the application of the usufruct to the land tenure systems of African societies can be found in Ghana. *See* Gordon Woodman, *The Scheme of Subordinate Tenures of Land in Ghana,* 15 AM. J. COMP. L. 457 (1967) (explaining the nature, scope, and details of the rights of the usufruct in Ghana).

buttressed by the right of exclusion, *the regime of usufructaury rights is concerned less with the power of exclusion and more with the right of access and use.* A property regime driven mostly by the need to use and the right of access is not unique to Africa. According to the Privy Council, the usufruct could be found in India, among the Indians of Canada (Native Canadians), and even in Scotland.[389] The question is whether the intellectual property regime of the United States would better serve the needs of society if Congress adopted the usufruct as the guiding light in designing solutions to the problems in the biotechnology arena.

It is apparent from this brief discussion of the usufruct and given the nature of ideas that the usufruct is well suited for the regime of intellectual property. Earlier sections of this Article notes that ideas have the characteristics of a "public good" in that they are diffusible and inexhaustible with multiple and simultaneous use. Unlike many tangible properties, ideas can be used concurrently over and over again by different people without ever depleting them. This inexhaustibility characteristic makes ideas most suitable for the application of the usufruct. As discussed earlier, under Roman law the usufruct can only exist if the property cannot be consumed or depleted by the mere use of it.[390] Ideas by their very nature are incapable of depletion with use; thereby making them perfect for the use of the usufruct. Concern may be expressed that the usufruct would diminish the creative drive thereby reducing the total number of ideas made available to a usufructuary system. Such concerns go to the incentive to invent not the need for access and can be appropriately addressed in the relevant policy considerations.

However, the fact that ideas have the characteristics of a "public good" is not sufficient reason for the adoption of the usufruct. An important supporting policy reason is the importance to society of access to biotechnology ideas. As noted in our discussion of the classical jurists, certain types of property were excluded from the property regime because of the important role they played in society. We have also pointed out that the mission of the biotechnology industry appears to be tinkering with life and existence. Such experimentation has produced and will continue to produce ideas that are critical to human existence and the ecological balance of the environment. Access to these ideas may be critical to the survival of humanity and the usufruct could play an important role.

The application of the usufruct to biotechnological inventions might be approached with the understanding that not all biotechnological inventions have the same characteristics or have the same level of importance and potential impact on society. Some inventions may involve real breakthroughs, others may be mere extensions of existing knowledge; yet others may tackle the most stubborn human diseases. A sound usufructuary policy might draw distinctions between inventions. A single policy would not suit an industry that has shown remarkable vibrancy and

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389. 2 A.C. at 404.

390. HUNTER, ROMAN LAW, *supra* note 381, PRINCIPLES OF ROMAN LAW, *supra* note 64, at 356.

unpredictable advances in many fields. However, the need for sensitivity in the application of the usufruct does not diminish the relevance of the usufruct to the biotechnological inventions.

While the focus of this Article is on the biotechnology industry, it should be pointed out that the application of the usufruct need not be limited to that industry. Indeed, the usufruct is also very suitable for industries where the inventive ideas are fluid and have a very short shelf life. Such is the case with many inventive ideas in the computer industry. Computer technology, hardware and software, has a very high rate of technological obsolescence. Patents that are obtained for seventeen years may be useless within three or two years if not sooner. Engineers and software designers continuously push the technological envelope building on old techniques and making new breakthroughs. Moreover, in today's economy, knowledge is being widely diffused at an ever increasing rate. As such, new ideas can effectively remain proprietary only for a short time. A regime of property rights that locks up ideas in the domain of exclusivity may be detrimental to society particularly when those ideas have been "dumped" as obsolete. Allowing access and use would permit others to tinker with those ideas and perhaps come up with better and improved results.

A. Summary

The central focus of this section is to suggest another paradigm shift from the Blackstonian power theory of property, particularly as it relates to ideas, to one that stresses less exclusion and more inclusion. The shift demands fewer restrictions to ideas by owners and greater access and use by non-owners. As argued throughout this Article, a concept of property that is substantially dominated by the power of exclusion is neither historically accurate nor socially beneficial. Thurow recently suggested that the continuing vitality of knowledge based capitalism depends on the vigor with which intellectual property rights are protected.[391] However, that existence of knowledge-based capitalism is threatened by the current intellectual property regime. An intellectual property regime that is as expansive as it is dominating in its creation and enforcement of rights would undermine the creation of the very knowledge on which capitalism relies so heavily. The power theory of property is therefore particularly troublesome as applied to ideas in general and biotechnological inventions and discoveries in particular.

If however, we are wedded to the idea of ownership of ideas, and also concerned about the dangers and the negative impact likely to be created by property rights in ideas, the usufruct offers a solution. Legal title to specific biotechnological discoveries and inventions can be held by their respective inventors or discoverers but the rest of society has the right to use them. This would make the experimental

391. THUROW, *supra* note 1, at ch. 6.

use exception and other solutions redundant. Congress could adopt a policy whereby all or certain categories of biotechnological inventions could be patented subject to the usufruct.

Naturally, the adoption of a usufruct-based policy should be informed by a thorough analysis of the nature, scope and impact of the usufruct on other policy concerns. Any discussion of the policy considerations necessary for the usufruct and its potential impact on secrecy, the incentive to invent, and other related topics must await some future endeavor.

