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Abstract:

Changes in U.S. patent policy over the last 30 years have led to the ballooning of patent applications in biotechnology, raising the question of whether biotech patents are economically efficient. The unique nature of the biotech industry suggests that certain inefficiencies in the patent system may be detrimental to future research and innovation. Of particular note is the “Anticommons Problem,” an inefficiency that arises when property rights become fragmented between individuals or firms. Multiple trading partners, highly complementary patents, and high transactions costs exacerbate the effects of an anticommons problem. Because these three sources of inefficiency are characteristic of the biotech industry, open-market bargaining is impeded. Thus, a non-market solution must arise to resolve the problem.

There is an optimal breadth of patent that must be achieved through the law such that incentives to innovate are preserved and future follow-on research is facilitated. Certain aspects of patent law may be important in reducing anticommons effects in the biotech industry. Four provisions: utility, novelty, nonobviousness, and adequate disclosure, possess possible safeguarding properties. These four provisions reduce adverse anticommons effects via two mechanisms: by reducing transactions costs and/or by eliminating “junk” patents.

In the U.S., patent law is not static; rather, the law evolves over time through the settlement of cases. According to some legal scholars, if the invisible hand of the law functions properly, the common law should develop in ways that are economically efficient. The efficiency theory of common law predicts that U.S. patent law must – and will – evolve to deal with the anticommons problem.

Although patent law can evolve to produce efficient outcomes, specific court cases must be analyzed in order to determine whether it has. Two representative legal cases within the biotech industry, Amgen, Inc. v. Chugai Pharmaceutical Co., and In re Dane K. Fischer, provide ample material for examination. Analysis of each case focuses on the particular provisions of the law that may prevent anticommons effects. Amgen sets a precedent that strengthens the enablement requirement (written description) of genomic patents, while In re Fisher strengthens the utility requirement. The Court’s decisions in these cases imply that U.S. patent law is, in fact, evolving towards efficiency.

Keywords: genomic patents, patent law, efficiency theory of common law, anticommons problem, complementarity, positive economic analysis of law.
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1. Introduction

…patent protection [is a] two-edged sword:
Happily, it spurs innovation by securing to inventors the fruits of their labors but,
unhappily, it also creates a vast thicket that gives each patent holder a potential veto right
over the innovations of others.
- Epstein and Kuhlik, 2004, p.54

Although U.S. patents provide essential economic incentives that encourage
research and development, patents also give rise to a significant deadweight loss. As
Richard Posner explains, “[o]nce an invention is made, its costs are sunk; in economic
terms, they are zero. Hence a price that includes a royalty to the inventor will exceed the
opportunity cost of the product in which the invention is embodied” (Posner, 2003, p.39).
Although it is unlikely that the costs of monopoly pricing outweigh the benefits of patent
incentives, there may be other major inefficiencies in the patent system, especially in the
market for biotechnology. One of these inefficiencies, the so-called “anticommons
problem,” has sparked much controversy within the scientific community.

The converse of the familiar “tragedy of the commons,” the “tragedy of the
anticommons” occurs when property rights are over-assigned and become fragmented
between individuals or firms. Independently operating property owners can exclude one
another from accessing each other’s protected research or property, leading to the under-
use of scarce resources (Heller and Eisenberg, 1998, p.698). The anticommons problem
poses a threat to markets in which exclusion rights such as patents are granted. A
proliferation of patents in markets where research is cumulative may be particularly
deleterious: when research is privatized, the ability of scientists to build upon each
other’s findings is inhibited, making it difficult for researchers to – proverbially – stand

The theoretical literature shows that when research is sequential and builds upon previous discoveries, stronger patents may discourage subsequent research on valuable, but potentially infringing, follow-on inventions. (p.132)

“Road-blocks” in the form of upstream patents may create serious impediments to downstream R&D, thus raising the question of whether patents on biotechnology may in fact deter, rather than encourage, innovation.

Multiple trading partners, complementary patents, and high transactions costs exacerbate the effects of an anticommons problem. High transaction costs in the biotech industry preclude bargaining, and therefore a non-market solution must arise to resolve inefficiency problems. According to the efficiency theory of common law, laws should evolve to promote economic efficiency. This hypothesis predicts that U.S. patent laws should develop to control for anticommons problems such that incentives to innovate are preserved and future follow-on research is facilitated. Several provisions of U.S. patent law may be important in reducing anticommons effects in the biotech industry, including the utility, novelty, nonobviousness, and adequate disclosure requirements.

This paper is in the spirit of Harold Demsetz’ seminal work on the evolution of property rights, Toward a Theory of Property Rights (1967). Demsetz asserts that property rights evolve in response to externalities created by changing conditions in the market:

changes in knowledge result in changes in production functions, market values, and aspirations. New techniques, new ways of doing the same things, and doing new things – all invoke harmful and beneficial effects to which society has not been accustomed. It is my thesis… that the emergence of new property rights takes place in response to the

¹ In a 1675 letter to fellow natural philosopher and scientist Robert Hooke, Sir Isaac Newton wrote, “If I have seen further it is by standing on the shoulders of giants” (Isaac Newton, Quotations; letter [1675], Encyclopedia Britannica Online).
While Demsetz explains how property rights evolve to avoid inefficient *commons* outcomes,² this paper is concerned with the ways in which intellectual property rights evolve to control for inefficient *anticommons* outcomes.

Biotechnology has placed a stress on the patent system where there previously was none. Biotech patents are entirely unique unto themselves, and patent laws must therefore develop to accommodate these technological changes. An examination of cases concerning patents in biotechnology must be conducted in order to assess whether patent laws are evolving efficiently. Two representative cases, *Amgen v. Chugai* and *In re Dane K. Fisher*, suggest that US patent laws are, in fact, advancing towards economic efficiency.

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² Demsetz analyzed the evolution of property rights amongst the peoples of the Labrador Peninsula. He found that there was a close relationship between the development of private rights in land the development of the commercial fur trade (Demsetz, 1967, p.351). Demsetz asserts that property rights developed to internalize the externalities associated with over-hunting. While Demsetz’ paper describes the evolution of safeguards against commons problems, this paper serves as Demsetz’ paper’s mirror image by describing the evolution of safeguards against anticommons problems.
2. The Anticommons Problem: Causes and Effects

Researchers and their institutions may resent restrictions on access to the patented discoveries of others, yet nobody wants to be the last one left dedicating findings to the public domain.

2.1 Background

Before 1980, most scientists held no pecuniary claim to their own research. The US Government practiced unpredictable and restrictive patent license policies that made it difficult to straightforwardly obtain a patent on scientific research. However, major policy changes have moved most scientific research and information from the public domain to the private domain. The implementation of the Bayh-Dole Act (1980) allowed universities, small businesses, and non-profits to pursue ownership of the intellectual property resulting from federally funded research (Sampat, 2006, p.778). Universities were encouraged to license their patents to firms within the United States, in hopes that these companies could transform the intellectual property into commercially viable products. Although the Act was designed to promote technology transfer between universities and the business sector, policy makers did not foresee the exponential increase in patent applications that it would trigger (Sampat, 2006, p.781).

In the last 30 years, the U.S. has seen an explosion of patent applications from universities, especially in the field of biotechnology (see figure 2.1).3 This ballooning of patents is a result of both the Bayh-Dole Act and a seminal Supreme Court decision of the same era. The Court’s 1980 ruling in *Diamond v. Chakrabarty* determined that biologically engineered bacteria could be patented, underscoring the idea that anything considered man-made was patentable. In this groundbreaking case, chief justice Warren

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3 The rate of increase in academic patents filed in biology has greatly outstripped the increase in overall patent application rates.
E. Burger found that because Congress had intended patentable subject matter to “include anything under the sun that is made by man,” Chakrabarty’s patent on genetically modified bacteria was viable (*Diamond v. Chakrabarty*). Burger explained, “[Chakrabarty’s] claim is… to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity” (*Diamond v. Chakrabarty*). Naturally occurring chemicals and substances, such as hormones and genes, may be patented, as long as the researcher can identify a use for the substance. These naturally occurring substances may only be patented, however, in an isolated form or sequence, not in their natural state.

