A Biotechnology Patent Pool: An Idea Whose Time Has Come?

David B. Resnik, J.D.*

* Professor of Medical Humanities, Brody School of Medicine, East Carolina University

Abstract: This paper discusses the idea of forming a patent pool in order to address some of the licensing problems in the biotechnology industry. The pool would be an independent, non-profit corporation that would manage patents and have the authority to grant licenses. The patent pool would not be a purely altruistic venture, since it would charge licensing fees. The pool would charge the market price for licensing services and reimburse patent holders for licensing activities. The pool would also provide patent holders with a minimum income based on a percentage of royalties generated from the pool. The pool would include patents on a variety of materials and methods that play an important role in biotechnology. It would also be international in scope, with the power to grant licenses in different countries.

1. Introduction

The main rationale for the patent system is that it promotes scientific progress and technological development by providing incentives for inventors, investors, and entrepreneurs. Under the “patent bargain” the government grants inventors a private right, i.e. ownership of the invention for 20 years, in exchange for a public good, i.e. their disclosure of information about their invention in the patent application. In theory, granting inventors a limited monopoly on their inventions provides them with an attractive alternative to trade secrecy and encourages the dissemination of scientific and technical information.[1]

The patent system, like any human invention, has various shortcomings and flaws. In some circumstances, patenting may hinder progress and development by allowing patent holders to obstruct the flow of scientific and technical information. One of the most persuasive arguments against patents on materials and methods used in biotechnology is that problems related to the licensing of patented inventions could impede discovery and innovation in biomedicine, which would result in an “anti-commons.”[2] Various writers and agencies have proposed a variety of solutions to these potential problems,[3] while others have argued that there should be no patents at all on some types of biological materials, such as human DNA sequences.[4]
On December 5, 2000, the U.S. Patent and Trademark Office (USPTO) distributed a white paper that developed the idea of a patent pool for biotechnology.[5] The paper outlined some of the benefits and risks associated with patent pooling, as well as some legal (i.e. antitrust) restrictions on pooling. The USPTO paper concluded that pooling is a “win-win” situation that could “serve the interests of both the public and private industry.”[6] While a patent pool for biotechnology sounds good in theory, one might wonder whether it would work in practice. Assuming that the main obstacles to patent pools in biotechnology are economic rather than legal, would enough biotechnology patent holders have sufficient economic incentives to join and sustain a patent pool?

This essay will defend the idea of patent pool for biotechnology and propose some ways to design a pool that would provide sufficient economic incentives for patent holders while promoting public interests. The paper will proceed as follows. Section 2 will clarify some terminological issues related to patents in biotechnology. Sections 3 and 4 will discuss several potential licensing problems in biotechnology that could lead to an “anti-commons.” Section 5 will outline various policy options for taking precautionary measures to prevent these potential problems from hindering research and development in biotechnology and biomedicine. Section 6 will develop and propose a patent pool for biotechnology. Sections 7 and 8 will evaluate the strengths and weaknesses of the pool and respond to the objection that a patent pool will not succeed because it will not provide sufficient incentives for patent holders.

2. Terminology Issues

Since lawyers, ethicists, and scientists use various terms to refer to the patenting of human genes, DNA, genetic information, and biotechnology, it will be useful to define these terms for the purposes of this essay. Although this essay cannot correct the ambiguities in the literature, it can shed some light how one should use these terms when discussing patenting issues.

DNA is a double-stranded helix composed of complementary nucleic acid base-pairs: adenine (A) pairs with thymine (T), and cytosine (C) pairs with guanine (G). DNA consists of sequences of nucleic acids, such as ACTTAGGAC. Proteins are composed of amino acids, which can fold to make complex structures. During DNA transcription, the DNA strand unwinds and a type of RNA, known as messenger RNA (mRNA), pairs with one half of the DNA strand. The mRNA is then released into the cell and the DNA strands rewind. During DNA translation, the mRNA is translated into a sequence of amino acids. It takes three nucleic acid bases (or codon) to code for a single amino acid. Some DNA base-pairs regulate DNA transcription: promoters tell the mRNA to start transcribing DNA and terminators tell the mRNA to stop transcribing DNA. When the amino acid sequence is complete, ribosomes package and modify the sequence before releasing it into the cell as a protein.[7]
A “gene” can be defined as the basic unit of heredity; it carries the information required to make one or more proteins. In human beings, genes include the base-pairs required to make a protein but not the regulatory sequences.[8] Only a small percentage of human DNA, perhaps less than 5%, consists of genes. The human genome includes about 35,000 genes, which code for about 100,000 proteins.[9] The rest of the genome consists of regulatory sequences as well as other DNA base-pairs that have no apparent function, which are also known as “junk DNA.” A gene consists of a large number of DNA base-pairs: genes range in size from about 1,000 DNA base-pairs to several thousand base-pairs. There are about 4 billion base-pairs in the genome. There are also smaller strands of DNA that have biomedical significance. These include expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs). An EST is a piece of a gene that serves as a useful marker for the whole gene. A SNP is a place on the genome where human beings exhibit genetic variation, and SNPs are very useful in studying genetic variation.[10]

The USPTO regards DNA sequences as chemicals similar to other isolated and purified compounds, such as digitalis (a heart medication found in the foxglove plant), salicylic acid (an anti-inflammatory medication found in the white willow plant).[11] The USPTO has issued patents on isolated and purified genes or isolated and purified DNA sequences, but it has not issued patents on natural occurring genes or DNA sequences. A gene patent is a type of DNA patent: it is a patent on an isolated and purified DNA sequence that codes for a protein. One of the key tenets of U.S. patent law is that one can patent products of human ingenuity but not products of nature. An isolated and purified gene (or DNA sequence) is a product of human ingenuity because it is something that does not exist in nature. Any patent that would give the patent holder control over products of nature would be unlawful.