VIII. CONCLUSION

In the history of the world, seldom has a single event presented humanity with so much promise for so much good or so much harm as did the discovery of DNA. It may be argued that the single most important invention of the millennium was the printing press because it irreversibly revolutionized human social, political economic organization. However, as we enter the next millennium, the discovery of DNA holds perhaps a deeper promise for humanity than did the printing press. DNA science has irreversibly opened the gates to a deeper understanding of the mysteries of life itself at the cellular level. It has given birth to an industry totally committed to the decoding of the elements of all forms of life at their most fundamental or basic level. With the mysteries of life and living organisms decoded, human civilization will have entered into a new era, in which life forms can take on new and specific designer characteristics. Parents can choose the perfect children and nations can develop the perfect race. In this new era, life could be prolonged by altering the genetic structure of people to eliminate defective genes; genetic engineering could lead to the development of a cure for some of the most terrible human diseases such as cancer, Alzheimer's disease and cystic fibrosis. Not only could human life forms be cloned but also the creation of human life itself *de novo* is not a remote possibility any more. With the Human Genome mapped, a brave new world of opportunities exists for using the power of genetic engineering to design specific and targeted vaccines or pharmaceutical products to combat the most stubborn diseases. But these advances may be only the tip of an iceberg. Future developments and advances may lead to even more revolutionary and unfathomable discoveries yet.

The advances and opportunities presented by the biotechnology revolution are not limited to biological life forms, however. They extend to all life forms including, in particular, those most critical to agricultural production. Through genetic engineering, new seed and plant varieties are being created with specific designer characteristics, such as high protein, herbicide-resistant, vitamin enhanced, or better taste. Properly used, genetic engineering in agriculture could revolutionize modern agriculture. It could be a powerful instrument for eliminating the curse of world hunger and malnutrition.

However, the advances made in biotechnology pose several new and significant moral, ethical and legal questions for humanity. One of the questions raised is whether discoveries and inventions of such momentous importance to life and living should be the subject of private property. Indeed, the very mission of the biotechnology industry of uncovering, at the cellular level, the secrets of life—including creating life forms—has serious implications for property rights. Private ownership of the secrets of life and living organisms carries with it awesome powers over life that could transform the human social, political and economic organization as we know it. Unwittingly, the property regime has the potential for creating a human "god" and we are not sure of how that person might exercise any acquired "godly" powers. Thus, biotechnology presents perhaps the best case for revisiting the concept of property in ideas. Such revisionism must be sensitive to the dynamic and complex nature of the industry, its activities and the research results. This Article provides an analytical framework for addressing the question of ownership of biotechnological discoveries and inventions within the context of an intellectual property regime.

Relying on a historical account of the nature, classification, and justifications for property, we have found that certain things have always been excluded from the property regime because they better serve the needs of society in the public domain than in the hands of private owners. We have also argued that the mission and nature of biotechnological discoveries and inventions invites a journey back into history and an inquiry into whether certain inventions and discoveries should likewise be excluded from the regime of private property. Similarly, certain biotechnological inventions fall into the category of things to be excluded from the regime of private property. Even if biotechnological inventions should be owned there is need for a much more robust intellectual property regime with better criteria for determining patentability. The current patent system which was designed for mechanical and simple devices is ill-suited for the complex and dynamic issues generated by biotechnological inventions. The solution to such a systemic problem lies not in tinkering at its margins but in a total regime transformation by Congress. Any reforms that fall short of an overhaul of the current structure of patent policy would be inadequate. In short, *dancing around the fire may contain it but does not extinguish it.*

The Article presents a framework for Congressional action instructed by the nature of the industry and need to manage scientific advances for the good of society. First, it argues that a separate patent policy and legislation for biotechnology is necessary to confront the very special issues raised. Second, as a part of the structure for such policy, Congress should adopt what may be termed a hierarchy of norms for addressing the question of patentability. Under the first norm, Congress should create a category of things that cannot be owned and therefore are not patentable. This norm is rigorous because those things that cannot be owned cannot even be the subject matter of enforceable secrecy agreements. The second norm defines those things that can be owned and on that account are patentable.

However, being patentable does not mean that every patentable invention should be protected by a patent. Certain inventions may be specifically excluded from patent protection or put in the public domain to achieve specific policy goals. Other inventions may be excluded from patent protection based on a new set of patentability criteria. The third norm provides for the public policy exception to patents. Even when an invention satisfies all the elements of patentability that invention may still be excluded from patent protection on public policy or morality grounds. Since one cannot predict or foresee every type or category of future inventions, a public policy exception is necessary to ensure that there is a final check on the patenting of inventions. A final check provides an opportunity for ensuring that inventions that pose certain unacceptable risks or advance certain fundamental policy objectives are excluded from the patent regime on a case by case basis.

If one of the concerns of any patent policy is to create a balance between the incentive to invent and access to new ideas Congress might consider a new approach to both concerns. In the case of the incentive to invent, it might be useful for Congress to focus on the individual who is always at the center of any inventive activity by focusing on the employment contract between the inventor and the institution for which the inventor works. Such attention would allow the policy to ensure that private bargains do not undermine the incentive to invent. With respect to the issue of access to ideas, one approach Congress might adopt is to employ the Roman law concept of the *usufruct* which merely allows one to use that which belongs to another. Thus, all patents, or certain patents of a specific category, might be granted subject to the *usufruct*.

In view of the fact that biotechnology presents certain opportunities and risks, a systemic change is necessary to ensure the opportunities and risks are identified and managed effectively for the benefit of humanity. Trying to manage the biotechnological inventions within the current patent policy and legislation is likely to create confusion and unnecessary fear of the potential harm resulting in unwarranted retrenchment. In a new policy, Congress will be able to confront and address the risks in a rational manner so that the power of the biotechnology industry can be unleashed in the most fruitful manner for the benefit of all.