![Figure 2.1: Biotechnology Patents Granted per Year](source: US Patent and Trademark Office)

### 2.2 The Biotech Industry

Biotechnology is defined broadly as the use of “biology” to solve problems and to make useful products. The biotechnology industry originated in the 1970’s, based largely on a new recombinant DNA technique[^4] whose details were published in 1973 by Stanley

[^4]: Recombinant DNA is a method of making proteins in cultured cells through the manipulation of DNA, under controlled conditions (Bio, 2007).
Cohen of Stanford University and Herbert Boyer of the UCSF (Bio, 2007). The most prominent area of biotechnology is the development of therapeutic drugs through the use of recombinant DNA and other genetic engineering techniques. Today, most patents in biotechnology are patents that claim DNA sequences (called “genomic patents”).

In the U.S., impediments to biotech research represent more than a mere nuisance to scientists; the fate of the biotech industry is of substantial importance to the U.S. economy. Extensive research is required to develop new biotech innovations, as these innovations consist mainly of genetic materials produced through painstaking recombinant DNA techniques. In 2005, the industry spent $19.8 billion on R&D, rendering biotechnology one of the most research-intensive industries in the country (Bio, 2007). Because of the R&D intensive character of biotechnology, an anticommons in the market for biotech research could deal the industry a devastating blow. Nancy Gallini explains that although patents are an effective mechanism for the protection of intellectual property in biotechnology,

…the controversial issues (aside from the prominent ethical issues) involve the types of innovations that merit protection… The fear is that granting patents on gene fragments could hold up productive research, since a firm attempting to market a product that embodied these fragments would have to negotiate licenses with multiple patent owners. (2002, p.146)

Anticommons research access problems are compounded when multiple individuals hold

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5 In 2005, a study showed that more than 4,000 human genes had already been patented in the United States alone (Bio, 2007).
6 As of December 31, 2005, the market capitalization (the total value of publicly traded companies) in the biotech industry was $410 billion (Bio, 2007). Corporate partnering has been crucial to biotech success: in 2005, biotech companies signed 564 new agreements with pharmaceutical firms and 354 with fellow biotech companies (Bio, 2007). Biotech developments serve as inputs to countless pharmaceuticals: biotechnology has created more than 200 new lifesaving therapies and vaccines, including those that treat cancer, diabetes, HIV/AIDS, and autoimmune disorders (Bio, 2007).
7 Gallini provides the following example: “…genetic sequences that are isolated or purified by human intervention (such as cloned genes that produce proteins) have received both process and product patents, whereas gene fragments with undefined therapeutic value have been denied protection…” (2002, page). Chapters 3 and 4 will discuss why gene fragments with no identifiable use are denied patent protection.
separate patents that would be more commercially viable if used in conjunction with one another. Overly-broad patents on upstream biomedical research are also threatening, as these patents leave little room for scientists to explore more detailed research under the field in question. Gallini cautions, “[o]f particular concern are patents awarded on broad concepts that are vital to the success of future research but cannot be used or imitated without infringing the patents” (2002, p.146). Anticommons problems are especially troubling in the biotechnology industry: patented inputs are highly complementary and transactions costs are high.

2.3 A Model of the Anticommons

In a 2000 paper entitled, *Symmetric Tragedies: Commons and Anticommons*, James A. Buchanan and Yong J. Yoon present a mathematical model of the anticommons using a stylized example and a geometric-algebraic illustration. They assert that the anticommons problem is essentially “symmetric” to the commons problem, in that both scenarios lead to an equal dissipation of property value. In the commons scenario, usage rights are afforded, while in the anticommons scenario, exclusion rights are granted. Buchanan and Yoon state:

> The anticommons tragedy, as measured in nonrealized economic value, takes the form of underusage rather than overusage of the resource; the size of the opportunity loss will, as in the commons model, depend on the number of persons (or firms) assigned simultaneous rights. The basic logic is equivalent in the two cases. The inefficiency arises because the separate decision makers, each of whom acts in exercise of assigned rights, impose external diseconomies on others who hold similar rights. (2000, p.4)

In the commons side of the model, individuals (or firms) reduce the value of all inputs by adding an additional input. This reduces the rent that each owner of usage rights receives. In the anticommons side of the model, individuals or firms reduce the rent per excluder
by limiting the number of inputs to the common facility (via price) (Buchanan and Yoon, 2000, p.4).

Buchanan and Yoon construct their mathematical model using the number of property owners as a metric for the reduction in value that a theoretical anticommons brings about. Although they do not discuss anticommons problem in the context of biotechnology, the basic framework of their model can be applied to the biotech industry. Buchanan and Yoon use the example of parking permits to illustrate their model. In this scenario, an abandoned lot is converted into a parking lot. Initially, one owner is given exclusion rights to the lot; this is the standard monopoly setting (see figure 2.2). If an individual is assigned single ownership, price is set at $P_m$ and quantity is set at $Q_m$. The total rent in this situation is denoted by the area $wQ_mE_m*P_m$.

When additional individuals or firms are assigned exclusion rights, monopolists compete independently to set the price of their own parking tickets. Each monopolist must take the price of the other owner’s ticket into account before he sets his own price. In the simplest case, two individuals possess exclusion rights: one owner (A) sells green tickets, while the other owner (B) sells red tickets. To gain access to the parking lot, any consumer must hold both tickets; thus A must consider the price of red tickets, and B must consider the price of green tickets. This anticommons situation leads to an inflation of price above the monopoly equilibrium price, and the depression of quantity below monopoly equilibrium usage (see figure 2.3).9

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8 In this case of independently acting monopolists, Coase-like bargaining between parties would lead to a more efficient outcome. However, Buchanan and Yoon assume that “such contracts between parties are, for some reason, impracticable” (2000, p.4). This preclusion of Coasean bargaining lies in the existence of transactions costs: the Coase theorem does not apply when transactions costs are high. This concept is discussed later in this chapter.

9 Conversely, in the commons setting, an additional holder of usage rights causes price to fall below the equilibrium monopoly price, and quantity to rise above the equilibrium monopoly quantity. In table 2.2, $E_2$
The anticommons equilibrium is attained at $E_2^*$, with total rent being equal to $wQ_2^*E_2^*P_2^*$. This rent, which is shared equally between A and B, is lower than the single monopolist’s rent; the difference between the two rents signifies the deadweight loss attributable to the anticommons effect.\textsuperscript{10} Buchanan and Yoon claim that the size of the deadweight loss in an anticommons situation is dependent upon the number of excluders involved. They construct a mathematical model based on these underlying principles.

\textsuperscript{10} Here, the single monopolist is more profitable than two independently acting monopolists. Varian explains: “…independent price setting [of complementary inputs] will lead to prices that are too high from the viewpoint of joint profitability…” (Varian, 2003, p.627).
The two-owner model, which provides the most basic illustration, is constructed as follows:

Each owner, A and B, faces the following demand schedule:

\[ P = a - bQ, \] (2)

where \( a \) is the price at which \( Q = 0 \), and \( b \) is a constant signifying the slope of the marginal value of parking in the lot as a function of the number of cars. In the case of exclusion rights, the price that the consumer (parker) faces is equal to

\[ P = P_g + P_r, \] (3)

where \( P_g \) is the price of a green ticket and \( P_r \) is the price of a red ticket. Equation (3) is a simplified manifestation of equation (1); here, \( X_g = 1 \), \( X_r = 1 \), and \( P \) is used in place of \( MC \). Thus, a user faces the following demand schedule:

\[ P_g + P_r = a - bQ. \] (4)

Given this constraint, owner A chooses \( P_g \) as to maximize her total rent (\( P_gQ \)):

\[ \max P_gQ = P_g(a - P_g - P_r)/b. \] (5)

Owner B plays the same “game” by maximizing \( P_rQ \), such that a Nash equilibrium is reached. In this game, the first-order condition for maximization is

\[ (a - P_g - P_r)/b - P_g/b = 0, \]

from which we can express \( P_g \) as a function of \( P_r \):

\[ P_g(P_r) = a/2 - P_r/2, \] (6a)

and likewise,

\[ P_r(P_g) = a/2 - P_g/2. \] (6b)

Solving the system of simultaneous equations, one finds that \( P_g^* = P_r^* = a/3 \). Because \( P = P_g + P_r \) (2), the price a customer faces is \( P^* = P_g^* + P_r^* = 2a/3 \). Given this, the total rent in the two-owner anticommons situation is

\[ (P_g^* + P_r^*)Q = (2a/3)(a/b)/3 = \]
(2/9)(a^2/b). From here, Buchanan and Yoon (2000) build the following generalized model: in a scenario with multiple excluders \( n \), the price of each separately designated colored ticket, \( P_n \), the quantity consumed \( Q(n) \), and the total rent, \( TR(n) \), are

\[
P_n^* = \frac{a}{n + 1},
\]

(7)

\[
Q(n) = Q_0(n + 1) = \frac{(a/b)}{(n + 1)},
\]

(8)

and

\[
TR(n) = n(a^2/b)/(n + 1)^2 \quad \text{(Buchanan and Yoon, 2000, p.10)}.
\]

(9)

Total rent and \( n \) (the number of holders of exclusion rights) are inversely related: as \( n \) increases, total rent decreases.\(^{11}\) Thus, the deadweight loss created by an anticommons situation is dependent upon the number of complementary inputs that must be purchased to develop a new product in that market.