Another important tenet of patent law is that patents pertain to applications, not ideas or information. For example, one cannot patent a computer algorithm, since this is an abstract idea. However, one might be able to patent a practical application of the algorithm, such as a method for controlling a robot. Thus, patents on genetic information are illegal, although patents on isolated are purified genes or DNA sequences are legal.[12]

It will also be useful to define the term “biotechnology” for the purposes of this essay. One could define this term very broadly so that it included all of the technologies related to biology, which would include agriculture, medicine, cosmetics, and food preparation and processing, and so on. Biotechnology in this broad since has existed for thousands of years. A more narrow definition of “biotechnology” focuses on the materials and methods related to genetic engineering that have been developed since the discovery of recombinant DNA techniques in the 1970s. These technologies include DNA cloning, RNA cloning, gene transfer, genetic manipulation, the polymerase chain reaction (PCR), gel electrophoresis, and other methods and materials used to create genetically modified organisms, develop genetic therapies, or bioengineer pharmaceutical products, such as synthetic proteins or hormones.
There are two basic types of patents that play an important role in the development of any technology, patents on compositions of matter, articles of manufacture, and machines (or materials), also known as product patents; and patents on methods, procedures and techniques (or methods), also known as process patents. In biotechnology, product patents include patents on biological materials, such as DNA, RNA, proteins, hormones, cell lines, organisms, engineered tissues, and artificial body parts. For example, Chakrabarty’s ground-breaking patent on bioengineered bacteria was a product patent.[13] Patents on processes in biotechnology would include patents on methods for cloning, isolating, sequencing, and manipulating DNA, RNA, or proteins. For instance, one of the first and most important patents in biotechnology was the Cohen-Boyer patent on techniques for recombining DNA in bacteria.[14] Companies frequently try to obtain product patents as well as process patents in order to maximize their intellectual property protection: while the patent would help protect the product, the process patent could protect various methods for making the product.

As one can see, patents on DNA and genes, though important, do not cover the entire spectrum of intellectual property related to biotechnology, since a researcher or company might also be interested in patenting RNA, proteins, or genetically engineered cell-lines, organisms, as well as methods and techniques. Although much of the moral, legal, and economic debate about patenting in biotechnology has focused on patenting DNA and genes, other types of patents also have a great deal of economic, if not moral or legal, significance. Since the progress of biomedical research and the growth of the biotechnology industry will depend on access to DNA, RNA, proteins, cell-lines, and other materials and methods in these emerging fields, it would be short-sighted to focus only on DNA patents. Thus, this paper will discuss a biotechnology patent pool, not a DNA patent pool.

One other terminological point requires some clarification. Many of the objections to patents on DNA suggest that it is immoral to patent human DNA or human genes,[15] yet human beings share as much as 98.5% of their DNA with chimpanzees.[16] All organisms on this planet use that same basic nucleic acids, ribonucleic acids, and amino acids to form DNA, RNA, and proteins, respectively. Basically, all living things are made out of the same molecular building blocks. So what does one mean by human DNA? (Or human RNA or proteins for that matter?)

There are two main approaches one could take to this question. One could say that human DNA consists of the DNA found only in the species *Homo sapiens*. One this view, 1.5% or less of the human genome would actually be “human”: the rest would consist of DNA found in other primates, mammals, and eukaryotes. But this is a very odd way of thinking about the relationship between the human body and its parts. We do not think of ourselves as animals with a few human parts that make us human: we are thoroughly human. All the bits of DNA in the human genome are human DNA, even if we share those parts with other species. To use an analogy: if a Ford Truck and a Dodge Truck both share many common parts, we would not say that a particular part is not a Ford Truck part if that part also occurs in the Dodge Truck.
These reflections suggest a better view of the matter: human DNA is DNA that resides in a member of the human species. Likewise, human RNA is RNA that occurs in a member of the human species, human proteins are proteins found in human beings, etc. A human and a chimpanzee can have many genes in common, but those genes are human genes when they are in a human body. Likewise, a Ford and a Dodge Truck may use the same type of spark plugs, but those spark plugs are Ford Truck parts when they are in a Ford Truck and Dodge Truck parts when they are in a Dodge Truck. A part is typically defined in terms of some larger whole. There are many genes that are found only in humans, and we could call those genes “uniquely human,” but even genes that are not uniquely human would still be human.[17]

3. The Anti-commons in Biotechnology

Having discussed these key terms, we can now address how an “anti-commons” might arise in biotechnology. Several different phenomena related to the licensing of materials and methods in biotechnology could prevent researchers and companies from making new discoveries or developing new products.

The first problem involves difficulties with negotiating and obtaining licenses for various patents in biotechnology. If someone owns a patent on an invention, then another person cannot make, use or commercialize that invention without permission from the patent holder. A patent holder could allow another person or organization to use, make, or commercialize his invention by granting that person or organization a license in exchange for a fee or percentage of royalties.[18] In any particular industry, a person developing a new product or service may need to obtain licenses from many different patent holders. For example, if a company is developing a new personal computing device that contains patented parts, such as chips, viewing screens, or keyboards, that company will need to obtain licenses in order to avoid potential patent infringement lawsuits. As we have already seen, there are many different DNA sequences, RNA sequences, proteins, and even cell-lines that might play an important role in the development of a new product or service in biotechnology.

Researchers and companies might find it very difficult to negotiate the dozens or even hundreds of licenses that they might require to develop a new product. For example, consider the potential licensing problems one might face in developing a genetic test for hereditary colon cancer. Perhaps as many as a dozen different genes are thought to play a role in hereditary colon cancer, and each of these genes could be associated many variations of mutated alleles.[19] Each of these different alleles could code for types of RNA and proteins. If the test is designed to test for genes or gene products that are associated with colon cancer, it might need to test for literally thousands of different variations of DNA, RNA, and proteins. Now suppose that over two-dozen companies own patents on various parts (DNA, RNA, or proteins) that would be used in performing this test. Someone developing this test might then need to negotiate over two-dozen different licenses to avoid patent infringement. Similar problems could arise when a
company or individual attempts to develop a genetically-engineered cell-line, since different companies might own patents on DNA, RNA, proteins, cell-lines, and other technologies (such as biotechnology techniques and methods) used in creating that cell line.

In many high technology industries, such as the computer and software industry, companies routinely negotiate and obtain many different licenses to develop goods and services. However, some writers have argued that it will be especially difficult to obtain licenses in biotechnology. Even if many companies are able to negotiate licenses successfully, the legal and administrative costs (or transaction costs) related to this “patent thicket” could be exceedingly high and could deter or even prevent research and innovation.[20]

The second problem has to do with the refusal of some patent holders to grant licenses. Companies might refuse to grant licenses in order to gain an edge over their competitors. The U.S., unlike some European countries, does not have laws that require licensing. In the U.S., licensing is optional, not compulsory.[21] Thus, under U.S. law a company may refuse to grant licenses in order to gain a competitive advantage over other companies. The company could also refuse to make, use, commercialize the invention if it so desires. If the company owns a piece of “upstream” technology, it can therefore effectively block many “downstream” inventions,[22] if it refuses to license that technology.[23]

For example, if one company owned a patent on an important gene in biotechnology and biomedicine, such as the p53 tumor suppressor gene, and the company did not license other individuals or companies to use or commercialize that gene, then it could effectively block many downstream inventions from that would depend on that key gene. The p53 gene is an important gene in biotechnology because many different cancers are associated with this gene. To develop products that treat cancer, it may be useful to develop products that stimulate the normal expression of p53, which might counteract abnormal expression of p53. This type of “blocking” might occur with techniques or methods as well. For instance, if Cohen and Boyer had not licensed their recombinant DNA methods to other researchers and companies, they could have blocked or hindered the growth of the biotechnology industry for the length of their patent. As it so happened, Cohen and Boyer licensed freely and generously, which encouraged the growth of the biotechnology industry.[24]

Third, licensing fees could impose a heavy toll that could deter or prevent research and innovation. Companies that hold patents on upstream patents might issue licenses only if they would be granted a percentage of profits from downstream products. Although downstream inventors have no legal obligation to share their profits with upstream patent holders, upstream patent holders may try to grab some of these profits by granting “reach through” or “stacking” licenses.[25] A reach through license is simply a license that attempts to control not only the use of the invention but also commercial developments from it. For example, the owner of the miniaturized transistor in the
example mentioned previously might attempt to demand royalties from the development of the computer chip or even the cellular phone.

Even companies that do not issue “stacking” licenses might still set very high licensing fees that could undermine access to materials and methods in biotechnology.[26] For example, many commentators have complained that Myriad Genetics has set an exorbitant fee for licensing its test for BRCA1 and BRCA2 mutations, which are associated with high rates of breast and ovarian cancer. Myriad charges $2300 to perform the test and has licensed only a few laboratories to conduct the test for about $1200.[27] Some commentators have argued that Myriad’s licensing practices have had a negative impact on women’s health, as well as the development of predictive and diagnostic testing for breast cancer.[28] Myriad’s licensing practices have also created an international controversy as some European countries have challenged its monopoly.[29]

In theory, a patent pool could help overcome some of these potential problems related to licensing in biotechnology, since it would make it easier to negotiate licenses, would eliminate blocking patents, and would exert some market pressure to lower licensing prices.[30]

4. Lessons from History

Do we have any good evidence that these potential problems related to licensing in biotechnology are likely to produce an “anti-commons?” Are these dire predictions little more than speculation or do they have some factual basis? History provides a relevant source of evidence for the effects of patent practices and policies. Two well-known examples from 20th century science and technology illustrate how problems with the licensing of patents can deter discovery and innovation in biomedicine. During the early history of aviation, licensing problems made it difficult to develop airplanes. The Wright Brothers, who held a variety of patents on key inventions in the industry, refused to grant licenses to competitors. They were able to stunt the growth of the industry until the Secretary of the U.S. Navy urged airplane manufacturers to form a patent pool prior to World War I. During the war, the U.S. government co-opted the patents and the aviation industry took off. Another technology that played a key role in World War I, radio, had also stalled for ten years as a result of a failure to negotiate licenses. This problem was not solved until, in 1919, the U.S. Navy again stepped in and urged private companies to form the Radio Corporation of America (RCA). During the war, the government also took over the radio industry for national defense purposes.[31] [32]

Those who are not concerned about the emergence of an “anti-commons” in biotechnology respond to these historical examples of licensing failures with their own examples of licensing success, such as the semiconductor industry. Since the 1970s, the semiconductor industry has been one of the most productive and innovative sectors of the economy.[33] To design and manufacture a new computer chip or electronic
device, a company may need to obtain licenses on thousands of parts, techniques, and methods. All of the occurrences that could lead to an emergence of an “anti-commons” in biotechnology—the patent thicket, blocking patents, and high licensing costs—have also posed a threat to the semiconductor industry, yet this industry has thrived because companies have been able to overcome these problems to reach licensing agreements. Moreover, the semiconductor industry is similar to the biotechnology industry because 1) one often needs access to thousands of different technologies to develop a new invention; 2) some of the technologies, such as transistors, are upstream technologies, and 3) many different companies hold patents in the industry.