In Buchanan and Yoon’s model, one ticket is useless unless used in conjunction with the other; they must be “consumed” together. This logic is displayed in equation (3), which shows that \( P = P_g + P_r \). Although the total price of the good consumed (\( P \)) is in this case the sum of the prices of the two inputs, \( (P_g + P_r) \), this relationship does not always hold. Equation (3) assumes that both inputs (the red and green parking tickets) are perfect complements. For perfect complements, the total price of each input must be completely factored into output price.

### 2.4 Genomic Patents: The Problem of Complementary Inputs

In theory, an anticommons yields an inefficient outcome when multiple owners of intellectual property hold patents that are complementary to one another. Complements are goods that are consumed together. In the simplest two-good case, the demand for

\(^{11}\) TR and \( n \) are also inversely related in the commons scenario.
good 1 decreases when the price of good 2 increases, such that: \( \Delta x_1/\Delta p_2 < 0 \) (Varian, 2003, p.112). A complementary relationship between inputs affects the price of a resulting output (product). In the most extreme case of complementarity- perfect complements- inputs only have value when they work together. In biotechnology, “inputs” are genomic patents that can only be accessed with a license, and “outputs” are- perhaps- vaccines, therapeutic drugs, or genetically engineered foods. The extent to which input prices determine output price depends on the degree of complementarity between the inputs and the number of inputs.

The degree of complementarity between biotech patents is high. Genomic patents are often dependent upon other genetic material (DNA fragments) that may also be under patent protection. Whether two genomic patents are complementary depends on the underlying science of the patented innovations, including the nucleotide sequence of the DNA and the location of the DNA fragment on the genome. Because many genomic patents are complementary, the fragmentation of rights in biotechnology leads to inefficient market outcomes. The following example illustrates this phenomenon.

---

12 Novel research (of commercial value) conducted using patented information is also considered an output.

13 In the simple case of two complementary inputs, if a consumer spends more money on good 1, she must spend less money on good 2 (assuming her income is fixed). However, when more than two goods are involved, “… it is perfectly possible that good 1 may be a substitute for good 3, but good 3 may be a complement for good 1” (Varian, 2003, p.112).

14 Gastón Llanes and Stefano Trento (2007) describe two quintessential examples of this dependency problem. The first example is the case of the MSP1 antigen (Plasmodium Falciparum Merozoite Protein 1). This antigen is “widely recognized” as the most promising candidate for an anti-malarial vaccine (Llanes and Trento, 2007, p.1). A 2002 study by the Commission on Intellectual Property Rights found: “there are currently 34 MSP-1 patent 'families' that describe and claim the antigen, process the fragments and constructs, as well as deal with production and delivery of the antigen” (Commission on Intellectual Property Rights, 2002). A potential innovator hoping to develop a vaccine using the MSP1 antigen would have to gain access to each one of these patents. The second example is the case of GoldenRice a biofortified rice enriched with vitamin A in the form of \( \beta \)-carotene. In GoldenRice two genes have been inserted into the rice genome by genetic engineering, and “this intervention leads in turn to the production and accumulation of \( \beta \)-carotene in the grains [of the rice]” (Golden Rice Project Homepage, 2008). Depending on the country where the current form of GoldenRice would be used, between zero and 44 patents apply to the product. In the USA and most countries of the European Union, around 40 patents apply (Kryder, Kowalski, and Krattiger, 2000, p.vi).
A scientist who wishes to develop a therapy for the treatment of malaria using the MSP1 protein must access several genomic patents in order to do so. This protein is dominant and/or present in all known species of *Plasmodium* (the parasite responsible for malaria,) and is considered to be a front-running candidate for anti-malarial vaccines. It is difficult to obtain MSP1 via natural extraction, thus the protein must be synthesized in the lab:

> faced with the difficulty of obtaining large quantities of parasites for *P. falciparum* and the impossibility of cultivating *P. vivax* in vitro, it has become clear that the only means of producing an anti-malaria vaccine is to resort to techniques which use recombinant proteins or peptides. (Longacre-Andre et. al., 2005)

Most patents relating to MSP1 are genetic patents that code for a fragment of the MSP1 protein. Because the protein is so large (about 200 kiloDaltons [kDa])\textsuperscript{15}, it is difficult to obtain or engineer as a whole (Longacre-Andre et. al.,2005).

Figure 2.4 shows a schematic of patent number 6,958,235, for a patent claiming the C-terminal\textsuperscript{16} portion of the MSP1 protein. The schematic shows both the sequence of nucleotides (GAA, TTC, AAC, ATC, TCG, CAG, etc…) and the amino acids for which these nucleotides code (as denoted by E-F-N-I-S, etc…)\textsuperscript{17} In order for the owner of the patent in question (Longacre-Andre) to effectively utilize her property, she must have access to all of the genetic material in the figure. Although in this case the owner has

\textsuperscript{15} A Dalton (Da), which is equal to one atomic mass unit, is a small unit of mass used to describe atomic and molecular masses. One amu is equal to 1/12 of an unbound carbon\textsuperscript{12} atom (i.e., approximately the weight of one proton or one neutron). Because proteins are large molecules, they are frequently referred to in kiloDaltons (kDa) (Berg et. al., 2007, p.35).

\textsuperscript{16} The C-terminus, or the carboxy terminus, denotes one end of a protein (or polypeptide sequence). At the C-terminus, the carboxy group of the terminal amino acid is unbounded. The N-terminus, found at the beginning of a polypeptide sequence, describes the end at which the amine group of the initial amino acid is unbounded. Whether unbounded carboxy and amine groups are free to react with other molecules. Out of formality, proteins are named from N to C terminus (Berg et. al., 2007, p.35).

\textsuperscript{17} A protein is a molecule composed of a sequence of amino acids. Amino acids, sometimes called “the building blocks of life,” are encoded for by DNA. DNA is made up of nucleotides bound to a sugar phosphate backbone. Each series of 3 nucleotides, called a “codon” codes for a specific amino acid (Berg et. al., 2007, p.25).
already secured the patent, we will use figure 2.4 to illustrate the problem of complementary patents.

![Amino Acid Sequence Coding for C-Terminal Fragment of MSP1 Protein](source)

Imagine that Longacre-Andre had not yet obtained patent number 6,958,235, but was conducting research on the MSP1 protein. An anticommons problem might arise if portions of MSP1’s genetic code were already under patent protection. In figure 2.4, three theoretical patents exist within the fragment of the genome comprising patent 6,958,235:
patent A, patent B, and patent C. Each numbered patent codes for a separate genetic fragment that is involved in the expression of the C-terminal fragment of MSP1. These three patents must be consumed together in order for Longacre-Andre’s patent to be of commercial (and therapeutic) value.

If no substitutes existed for patents A, B, or C, then Longacre-Andre would have to purchase usage rights to each patent in order to use the entire sequence displayed in figure 2.4. In this case, patents A, B, and C are perfect complements. However, biotech patents are not always perfectly complementary.

Genomic patents may range from weak complements to perfect complements, such that the relationship can be more accurately described as:

\[ P_{\text{output}} = f(P_1, P_2, \ldots, P_n). \]  
\[ (10) \]

If inputs are not perfectly complementary to one another, there may exist other inputs—perhaps inputs that are not under patent protection—that may be substituted for one of the original inputs.