Those who are not concerned about the emergence of an “anti-commons” in biotechnology also argue that we should maintain the patent system as it currently stands because the free market, patent agencies, and the courts can overcome potential licensing problems. First, companies will negotiate licensing agreements and they will be able to afford the transaction costs; second, “blocking” patents will be rare because most patent holders will find that it is more profitable to license inventions than hoard them; and third, high licensing fees will fall in response to weaker consumer demands at that price, especially if competitors are able to develop “work-around” inventions.[34] [35] [36]

It is still too soon to tell whether patents on materials and methods in biotechnology, such as patents on DNA, RNA, proteins, and biotechnology techniques, are having or will have a detrimental impact on biomedical discovery and innovation. Some studies suggest that DNA patents have had beneficial impacts, since increases in DNA patenting have also been accompanied by increases in publications in the genetic sciences,[37] and other studies suggest that companies and universities are developing ways of working around problems related to restrictive patents.[38] On the other hand, some studies suggest that problems related to licensing and potential patent infringement lawsuits may be having a chilling effect on research because scientists are concerned about licensing problems.[39] Some researchers are having difficulty gaining access to data as a result of intellectual property interests.[40]

5. Taking Precautionary Measures to Prevent an Anti-commons

Although policy makers do not yet have enough data to determine whether (or to what extent) patents in biotechnology are having a detrimental impact on progress in biomedicine, it would still be wise to take precautionary measures to prevent or minimize the potential negative effects of patents on discovery and innovation. We often lack sufficient evidence in many areas of public policy, ranging from the introduction of genetically engineered crops to global climate change. Many commentators have argued that we should not let this lack of knowledge stop us from taking precautionary measures to avoid undesirable consequences. The commonsense idea that an ounce of prevention is worth a pound of cure finds its expression in a controversial doctrine known as the Precautionary Principle. There are many different versions of this
principle, some of which have been criticized as excessively risk-aversive and anti-scientific.[41] According to a defensible version of the Precautionary Principle, society should take precautionary measures to address threats that are plausible and preventable. Precautionary measures should be reasonable, i.e. they should be proportional to the level of danger, non-discriminatory in application, consistent with similar actions already taken, and based on a careful balancing of benefits and risks.[42]

One can apply this decision-making framework to the controversy over patents on DNA sequences. The “anti-commons” –or something like it—would be the undesirable consequence. What would the precautionary measures be that society could take to prevent or minimize this threat? There are three basic precautionary responses society can make to the threat to discovery and innovation posed by patents in biotechnology: (a) ban some types of patents, such as patents on DNA; (b) maintain the status quo; or (c) develop policies to minimize the threats posed by biotechnology patents.

While option (a) sounds like a reasonable response, one might argue that it would not be proportional to the level of danger posed by biotechnology patents, it would not be consistent with similar actions, and it would not be based on a careful balancing of benefits and risks. Option (a) would not be proportional to the level of danger because it would be an overreaction to the threats posed by patents. Indeed, if society always took steps to ban patents that could pose a threat to the progress of science and technology, very soon there would be no more patents left, since every patent has potential risks as well as potential benefits. Option (a) would not be consistent with similar actions because society allows patents in other areas of science, technology, and industry, such as electronics. It would be inconsistent to treat the biotechnology industry differently from the electronics industry. Finally, option (a) would not represent a careful balancing of benefits and risks because it would sacrifice important benefits of patenting, i.e. incentives from for inventors and entrepreneurs, in order to avoid potential harms.

Option (b) is also an unreasonable response because it would not be proportional to the level of danger pose by biotechnology patents and it would not reflect a careful balancing of benefits and risks. Unlike option (a), option (b) would be an under-reaction to the threat posed by patents. Intellectual property laws and policies need to consider the potential benefits of intellectual property for science, technology, and society as well the potential risks. Indeed, the history of intellectual property law in the U.S. since the 1800s reflects this careful balancing of public and private interests. Option (b) would not reflect a careful examination of the benefits and risks biotechnology patents because many of these patents do pose some threats to biotechnology and biomedicine that need to be addressed.

Option (c), developing policies to minimize the threats posed by biotechnology patents, would appear to be the most reasonable course of action to take. It would be proportional to the level of the threat posed by biotechnology patents because it would take some response to this threat beyond simply maintaining the status quo. It would
also reflect a careful balancing of benefits and risks because the policies that are developed would be designed to maximize the scientific, technological, and social benefits of patenting and minimize the risk. So what are some policies that could be developed to minimize threats to discovery and innovation in biomedicine posed by biotechnology patents? Many different writers have suggested a wide variety of policies (some of which have been mentioned earlier) for minimizing the harmful effects of such patents. Some of these are as follows:

1. Raise the bar on the various conditions for awarding patents in biotechnology, such as novelty, non-obviousness, utility, or the enabling description.[43] [44] For example, in 1999, the USPTO raised the bar for proving the utility for a patent on DNA.[45] Raising the bar on patents in biotechnology may help prevent some of the problems related to licensing, since it may decrease the number of patents awarded. It may also increase the amount of work required to defend a patent application, which will increase the legal costs associated with patenting. However, raising the bar too high could have a negative effect in research and development in biotechnology by reducing the incentives for researchers and companies. Thus, while this solution could help alleviate some of the potential licensing problems in biotechnology, it is no panacea.