Substitutability could lead to a situation in which:

\[ P_{\text{output}} < (P_1 + P_2 + \ldots + P_n). \]  
\[ (11) \]

Note that this assumes that the output uses exactly one unit of each input here. The above scenario leads to a lower output price (compared to the result shown in equation 10), but the relationship assumes that there exists a substitute or substitutes that are available to one or more of the inputs. Substitutes may be goods that are already going into the product (i.e., good 1, 2, …, n -1, n), or entirely different inputs all together. Equation 11 illustrates Samuelson’s (1974) idea of substitutable goods: “the benefit from both [substitutable goods] together is surely less than the sum of each’s separate benefit…”
The availability of substitutable inputs in biotechnology could lead to lower output prices and higher levels of innovation.

The lower the input prices (here, the price of purchasing patent rights), the more willing a scientist will be to incorporate its findings into his or her own research or product. If substitutes are available in biotechnology, the fragmentation of property rights will be less likely to produce an inefficient outcome. However, substitutes in biotechnology rarely (or never) exist, as inputs are extremely specific; there are no substitutes for a particular piece of DNA, as a segment is uniquely defined by a sequence of nucleotides. Thus, other measures must control for the inefficient outcomes that anticommons problems can produce.

2.5 Transaction Costs: Impediments to Bargaining

From an economic standpoint, complementary genomic patents only become problematic when transactions costs are high. If bargaining is possible, a patent should eventually be assigned to the party that values it most. This idea, defined by the Coase Theorem, means that if transactions are costless, “the initial assignment of a property right will not affect the ultimate use of the property” (Posner, 2003, p.7). Richard Posner explains:

By a process of voluntary exchange, resources are shifted to those uses in which the value to consumers, as measured by their willingness to pay, is highest. When resources are being used where their value is highest, or equivalently when no reallocation would increase their value, we say they are being employed efficiently. (Posner, 2003, pp.9-10)

When transactions costs are high, the Coase Theorem does not apply. As Buchanan and Yoon (2000) imply, bargaining between parties, although efficient, does not occur in the anticommons scenario: the existence of transactions costs renders collusion between
independently acting monopolists difficult (Buchanan and Yoon, p.8).

William Landes and Richard Posner (2003) assert: “… the existence of separate patents on complementary gene fragments may make the transaction costs of assembling genetic material needed for research very high” (Landes and Posner, 2003, p.316). These high transaction costs might deter scientists from developing products requiring complementary inputs. In the case of the MSP1 protein, low transactions costs would allow Longacre-Andre to easily gain access to patents A, B, and C. Even if these three patented inputs were perfectly complementary, the market would lead to an efficient solution and the anticommons problem would be avoided: Longacre-Andre would purchase the rights to the patents if she valued them more highly than the cost of accessing them.

High transactions costs may arise for a multitude of reasons, including lack of mutual trust in the scientific community and disparate interests or unrealistic expectations of the parties. The increasing privatization of scientific research has created a competitive environment for research scientists. Uncertainty is also an important factor contributing to high transactions costs in biotechnology. Klaus Brockhoff (1992) explains that transactions costs depend upon the degree of formality and technological scope of cooperative agreements (Brockhoff, 1992, p.516). Formal agreements decrease the level of uncertainty associated with a transaction, thus lowering transactions costs. Conversely, highly technical agreements may increase uncertainty (especially if there is an asymmetry of information between parties), thus increasing transactions costs. Multiple partners complicate the bargaining process, especially in light of the scientific community’s competitive nature.
Brockhoff (1992) explains that the technological life cycle of a product or an industry also affects transactions costs. In the early stages of an industry, uncertainty is likely to increase transactions costs, whereas in later stages, specificity of assets is likely to increase transactions costs. The biotech industry seems unique in that although its assets are highly specific (technical), they are also extremely uncertain. It is very common for a scientist to apply for a patent on a genetic sequence that he has isolated without knowing exactly what the sequence is or what type of useful product might be developed using the sequence. This kind of uncertainty might cause scientists to be wary of other genomic patents.

2.6 When Market Solutions Fail

We have seen that the number of excluders and the degree of complementarity of patented inputs contribute to the scope of the anticommons problem in biotechnology. However, high transactions costs, which are most likely attributable to uncertainty, preclude the achievement of efficient market solutions. When high transaction costs render the invisible hand of the market inoperable, we must rely on a non-market solution to prevent anticommons problems.

Although transactions costs are unavoidable in most markets, they are especially pronounced in the market for biotechnology. Posner states:

Transaction costs are never zero. In fact they may be quite high even in two party transactions... Generally, however, the costs of a transaction rise with the number of parties to it — and very steeply; the formula for the number of links required to join all members of a set of n members is suggestive in this connection: n(n – 1)/2. Even though transaction costs are never zero, the Coase Theorem should approximate reality whenever the transaction cost is less than the value of the transaction to the parties.” (Posner, 2003, pp.50-51)

This model agrees with Buchanan and Yoon’s, showing that more excluders lead to
larger inefficiencies. The number of excluders must be limited to promote efficiency, as fewer excluders lead to lower transaction costs. Patent law can limit $n$ by carefully designating patents: more stringent specifications of the law will ensure that patents contribute to social utility. The law defines patents through several different provisions, codified under title 35 of U.S. Code. An examination of these provisions reveals how U.S. patent law can evolve to promote efficiency and avoid anticommons problems.

Starting from the premise that patent protection on...biotechnology is not likely to be revoked, several scholars have directed their attention toward ameliorative policy amendments. The focus has often been on reducing impediments to future progress for the second-stage researcher without impinging significantly on the initial innovator’s incentives.
- Nancy T. Gallini, 2002, p.146

3.1 Background

When patented inputs are complementary to one another and transactions costs are high, the particulars of patent law become important in safeguarding against anticommons effects in the market for biotechnology. In the United States, patent law is not static; rather, the law evolves over time through the settlement of cases. This designation of the law through courtroom decisions is known as “common law.”

According to some legal scholars, if the invisible hand of the law functions properly, common law should develop in ways that are economically efficient. Richard A. Posner supports this hypothesis in his influential textbook *Economic Analysis of Law* (2003), He states:

What we may call the efficiency theory of the common law is not that *every* common law doctrine and decision is efficient. That would be highly unlikely, given the difficulty of the questions that the law wrestles with and the nature of judges’ incentives. The theory is that the common law is best (not perfectly) explained as a system for maximizing the wealth of society. (Posner, 2003, p.25)

Evolution of the common law towards economic efficiency will maximize social benefit.

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18 Posner defines “common law” as “the fields of law that have been created largely by judges as the by-product of deciding cases, rather than by legislatures; or any field of law shaped largely by judicial precedents” (Posner, 2003, p.31). Although title 35 of US code is statutory and constitutional, U.S. patent law is largely shaped by the outcomes of cases.

19 Posner (2003) explains: “As for the positive role of economic analysis of law- the attempt to explain legal rules and outcomes as they are rather than to change them to make them better- we shall see … that many areas of the law, especially but not only the great common law fields of property, torts, crimes, and contracts, bear the stamp of economic reasoning… It would not be surprising to find that many legal doctrines rest on inarticulate gropings toward efficiency” (Posner, 2003, p.25).
Unfortunately, common law cannot always keep pace with the changing conditions in a given market. Industries in which technologies advance rapidly are particularly challenging to the invisible hand; laws in these markets must continuously adapt to accommodate technological changes. The biotech industry, an extremely dynamic market, is one of these industries. In order to assess whether common law is maximizing social welfare with respect to patents on biotechnology, it is necessary to perform a thorough study of legal cases in the biotech arena. Positive economic analysis of the law will determine whether US patent laws are in fact readjusting to technological changes and dealing with biotechnology efficiently.

The Constitution of the United States declares: “Congress shall have power… to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries” (U.S. Const., art I, § 8). The earliest U.S. patent laws were enacted in 1790, and have been revised several times. Cases concerning patent law are tried in the US Court of Appeals for the Federal Circuit.

US patent laws are codified under Title 35 of United States Code. Title 35 begins by describing the nature of subject matter that may be patented. Section 101 of the title explains:

Whatever invents or discovers any new and useful 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. (Patent Act of 1952, § 101)

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20 Patent laws underwent a major revision effective January 1, 1953. Then, on November 29, 1999, Congress enacted the American Inventors Protection Act of 1999 (AIPA), which further revised the laws (US Patent and Trademark Office).

21 Because § 101 of US Code 35 is rather vague as written, the courts rely upon previous legal cases to guide their decisions on whether subject matter meets the conditions and requirements of the section (i.e., Cochrane v. Deener and Diamond v. Chakrabarty). Due to the dynamic nature of the biotech industry, courts must be willing to constantly alter the definitions of patentable subject matter to accommodate
Although an invention must fall into one of the four categories laid out in the code in order to obtain a patent, “[t]he question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to… but rather on the essential characteristics of the subject matter, in particular, its practical utility” (Epstein, 2006, p.5-7). Not all “patentable” subject matter fulfils the necessary conditions and requirements of the law that must be met in order to secure a patent.

3.2 Possible Safeguards Against An Anticommons

The successful enforcement of several statutory requirements of title 35, including utility, novelty, nonobviousness, and adequate disclosure, may be crucial to the prevention (or alleviation) of adverse anticommons problems associated with the emerging technologies. Over time, the courts have developed the following definitions of subject matter. A process is an act or a series of acts that produces a desired result. In Epstein on Intellectual Property, Richard Epstein lays out a Supreme Court definition of a process from the case Cochrane v. Deener: “A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing” (2006, p.5-6). Many patents in biotechnology are “process” patents. These processes often include new methods of purifying proteins. The definition of “machine,” as laid forth in title 35, requires no explanation. A manufacture is any tangible object (other than a machine or a composition of matter) that is “man-made and not found in substantially the same form in nature” (Epstein, 2006, p.5-7). The findings in Diamond v. Chakrabarty reinforce the idea that although naturally occurring life forms are not patentable, anything manmade is patentable (see chapter 2, section 2.1, page 5). In Diamond v. Chakrabarty, which approved the first “manufacture” patent in biotechnology, the Supreme Court stated: "[g]uided by these canons of construction, this Court has read the term 'manufacture' in §101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery’” (Diamond v. Chakrabarty). Since this seminal case, numerous “manufacture” patents have been obtained in biotechnology, consisting mainly of genetically engineered proteins or proteins that have been purified. Purified proteins may be naturally occurring proteins, but these proteins are not patentable as found in their natural state: in order to meet patent specifications, a scientist must purify a protein through a specific method or extraction process that is, or reasonably could be, commercially viable. A composition of matter is a physical or chemical composition of two or more ingredients to produce a mixture or compound (Epstein, 2006, p.5-7).
patenting of biotechnology. These measures safeguard against anticommons problems via two mechanisms: through the reduction of transactions costs, or through the elimination of junk patents.

High transactions costs impede the transfer of technology, especially when patents are complementary to one another. If transactions costs are too high in biotechnology, scientists may be discouraged from pursuing research in areas requiring the accession of multiple property rights. Other things being equal, the problem of high transactions costs in biotechnology can be avoided if a patent is initially granted to the party who values it most. However, in a common law system, arduous (and costly) legal procedures are often required in order to determine which party most values a patent. Richard Posner (2003) reports:

Unfortunately, assigning the property right to the party to whom it is more valuable is not a panacea. It ignores the costs of administering the property rights system, which might be lower under a simpler criterion for assigning rights… and it is difficult to apply in practice. (Posner, 2003, p.52)

The costs of administering property rights—litigation costs—“delay” the economic efficiency of the common law. Lengthy law suits impede the invisible hand of the law by preventing the law from modifying itself quickly enough to keep up with the rapidly changing conditions of the biotech market. Although costly litigation procedures may delay efficiency, they must be incurred to increase efficiency in the legal system. Thus litigation costs will be ignored, as they are necessary to the evolution of the law.

23 A market solution may be achieved through the formation of patent pools. Although patent pools may lead to an efficient outcome, such pools have not been formed in the biotech industry. This paper
24 See discussion of the Coase Theorem, section 2.5.
25 The adequate disclosure requirement of patent law helps to lower these costs, as will be discussed in section 3.2.4.
26 If litigation is so costly, why don’t most parties settle out of court? Would this be more efficient? In a common law system, out of court settlement may actually be less efficient: the more times a rule is brought to court, the more opportunity the court has to reexamine it. Parties are more likely to bring higher-stakes cases to court, so it is important that the laws regarding high-stakes situations are efficient. Posner (2003)
Another notable impediment to economic efficiency in biotechnology is the formation of “junk patents.” Junk patents are patents that add little value to society but lead to the dissipation of rent. In order to understand the inefficiencies that junk patents produce, the term may be defined in reference to Buchanan and Yoon’s theoretical model of the anticommons: a “junk” patent represents an increase in “n” that provides no social value in and of itself. Each additional “n,” signifying one “unit” of exclusion right (in the case of biotechnology, one patent), increases the size of the deadweight loss in the market by augmenting inefficient anticommons effects. The existence of junk patents means that an upsurge in patents does not necessarily reflect a marked increase in innovation: higher patent counts “may result from a decision to seek many insignificant patents rather than a few larger patents on more fundamental inventions” (Gallini, 2002, p.138). Similarly, the granting of questionable patents may increase the likelihood of costly infringement lawsuits.27 In light of the inefficiencies arising due to high transaction costs and junk patents, the following measures seem to be evolving to control for anticommons problems in the market for biotechnology.

3.2.1 Utility (35 U.S. C. §101)

Section 101 states that patentable subject matter must be “new and useful.” A patent is only bestowed upon an innovation if that invention is considered to have a practical utility. This utility requirement sorts the “junk” patents, which pose as a threat to innovation, from the legitimate patents, which provide important incentives and

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27Approximately 6 percent of all biotechnology patents are litigated. This number is significantly higher than that of other markets: the overall litigation rate is only 1 percent of all patents (Gallini, 2002, p.148).
produce commercially viable products. Unless a patent embodies some sort of practical use, it cannot contribute to total social utility.

Modern judicial interpretation of the utility requirement starts with the 1966 Supreme Court decision in Brenner v. Manson (Baillie et. al., 1996). This case dealt with the patent application for a process of the production of a steroid compound for which no utility was disclosed (although utilities for other steroids were known). The court found that the mere result of scientific research does not justify the grant of a patent: “[u]nless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field” (Brenner v. Manson). The avoidance of broad patents similarly alleviates anticommons problems by decreasing the likelihood of complementary patents.28 Broad patents are problematic, but small fragmented patents can also lead to inefficient outcomes: just as broad patents can “block” more precise patents, smaller patents can “block” broader patents (if transaction costs are high). Some sort of middle ground must be reached between overly broad and overly precise patents. The statutory requirements of US patent law attempt to guide patents towards this middle ground.

Although it is important that all patents be useful, overly stringent utility requirements could stifle biotech research. In 1994, the Commissioner of the US Patent

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28 Patents protecting broad concepts in biotechnology are more likely to be complementary to other patents due to the nature of genomic patents. In figure 2.4, a “broad” patent might be one comprising the entirety of the genetic sequence of the C-terminal portion MSRP1. Thus, patent 6,958,235 is a broad patent. The broader a patent, the more likely it is that smaller, more “precise” patents may exist within the scope of the broad patent. Smaller patents (i.e., patents A, B, and C in figure 2.4) may be entirely valid: they may not infringe upon the broader patent, and they may be beneficial to society. However, a scientist who attempts to conduct research in hopes of attaining a patent in the area of patent A, B, or C must gain access to information protected by the broader patent. The broader patent covering the entire genomic region of figure 2.4 is complementary to any smaller patents within its domain.
and Trademark Office (PTO) instituted a review of biotechnology patent prosecution, including the issue of utility. Many applicants for biotech patents complained that:

[E]xaminers in the biotechnology group were requiring, in many cases, the submission of clinical data in order to overcome a lack of utility rejection… Such rejections led to difficulty for many applicants because without a patent or the likelihood of obtaining a patent, an applicant could not raise the funds to conduct clinical trials and without clinical trials the applicant could not obtain a patent. (Baillie et. al., 1996)

The PTO proposed new Utility Examination Guidelines on January 3, 1995, which no longer require the submission of clinical data before granting a patent on a biotech product.29 US courts must find the correct level of utility requirement that strikes a balance between the incentive to innovate and the avoidance of “junk” patents.