2. Restrict the scope of patents on materials and methods in biotechnology in order to allow competitors to develop "work-around" inventions, i.e. new inventions or improvements on existing inventions.[46] Patent attorneys usually attempt to state very broad claims in patent applications in order to give the patent holder maximum control over the invention. A patent examiner or a court may reduce the scope of patent claims that are excessively broad in order comply with legal requirements and protect public interests. However, if the scope of a patent is too narrow, the patent holder may not be able to obtain an adequate return for his investment. Thus, overly restrictive limits on the scope of patents can also reduce incentives and therefore deter discovery and innovation. In establishing the scope of a patent, patent agencies and the courts must strike the correct balance between private interests and public access.[47] Since there are some legal and practical limits to restricting the scope of patents, this proposed solution also does not adequately address potential licensing problems.

3. Reinforce, clarify, and legislate the research exemption for researchers in biotechnology and biomedicine.[48] In the U.S., the research exemption is a rarely used defense to patent infringement that allows academic researchers to use or make patented inventions without the permission of the patent holder.[49] The exemption is not part of the U.S. patent statute but is based on judicial interpretations of the statute. As it currently stands, the research exemption applies only to research undertaken for "philosophical" or "academic" purposes with no prospect of commercialization.[50] Since the line between commercial and non-commercial research is often very difficult to draw in biomedicine, any research exemption would need to be carefully worded and implemented, and researchers who want to take advantage of the exemption would have to adhere to stringent conditions. The research exemption, like the other proposed solutions, is probably not an adequate solution to address licensing problems because most research in biomedicine today has commercial implications. Unless the exemption
is interpreted very narrowly, it could significantly erode patent protection in biotechnology and also deter investment in research and development.

4. Use antitrust laws to respond to anti-competitive practices in biotechnology and biomedicine. Since a patent explicitly grants a patent holder a monopoly on an invention for a limited time period, one does not normally think that antitrust laws would have any bearing on patents. However, U.S. antitrust laws can apply to situations where patent holders refuse to deal with competitors and collude to fix prices.[51] For example, if a company attempted to corner the market on genetic tests and refused to license its tests to other companies or organizations, this might be a situation where antitrust laws might apply. Patent pools can also raise antitrust issues when members of the pool fix prices. Indeed, the courts have applied antitrust to several cases involving patent pools, and the justice department has issued guidelines for forming patent pools so that they do not raise antitrust issues.[52] However, most of the licensing problems in biotechnology, with the possible exception of “blocking” patents, raise no significant antitrust concerns. Thus, antitrust laws would also not be very effective at addressing the wide range of licensing problems in biotechnology.

5. Use compulsory licensing laws to prevent patent holders from engaging in problematic licensing practices. The U.S., unlike some European countries, has no compulsory licensing provision in its patent laws.[53] Under U.S. law, it is perfectly legal to patent an invention and then keep it on the shelf for the entire duration of the patent. In countries that have compulsory licensing, the inventor must make, use, or commercialize his invention or license others to do so.[54] Although compulsory licensing might be useful to deal with some situations, such as patents on upstream technologies that block downstream inventions, it is probably not a very effective solution to potential licensing problems. First, many corporations operating within the U.S. economy would oppose any changes in the current patent statute, including a change that would implement compulsory licensing. Second, even if the U.S. passed a compulsory licensing law, patent holders could still stifle downstream research by issuing “reach through” licenses.

To summarize, these five precautionary measures represent viable options for preventing licensing problems from undermining access to materials and methods in biotechnology. Any policy framework for regulating and controlling biotechnology patents should incorporate parts of these proposed solutions to potential licensing problems. However, it is unlikely that any of these solutions by themselves, or even all of these solutions taken together, will suffice to preventing licensing problems from occurring. Even if these five policy options are applied rigorously, it is still likely that many different companies and individuals will own useful patents in biotechnology. Therefore, those who develop new inventions could face a “patent thicket,” blocking patents, or steep prices for licensing. Thus, we have good reasons for considering the patent pool proposal.
6. A Biotechnology Patent Pool

The idea of a patent pool is not new. As mentioned above, the U.S. government prodded the aviation industry and the radio industry into forming patent pools during World War I. More recent examples of successful patent pools include a patent pool formed in 1997 for patents related to the MPEG_2 compression technology, and patents pools formed in 1998 and 1999 related to DVD-Rom and DVD-Video formats.[55] A patent pool can take many different forms. Some patent pools may even do more harm than good for science and society. However, a patent pool in biotechnology might be defensible if the following guidelines were embraced.

First, the patent pool should be designed to minimize transaction costs: it should enable patent holders to reach licensing agreements with other members of the pool and with individuals or corporations outside the pool.[56] The pool would negotiate licenses on behalf of its members and reimburse members for licensing activities. All members of the pool would retain their exclusive rights to use, make, or commercialize their own inventions, but they would also grant the pool the authority to license their inventions, which would help reduce transaction costs by enabling licensees to negotiate directly with the pool instead of with dozens of patent holders.

Second, the patent pool should have policies and rules that are explicitly designed to avoid antitrust problems and to encourage licensing: the pool should avoid price-fixing, collusion, and other anti-competitive practices.[57] Thus, the pool should have a mechanism for determining the market value of a patent and it should license patents according to their market value. All members of the pool should agree to license their inventions according to the market value; the pool should not permit blocking patents. Furthermore, in order to avoid the emergence of patent cartel, the pool should be open to all patent holders in biotechnology and should not exclude particular patent holders in order to keep them from competing.

Third, the patent pool should be designed to prevent fraud and abuse.[58] All patents in the pool should be valid. The pool should not afford an unscrupulous company the opportunity to profit from invalid and fraudulent patents. When patents expire, they should be removed from the pool. Furthermore, the pool should develop procedures for preventing “double-patenting” and other abuses of the patent systems.[59]

Fourth, in order to ensure that all patent holders have some guaranteed income, the pool should pay all members a percentage of royalties from licensing activities.[60] Pool members would also benefit from discounted fees for licensing the inventions of other members of the pool. These policies would encourage patent holders to enter their patents into the pool when they are unsure of their market value.

Fifth, to maximize convenience and access and minimize transaction costs, the patent pool should be comprehensive in scope. It should include patents on a variety of essential products and processes used in biotechnology and biomedicine, such as DNA, RNA, proteins, receptors, the polymerase chain reaction (PCR), recombinant
DNA techniques, gene therapy techniques, cell lines, and laboratory animals. It should not be a DNA patent pool, a protein patent pool or a cell-line patent pool: it should be a biotechnology patent pool. For example, a company developing a new drug to affect a receptor target might need to be able to obtain a license on the receptor, as well as licenses on proteins, RNA, and DNA. The company might also need to obtain licenses on important processes, such as PCR or recombinant DNA techniques. The company would find it far more convenient to negotiate licenses with a single pool, instead of with many different patent holders or patent pools.

Sixth, in order to avoid bias or the appearance of bias, the patent pool should be an independent, non-profit corporation. Although influential companies and government agencies could play a key role in launching the patent pool, the patent pool should have its own charter, bylaws, trustees, and management. The pool would be supported by contributions from members of the pool, which could include an annual fee or a percentage of royalties from licensing. An independent board established by the pool would arbitrate and review disputes put forward by patent holders.

Seventh, since public and private sectors hold patents on materials and methods in biotechnology, the patent pool should include private corporations and private universities as well as public universities and government agencies. It should promote public-private collaboration.

Eighth, the pool should be entirely voluntary and contractual; the government should not use force to induce patent holders to join the pool.

Ninth, while inventions in the pool would be open to the public for a fee, they would not be in the public domain. The corporation that manages the patent pool is organization would be analogous to agencies that manage copyrights, such as the Copyright Clearinghouse Center, King Features Syndicate, or Broadcast Music Incorporated (BMI), or the American Society of Composers, Authors, and Publishers (ASCAP).

7. Strengths: Overcoming Licensing Problems

A biotechnology patent pool would go a long way toward preventing the licensing problems discussed earlier. First, the pool would directly attack the problem of the failure to reach licensing agreements by providing a medium for quick and easy licensing. While it would be relatively easy to obtain licenses on products within jurisdiction of the pool, some difficulties might remain for licensing products outside the pool. If most patent holders join the pool, this should not be a significant problem. If there are a large number of patent holders who find not value in joining the pool, the pool may not greatly increase the efficiency of licensing.

Second, the pool would also directly attack the problem of blocking patents, since members within the pool would agree to allow the pool to license their products. Once
again, some difficulties could arise as a result of potential holdouts. If a large number of patent holders do not join the pool, there could still be significant problems with blocking patents.

Third, the pool would greatly reduce transaction costs because licensees could negotiate with a single organization instead dozens of companies or universities. The pool would also reduce transaction costs by eliminating “reach through” license agreements. Although many larger biotechnology firms have sufficient funding to cover transactions costs, smaller biotechnology companies and universities often cannot afford transaction costs.[61] Thus, the reduction in transaction costs would be an important advantage for these organizations. However, the pool would not reduce transaction costs significantly if few patent holders do join the pool, since licensees might still need to negotiate licenses with the pool and with patent holders outside the pool.

Fourth, the pool would give patent holders a steady and predictable source of income.[62] Frequently companies that patent new products do not know whether their patents will generate income from licensing fees: patenting often amounts to a research and development gamble. Companies can reduce their risk and uncertainty by contributing their patents to the pool, which will give them a guaranteed percentage of royalties generated from the pool. Companies will also be able to earn income beyond the guaranteed minimum income in proportion to the licensing activity of the patents they contribute to the pool.

Fifth, a patent pool could also address the criticism that biotechnology companies are benefiting unfairly from the Bayh-Dole Act, since members of the pool would have discounted licensing fees for access to other inventions in the pool.[63] If U.S. government agencies, such as the National Institutes of Health (NIH) and the Department of Energy (DOE), contribute patents to the pool, they would only have to pay discounted fees. Public universities that place their patents in the pool would also receive discounted fees. Currently, government agencies and public universities must pay the market rate for licenses on inventions that have been partly funded by public money. Although granting discounted fees to public institutions would not negate the charge that the Bayh-Dole Act is a form of corporate welfare, it would weaken the impact of this claim.