3.2.2 Novelty (U.S.C. §102)

In order to be patented, an innovation must be entirely novel. If subject matter has been used, known, claimed, patented, or described in a printed publication by the inventor or someone other than the inventor prior to the inventor’s alleged date of invention, the subject matter is not patentable under US law (Epstein, 2006, p.5-9).30 Patents exist as a means of incentivizing the innovation process: unless an individual develops something new, no innovation has actually occurred.31 US patent law operates under the tenet that an individual deserves to enjoy the temporary monopoly rights that patents afford only if the innovator introduces something novel to society.

29 In a statement to the press, the Commissioner explained, “while drug makers will still have to show the potential usefulness of new biotechnology products, they can satisfy the requirement by submitting any kind of evidence to demonstrate that their claims are credible” and that the “examiners will no longer impose unrealistic and unattainable evidentiary requirements on patent applicants” (Baillie et. al., 1996).
30 An invention can be precluded under section 102 only if it has been “completely” anticipated. Complete anticipation occurs “when each and every element of the invention as claimed can be found in a single prior art reference” (Epstein, 2006, p.5-9).
Section 102 allows inventors a one-year grace period prior to the date of a patent application. An inventor may not receive a patent if the subject matter of the claimed invention was “publicly used or on sale in the United States by anyone, including the inventor, more than one year before the effective filing date of the U.S. application” (Epstein, 2006, p.5-10). An invention may be classified as “used” if it has been reduced to practice in any way.32 The one year time constraint that patent applicants must adhere to may foster a culture of secrecy within the scientific community: scientists must be very secretive about their findings before they prepare and file a patent application. Jeremy M. Grushcow explains:

The Patent Act’s 1-year clock provides an incentive to withhold publication [of scientific data] until work is substantially complete and ready for patent filing (or until the patent application has already been filed). (Grushcow, 2004, p.73) 33

32 An invention may be classified as “used” if it has been reduced to practice in any way. Epstein (2006) explains: “Reduction to practice may be actual, i.e., the invention is reduced to a tangible embodiment, or constructive, i.e., described with sufficient detail in a filed U.S. patent application” (p.5-9).

33 In a 2004 paper, Grushcow empirically measures scientists’ secrecy “by measuring the delay between a scientist’s presentation of data at a scientific meeting and the formal publication of that work in a peer-reviewed journal” (2004, p.60). He calls this delay the “publication gap.” A short publication gap suggests that scientists have engaged in secretive behavior by delaying the presentation of data to their peers until their work is substantially complete. By examining data from the 1980 and 1990 meetings of the American Association for Cancer Research, Grushcow found that scientists seeking patents did indeed exhibit shorter publication gaps, suggesting the practice of secrecy. The table below, taken from Grushcow’s paper, displays his findings. University scientists and scientists at the NIH who were seeking patents displayed much shorter publication gaps than their non-patent-seeking counterparts. Patent-seeking industry scientists, however, display a loner publication gap than their non-patent-seeking counterparts. Grushcow explains: “This behavior may reflect the fact that once a patent application has been filed, formal publication is no longer necessary to protect the inventor’s economic interest. Presumably, having satisfied their primary goal of patent filing, formal publication becomes very low priority for industry scientists” (pp.74-75). The publication of research findings is more important to the careers and reputations of university and NIH scientists than industry scientists.

<table>
<thead>
<tr>
<th>Table 4. Effect of Patent Seeking on Early Data Sharing: Average Years to Publication after Meeting Presentation</th>
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<tbody>
<tr>
<td>University Scientists</td>
</tr>
<tr>
<td>Not seeking patent</td>
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<tr>
<td>Seeking patent</td>
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<td>p-Value</td>
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Note. Values presented are mean ± standard error of the mean.

Source: Grushcow, 2004, p.74
Withholding scientific findings from the public domain could lead to the under-use of scarce resources. A strict novelty requirement could hinder the dissemination of information. The problem of secrecy, however, may be curtailed by the disclosure requirement of patents, as set forth in section 112.

Another problem associated with exceedingly strict novelty specifications is that these requirements may lead to costly legal challenges concerning infringement. In biotechnology, where genomic patents may differ by only a few amino acids, the question of novelty is often disputed. This sort of dispute occurs in *Amgen v. Chugai*, which will be discussed further in chapter 3. In assessing priority of invention, both the date of conception of invention and date of reduction to practice must be considered. In the *Amgen* case, the Federal Circuit found that although the method of isolating a specific protein had already been conceived of, it had not yet been reduced to practice. Thus, Amgen’s patent (in which said method was claimed) was indeed novel, as Amgen was the first to succeed in using the difficult method to yield a protein. Like the utility requirement, the novelty requirement rewards innovators who produce commercially viable (i.e., socially beneficial) innovations.

### 3.2.3 Nonobviousness (U.S.C. §103)

Patentable material must not only be new and useful but also “nonobvious.”

Section 103 (a) of US Code 35 states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. (Patent Act of 1952, 35 U.S.C. §103a)
A “person having ordinary skill in the art” is not a lay person, but one who is familiar with the subject matter at hand. Whether an invention is “obvious” depends on the particulars of the industry in which it is produced, and in the case of the biotechnology, the definition of “obviousness” is highly contested. In 2004, the National Research Council, a sector of the National Academy of Sciences and the National Academy of Engineering, issued a report (“A Patent System for the 21st Century”) recommending several significant changes to US patent law. The Academies’ standing Board on Science, Technology, and Economic Policy (STEP)34 initiated the study because it realized that the rapid pace of technological change across many industries—especially the biotech industry—was creating stresses in the patent system that needed to be examined to ensure that patents continue to stimulate innovation, rather than impede it (Merrill et. al., 2004).

These concerns surrounding the biotech industry seem to be closely associated with the anticommons problem. Although the report does not mention an “anticommons effect” or “economic efficiency,” its recommendations point towards solutions to the anticommons problem.

The report makes seven recommendations to improve US patent policy. Recommendation number 2, “Reinvigorate the nonobviousness standard,” urges courts to reconsider nonobviousness standards in the biotech industry:

The requirement that to qualify for a patent an invention cannot be obvious to a person of ordinary skill in the art should be assiduously observed… Gene sequence patents present a particular problem because of a Federal Circuit ruling making it difficult to apply the obviousness test in this field. This is unwise in its own right and is also inconsistent with patent practice in other countries. (Merrill et. al., 2004)

34 The Academies assembled a committee that included three corporate R&D managers, a university administrator, three patent holders, and experts in biotechnology, bioengineering, chemicals, telecommunications, microelectronics, and software, as well as economists, legal scholars, practicing attorneys, and a former federal judge (A Patent System for the 21st Century, 2007).
The ruling that the report refers to in the above recommendation is the Federal Circuit’s decision in *In re Bell*. In this case, the court held that a gene qualifies as nonobvious unless its sequence is “predictable” from the prior art.\(^3\) However, the report alleges that because a gene’s sequence is so rarely “predictable,” the Patent Office has been allowing many undeserving applications to issue.

In legal terms, a *per se* rule dictates that a certain action or activity is legal by its very nature. *Per se* decisions ignore the surrounding circumstances of a case, and are usually determined by statute or case law. The alternative to a *per se* ruling, a “rule of reason” approach incorporates the specific details of a case into account. In the case of genetic sequences, a *per se* rule dictates that, because of the degeneracy of the genetic code (i.e., because of its inherent nature), knowing the amino acid sequence of a protein does not render the protein’s genetic sequence obvious. In their report, The National Research Council recommends “that this ‘per se’ rule of non-obviousness [as determined in *In re Bell*] for a genetic sequence should be overturned and that the courts should return to the stricter ‘reasonable expectation of success’ standard applied in *In re O’Farrell*” (Scheinfeld and Bagley, 2004). Saying that any genetic sequence is unpredictable is inefficient, especially as better research tools are developed. It is likely that too many patents are granted on account of the *per se* rule.