Sixth, a biotechnology patent pool could encourage the type of public-private cooperation that is necessary to research and innovation in biotechnology and biomedicine.[64] Corporations that hold biotechnology patents, such as SmithKline Beecham, Incyte Pharmaceuticals, Genentech, Eli Lilly, and Monsanto, as well prominent universities that hold biotechnology patents, such as the University of California, the Massachusetts Institute of Technology, North Carolina State University, the University of Texas, could cooperate to form a patent pool and encourage others to join. Other influential parties, such as the Biotechnology Industry Organization, the Pharmaceutical Research and Manufacturing Association (PhRMA), the NIH and the DOE could lend their support to a pool.
8. Weaknesses: Insufficient Benefits to Patent Holders?

A patent pool for biotechnology sounds like a good idea in theory, but would it work in practice? Many companies, universities, and government agencies may decide that they currently have no significant problems with licensing materials and methods in biotechnology and that they do not anticipate any future problems. Thus, they might decide that they would not benefit from joining a biotechnology patent pool. Indeed, many private companies with valuable patents on key technologies may decide that joining a patent pool would be a financial blunder. Why would any company allow an outside organization to control its golden egg laying goose?

Thus, an important obstacle to starting, developing, and sustaining a patent pool is convincing the various parties that the benefits of joining the pool outweigh the risks, which is no small feat. This aim of this essay is to defend and develop the idea of a patent pool in biotechnology, not to sell the idea to government and industry leaders. However, I propose that an effective way of convincing various parties to join a biotechnology patent pool would be to appeal to their long-term economic interests. It may be the case that a company or university will realize no short-term benefits from joining a biotechnology patent pool. The benefits of the pool are likely to occur several years after the pool is formed. As noted above, the pool will offer the parties many benefits, including efficient licensing and reduced transaction costs for the whole industry, a steady source of income, reduced licensing fees, and public-private cooperation. Moreover, parties that join the pool will still be able to profit from their licensing activities, since the pool will grant licenses at their market value. The risks of the pool are that some companies might derive fewer economic benefits from their valuable patents by placing those patents in the pool. Companies would also need to forego their ability to use their patents to block competitors or to impose “reach through” licenses on licensees. They would also need to give some of their profits to the pool in order to support its operation.

Although one often thinks of biotechnology companies as fiercely competitive, there is precedent in biotechnology for the cooperative spirit necessary to form a patent pool. In 1999, ten pharmaceutical companies and a British charity formed a non-profit corporation, the SNP Consortium, which they established to disseminate and archive the estimated 300,000 human single nucleotide polymorphisms (SNPs).[65] The companies understood that they would all need access to SNPs, since they are valuable research tools. In order to avoid licensing problems related to acquiring rights to thousands of SNPs, the companies decided to work together to form the consortium. The companies decided to forego patents on human SNPs and placed all of their data in a public database, thereby undercutting future patenting efforts.[66] The SNP consortium is not a patent pool; indeed, it might be best characterized as an “anti-patent” pool. However, the fact that the consortium exists and that it is very well established indicates that private companies can work together to overcome licensing problems in biotechnology.
The SNP consortium is a classic example of a response to a multi-person, cooperative game. In this type of game, the players may choose among various strategies, such as "cooperate" and "don’t cooperate," and they are free to coordinate their strategies to achieve common goals.[67] The companies who formed and joined the SNP consortium could choose between “joining the consortium” and “not joining the consortium,” as well as variations on these strategies. Yet the companies choose to cooperate because they understood the economic benefits and risks of various strategies and as well as the choices facing other companies. The companies decided to join the SNP consortium because they determined that there would be clear and substantial economic benefits from cooperating.

Although the SNP consortium is a stellar example of the triumph of cooperation over selfishness in biotechnology, it is not the appropriate model for all biotechnology patents. SNP patents, unlike patents on genes that code for useful proteins or genes that can be used in diagnosis, have very little practical value on their own. SNPs derive most of their value and usefulness from their ability to serve as research tools. Researchers can use a large group of SNPs to compare genomes in order to understand the relationship between genotypic variation and phenotypic variation. To make meaningful comparisons between genomes, researchers require access to hundreds or even thousands of SNPs. The companies that formed the SNP consortium understood that they would benefit very little from exclusive control over a few SNPs but that they might benefit a great deal from having non-exclusive access to thousands of SNPs.[68]

If one thinks of the decision to join the biotechnology patent pool as a business decision made in the context of a cooperative game, it follows that patent holders would join the pool if they determined that the benefits of belonging to the pool outweigh the risks (in the long run). One might argue, as above, that patent holders would have much to gain and very little to lose by joining a biotechnology patent pool. Many companies probably would determine that the benefits of joining a biotechnology patent pool outweigh the risks. However, there would probably be some holdouts. For example, a company with patents related to a valuable protein, such as erythropoietin, would probably not place this patent in the pool because it would find it more profitable to cash in on its patent than to cooperate with other patent holders. Thus, it is possible that companies and universities might place some of their less valuable patents in the pool but retain control over their highly valuable patents. While this development would be less than ideal as far as the pool would be concerned, it would not automatically make the pool obsolete. The pool could serve a useful purpose as long as companies and universities contribute enough patents to the pool to provide sufficient benefits for sustaining the pool, such as reduced transaction costs, access to technology, and so forth.

9. Conclusion
This paper described some potential problems related to the licensing of materials and methods in biotechnology that could undermine scientific research and technical innovation. The paper has argued that companies, universities, and other interested parties should form a biotechnology patent pool to prevent these problems from occurring or to at least reduce their impact. The paper also outlined the basic structure and organization of a patent pool in biotechnology as well as its rules and procedures. Although any patent pool must avoid legal problems related to antitrust laws and possible abuse of the patent system, the biggest obstacle to forming and sustaining a biotechnology patent pool would be economic rather than legal. The parties who would consider joining the pool must decide that membership in the pool is in their long-term financial interests. Some members of the pool may decide to place some of their less valuable patents in the pool but retain control over their highly valuable patents. While critics of the biotechnology industry view companies and researchers as profit-driven capitalists, industry leaders and scientists could choose the path of enlightened self-interest by forming a biotechnology patent pool. The SNP consortium has already shown the world how cooperation and self-interest can coexist under mutually advantageous schemes. Hopefully, leaders in the biotechnology industry will continue to follow this example.

Acknowledgements

The author is grateful for useful comments and suggestions from anonymous reviewers.

Key words: patents, biotechnology, patent pools, DNA, anti-commons, licensing, SNP consortium, Precautionary principle, game theory


[2] M. Heller and R. Eisenberg. Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science* 1998; 280: 698-701. The authors coin the term “anti-commons” to contrast this situation with the “commons,” which was public land that existed in England prior to the industrial revolution. The enclosure movement, in which individuals put fences around their private property, destroyed the commons.


[8] Ibid.


[13] A. Chakrabarty. Microorganisms Having Multiple Compatible Degradative Energy-Generating Plasmids and Preparation Thereof. US Patent 4,259,444 (1981). This patent was awarded after Chakrabarty won a case that he appealed to the Supreme Court. The USPTO had refused to grant Chakrabarty's patent on a genetically engineered bacterium on the grounds that it was a product of nature, but the Supreme Court vacated this decision and held that the bacterium resulted from Chakrabarty's ingenuity. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).


[17] Many people and organizations have claimed that patents on human genes are immoral. However, since humans and animals share many genes, would it make any sense to say that a patent on a particular gene is immoral if it is derived from a human cell but morally acceptable if not? If it's the same gene, what difference does it make
where we obtain it? To deal with questions like this, our query should focus on the morality of patenting DNA, not on the morality of patenting human genes. For further discussion, see D. Resnik. The Morality of Human Gene Patents. *Kennedy Institute of Ethics Journal* 1997; 7, 1: 43-61.


[19] An allele is simply a variation of a gene. For example, the gene for eye color has the alleles “blue,” and “brown,” among others. A person with a blue allele and a brown allele will have brown eyes because brown is a dominant allele. A mutation of a particular gene is simply a different allele. In some genetic diseases, there may be dozens of different mutations that are associated with the incidence of disease.


[22] The upstream/downstream distinction is relative to the scientific and technological context. A patent is an upstream patent if is vital to the development of many other inventions. For example, a type of miniaturized transistor would be an upstream invention and a computer chip would be a downstream product, if the transistor plays a vital role in the computer chip. However, the same computer chip might be an upstream invention relative to a device that uses the chip, such as cellular phone.


[26] Ibid.


[30] This idea will be discussed in greater depth in Sections 7 and 8.

[32] This paper is not proposing that the government should take over biotechnology patents in order to overcome licensing problems. However, these examples show how problems related to licensing can stunt the development of science and technology, and how patent pools can address these problems.


[36] A “work-around” invention is an invention that “works around” a patent because it is a new or improved product or process and therefore does not infringe the existing patent. For example, a “better” mousetrap would be an invention that “works around” the original mousetrap.


Before the USPTO will award a patent to an inventor, the inventor must prove that his invention is novel or original, not obvious to someone trained in the relevant field or discipline, and has some definite, practical use. In addition, the inventor must disclose enough information about the invention on the patent application to allow someone trained in the relevant field or discipline to make and use the invention. European countries have similar requirements for awarding patents. For further discussion, see Miller and Davis and the Nuffield Council on Bioethics.

USPTO, Revised Utility Examination Guidelines. Federal Register (21 December 1999) 64, 244: 71440-71442. The USPTO requires proof of a substantial and practical utility before it will issue a DNA patent.


Miller and Davis, 2000.


Ibid.


Miller and Davis, 2000.


Ibid.

Ibid.

Ibid.

“Double patenting” is patenting the same invention twice. Although “double-patenting” is illegal in the U.S. and Europe, companies sometimes try to circumvent the law by developing trivial improvements on their patented products or processes.

[61] Ibid.
[62] Ibid.

[63] Congress passed the Bayh-Dole Act in 1980 to encourage technology transfer from
the academic setting to the private sector. The Act allows private companies to patent
inventions that result from public investments in research. Some critics of the Act have
characterized it as "cooperate welfare." For further discussion see R. Dreyfuss.
Collaborative Research: Conflicts on Authorship, Ownership, and Accountability.

[64] Biotechnology Industry Organization. Primer: Genomic and Genetic Research,

[65] A SNP is a sequence of DNA smaller than a gene that is useful in studying
variation. SNPs occur in regions of the genome that code for proteins as well as in non-
coding regions.


[67] J. Harsanyi, Rational behavior and bargaining equilibrium in games and social


[69] This paper has focused on the implications of a patent pool for biotechnology and
biomedicine and has not considered the benefits of a patent pool for medicine. If a
patent pool increases access to goods and services in medicine, such as genetic tests,
gene therapy, and bio-engineered pharmaceutical products, then it will also benefit
patients and increase access to healthcare. For further discussion of these issues, see