\(^3\) The court commented: “…it may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. However, because of the degeneracy of the genetic code, there are vast numbers of nucleotide sequences that might code for a specific protein” (*In re Bell*). The “degeneracy” of the genetic code refers to the way in which nucleotides (A, T, C, and G,) code for amino acids. Amino acids are the building blocks of proteins, and nucleotides are the building blocks of amino acids. Every amino acid is described by a series of 3 nucleotides. However, several amino acids are described by more than one series of 3. For example, although the genetic sequence for the amino acid methionine is always ATG, the nucleotide sequence of the amino acid leucine can be TTA, TTG, CTT, CTC, CTA, or CTG (Berg et. al., 2007, p.125). Thus, it can be very difficult and painstaking to determine the genetic sequence of a particular protein, especially if this protein is large (i.e., 700+ amino acids). The genetic code will be discussed further in chapter 4.
The “reasonable expectation of success” standard that the report recommends adheres to a “rule of reason” approach to law. The court’s decision in *In re O’Farrell* rejects a per se ruling on the unpredictability of a genetic sequence, stating: “obviousness does not require absolute predictability of success, merely a reasonable expectation of success” (Baillie et. al., 1996). This standard is likely to deter junk patents that are, in fact, obvious.

### 3.2.4 Adequate Disclosure (U.S.C. §112)

An inventor must disclose his or her invention upon the application for a patent. Nancy Gallini explains:

A [main] purpose of patents is to promote disclosure, a benefit that remains intact under the modern dynamic theory of patents. Inventions that would be kept secret without patents are more likely to be revealed when under patent protection, making them freely available after the patent expires. (Gallini, 2002, p.132)

There are three main stipulations under the adequate disclosure requirement: written description, enablement, and best mode. The description requirement asks that the inventor describe his or her invention with enough detail such that one ordinarily skilled in the art is led to believe that the inventor had the invention in his or her possession at the time of filing the claim to the invention. Enablement requires that disclosure is sufficient enough that a person reasonably skilled in the art could make or use the invention as described. The best mode of the invention known to the inventor – at the time a patent application is filed – must also be disclosed. Epstein (2006) explains, “This [best mode] requirement precludes the inventor from concealing a preferred embodiment

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36 This description must be “definite:” an inventor’s claims must be clear, concise, and exact enough such that “the claims have a definite meaning understandable to those skilled in the art” (Durham, 1999, p.66).
of the invention at the time the patent application is made” (Epstein, 2006, p.5-21).

Adequate disclosure is socially beneficial for several reasons.

By placing valuable information in the public domain, disclosure provides free access to an invention once its patent expires. Additionally, disclosure helps to prevent inadvertent infringement and may prevent wasteful duplicative research. Finally, disclosure may inspire further new ideas (Gallini, 2002, p.139). This spurring of new ideas would actually aid in future innovation, rather than impede it, thus alleviating an adverse effect of the anticommons problem. Importantly, when an innovation is described in detail, there is less uncertainty concerning the patent.

The more accurately a patent is described, the more efficiently it behaves as a piece of private property. When multiple parties know precisely what they are bargaining for, transactions costs are greatly reduced in a market. A reduction in uncertainty could have vast implications in the biotech industry, as far as transactions costs are concerned: lower levels of uncertainty facilitate bargaining between parties. Licensing agreements are more easily negotiated if each party knows what it will get out of its license. In turn, well defined rights foster mutual trust between scientists, as successful negotiations will build rapport between bargaining parties.

3.3 Is the Efficiency Theory of Common Law Working?

As has been shown, certain technical provisions of U.S. patent law can evolve in ways that facilitate efficient outcomes. However, the fact that the law can evolve to promote efficiency does not mean that it will. It is impossible to tell how the law is evolving without looking at specific court cases. In some cases, the courts have an
opportunity to reevaluate their interpretation of U.S. patent law with respect to genomic patents in biotechnology. The provisions set forth in this chapter (chapter 3) will serve as a metric for determining whether a court’s ruling is likely to promote – or impede – economic efficiency. Some major trends in recent court rulings seem to support Posner’s economic efficiency of common law hypothesis. The next chapter provides evidence of the evolution of U.S. patent law towards efficiency in the biotech industry.

Trying to patent a human gene is like trying to patent a tree.
You can patent a table that you build from a tree, but you cannot patent the tree itself.
-William Haseltine
President, Human Genome Science

4.1 Rationale

If patent laws are to promote economic efficiency, they must inspire innovation, promote disclosure, and facilitate technology exchange. The US Federal Circuit’s treatment of the utility, novelty, nonobviousness, and adequate disclosure of patents should indicate whether the common law is moving towards – or away from – economic efficiency in the market for biotechnology.

For this exercise in positive economic analysis to be accurate, each court case must be chosen carefully. Firstly, the cases must be representative of the biotech industry. Analyzing an anomalous case will lead to erroneous conclusions; unique cases leave little room for generalizations concerning the efficiency of the law. Secondly, cases that have set a common law precedent are particularly desirable candidates for analysis. These cases provide a clear picture of the direction in which the law is evolving, as each new precedent steers the law in a particular direction.

Two well-known US Federal Circuit cases, *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd* (hereafter *Amgen v. Chugai*) and *In re Dane K. Fisher and Raghunath V. Lalgudi* (hereafter *In re Fisher*), meet the preceding criteria. Both *Amgen v. Chugai* and *In re Fisher* deal with the patenting of specific DNA sequences – the most common kind of patent in the biotech industry. The two cases also set strong precedents for subsequent cases: the Federal Circuit’s ruling in *Amgen* increased the scope of enablement necessary to obtain a genomic patent, while the court’s *In re Fisher* decision clarified and
strengthened the utility statute. The remainder of this chapter is devoted to analyzing the court’s decisions in these two cases.

### 4.2 Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.

#### 4.2.1. Case Background

Decided in the Spring of 1991, the Federal Circuit’s ruling in *Amgen v. Chugai* is considered a landmark decision on genomic patents. The case deals with a pair of patents on a gene fragment coding for the human protein erythropoietin (EPO).\(^{37}\) EPO stimulates the production of red blood cells, and is a useful therapeutic agent in the treatment of certain blood disorders, notably anemia.\(^{38}\) Chugai’s patent (patent ‘195)\(^{39}\), issued on June 30, 1987, claims homogeneous EPO (and compositions thereof) and a method for purifying human EPO. Amgen’s patent (patent ‘008)\(^{40}\), issued on October 27, 1987, claims “[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin… and host cells transformed or transfected with [the] DNA sequence” (*Amgen v. Chugai*).\(^{41}\)

The same day the ‘008 patent was issued, Amgen filed suit against Chugai, alleging that the pharmaceutical company had infringed upon the ‘008 patent by producing recombinant EPO similar, but not identical, to purified human EPO. Chugai had manufactured recombinant EPO by use of transformed host cells containing vectors

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\(^{37}\) Human EPO consists of 165 amino acid residues (*Amgen v. Chugai*).

\(^{38}\) Amgen manufactures Epogen®, a top-selling anemia drug.

\(^{39}\) “Method for the Purification of Erythropoietin and Erythropoietin Compositions”

\(^{40}\) “DNA Sequences Encoding Erythropoietin”

\(^{41}\) *Amgen v. Chugai* serves as a fine template for the analysis of the anticommons problem: the ‘008 and the ‘195 patent are remarkably similar. In order for either company to effectively utilize their patent, they must access the other company’s patent as well. It is for this reason that Amgen filed suit against Chugai on the very day that Amgen received its patent; the company feared that its own property would be much less valuable if Chugai’s patent were enforceable.
with DNA coding for the production of human EPO. Chugai answered Amgen’s claim and counterclaimed, alleging that Amgen’s ‘008 patent was invalid under 35 U.S.C. §§101, 102, 103, and 112. The lower court held that Chugai’s infringement of Amgen’s ‘008 patent was not willful, and held that some of the ‘008 and ‘195 patents’ claims were valid, while some were not. Chugai appealed and Amgen cross appealed, finally bringing the case to the Federal Circuit. Of note are the Federal Court’s rulings concerning the ‘008 patent’s obviousness, best mode, and enablement.

4.2.2. Federal Circuit Ruling

Dr. Fu-Kuen Lin, an employee of Amgen, was the innovator behind the ‘008 patent. Chugai alleged that Lin’s method of isolating the DNA sequence of EPO was obvious. However, expert witnesses attested that none of the prior art references suggest that Lin’s method would be likely to succeed in pulling out the gene of interest. Lin used a set of “fully degenerate” probes to determine the gene’s sequence:

Because some amino acids have several possible codons and the researcher cannot know which of the possible codons will actually code for an amino acid, he or she may decide to design a set of probes that covers all possible codons for each amino acid comprising the protein, known as a “fully-degenerate” set of probes. (Amgen v. Chugai)

The Federal Circuit agreed with the district court, explaining that Lin’s method of using a fully-degenerate set of probes was nonobvious. Lin succeeded in using a difficult, albeit known, method of isolating the DNA sequence of the EPO protein. Notably, the court found that “no one had successfully screened a genomic library using fully-degenerate

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42 A vector is an entity that transports a specific sequence of DNA and inserts itself into the DNA of a host cell. This process allows for the production of recombinant DNA (Berg et. al., 2007, p.154).
43 Court cases are filled with extraneous claims, as lawyers are always looking for details that will win their client’s case. The details of any case may or may not be relevant, and the legal gibberish must be sorted from the meat of the case. Only decisions concerning economic efficiency and anticommons problems are of interest; therefore, the remainder of this analysis will focus on these decisions.
44 A probe is a radiolabelled nucleic acid sequence placed in a DNA library to detect a complementary base sequence by hybridization. See figure 4.1.
probes of such high redundancy as the probes used by Lin” (*Amgen v. Chugai*).

Although scientists had conceived of using such a method to determine EPO’s genetic sequence, Lin was the first to succeed; he was the first to reduce the method to practice.

Chugai also contended that Lin had failed to divulge his best mode of practice in his application for patent ‘008. The court explains: “[o]ne must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode known to him of carrying out his invention” (*Amgen v. Chugai*). Lin’s best mode of practice was by use of a “specific genetically-heterogeneous strain of Chinese hamster ovary (CHO) cells,” which produce EPO at a faster rate than other cells. Chugai alleged that, to divulge his best mode of practice, Lin would have to make a deposit of the CHO cells, as one skilled in the art could not duplicate Lin’s best mode without the use of these cells. In patent ‘008’s written description, Lin did not specify which of two CHO cell lines he considered to be best for isolating the EPO gene. However, both the district court – and the Federal Circuit – found that Lin’s best mode was disclosed because both cell strains were disclosed. The Federal Circuit relied on a PTO-prescribed guideline concerning the deposit of biological materials in their decision:

> The best mode requirement is a safeguard against the possible selfish desire on the part of some people to obtain patent protection without making a full disclosure. The requirement does not permit an inventor to disclose only what is known to be the second-best embodiment, retaining the best… If a deposit is the only way to comply with the best mode requirement then the deposit must be made. (*Amgen v. Chugai*)

The court held that a scientist of ordinary skill in the art could produce mammalian host cell strains with similar levels of EPO production without a deposit from Lin’s line.

Chugai’s counterclaim involving the enablement of Amgen’s ‘008 patent is of particular significance to the biotech industry. In the case’s initial trial, the district court

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45 See footnote 35, chapter 3.
found that Lin’s written description of his method of isolating EPO’s genetic sequence did not sufficiently enable anyone skilled in the art to replicate his process. The Federal Circuit affirmed this ruling, explaining that the scope of an inventor’s enablement must match the scope of his claim. In this case, Lin’s claim was extremely broad, claiming all genetic analogs of EPO and all genetic sequences containing “at least part” of EPO’s DNA sequence. The Federal Circuit stated that Lin’s disclosure would justify only a generic claim on the few analogs that he disclosed, instead of the over 3,600 possible EPO analogs:

This “disclosure” might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen’s desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them. (Amgen v. Chugai)

Lin’s claim outstrips his description of enablement in scope; the amount of experimentation necessary for one skilled in the art to replicate his procedures would be excessive. A scientist would have to synthesize thousands of DNA analogs in order to reproduce Lin’s experiment. The court’s above ruling underscores the importance of avoiding overly broad enablement descriptions, such as Lin’s. Such a broad enablement description implies that an innovator is not familiar with his invention. By assuring that a patent applicant knows precisely what he has discovered and what he will own, the

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46 Lin’s broad claim was as follows: “DNA sequences provided by the present invention are thus seen to comprehend all DNA sequences suitable for use in securing expression in a prokaryotic or eukaryotic host cell of a polypeptide product having at least a part of the primary structural conformation and one or more of the biological properties of erythropoietin, and selected from among: (a) the DNA sequences set out in [Lin’s written description], (b) DNA sequences which hybridize to the DNA sequences defined in (a) or fragments thereof; and (c) DNA sequences which, but for the degeneracy of the genetic code, would hybridize to the DNA sequences identified in (a) and (b)” (Amgen v. Chugai).

47 Human EPO consists of 165 amino acid residues (Amgen v. Chugai). Each of these residues consists of a sequence of 3 nucleotides, and most amino acids are described by more than one 3-nucleotide sequence (up to four). Thus, if each residue in EPO has two possible nucleotide sequences, there are 27,225 (165^2) possible DNA analogs.
enablement requirement reduces uncertainty in the market for genomic patents. This reduction in uncertainty lowers transaction costs, alleviating anticommons problems.

4.2.3. A Heightened Disclosure Requirement

The nonobviousness requirement of U.S.C. §103 deters the accumulation of junk patents in the biotech market. As discussed in chapter 3, the use of *per se* rules of nonobviousness is dangerous, as this approach can augment anticommons problems associated with patents lacking social utility. The court’s ruling on the obviousness of patent ‘008 seems to be consistent with the avoidance of anticommons problems. Instead of stating that the patent is nonobvious due to the unpredictable nature of recombinant DNA techniques, the court highlights the important fact that Lin was the first individual to successfully reduce the particular process to practice. Innovators who produce viable products should be rewarded, as these products (allegedly) contribute to social utility. Here, Lin’s patent is nonobvious because the *product* is nonobvious – although the conception of the product is not. If the court had ruled that Lin’s process was obvious, this decision would serve as an impediment to future research.

In what was perhaps the most significant ruling on adequate disclosure in the history of the biotech industry, the Federal Circuit’s decision on Lin’s enablement of patent ‘008 set a strong precedent for future cases involving genomic patents. Subsequent cases have often citing the following ruling:

A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. (*Amgen v. Chugai*)
As a result of Amgen, the common law concerning genomic patents is more stringent. If a patent’s written description does not include a sufficient number of examples of DNA analogs of a desired protein, it is not enabling.48

Since the Amgen case, the courts have further refined the written description requirement necessary to obtain a genomic patent (Berman and Schoenhard, 2004, p.1307). In Fiers v. Revel (1993), the courts found that “[a]dequate written description of DNA requires ‘more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself’” (Berman and Schoenhard, 2004, p.1307). The court’s ruling shows that the unpredictable nature of biotech inventions mandates a heightened enabling disclosure.

In a 2002 meeting of the Boston College Intellectual Property and Technology Forum, Adam I. Hasson wrote:

The enabling and written description requirements require heightened standards in biotechnology prosecutions if the patent system is to operate at optimum health. By applying such standards to an unpredictable art such as biotechnology, the Federal Circuit has assured that the public will continue to gain the knowledge and innovation of inventors in exchange for the grant of a valuable exclusive monopoly. (Hasson, 2002)

Although this account does not mention an anticommons, a heightened disclosure requirement in biotechnology is directly targeted towards avoiding this problem. The enablement description exists to ensure that an innovator knows precisely what he has discovered and what he will own. By assuring that patent applicants are familiar with their intellectual property, the enablement requirement reduces uncertainty with respect to genomic patents. This reduction in uncertainty reduces the level of transaction costs in the market, thus alleviating anticommons problems. Enablement standards are not the same across industries, thus it is clear that the law has developed to take the unique

48 See section 3.2.4 for a description of the enablement requirement.
obstacles present in the market for biotechnology (uncertainty, rapidly developing technology, etc…) into account.

4.3 In re Dane K. Fisher and Raghunath V. Lalgudi

4.3.1. Case Background

In January of 2001, Dane K. Fisher and Rughunath Lalgudi (hereafter “Fisher”), claimed an invention (patent ‘643) relating to five purified nucleic acid sequences that encode for proteins and protein fragments in maize plants. The sequences that Fisher claimed are commonly referred to as “expression sequence tags” or “ESTs” and are used to locate and “tag” complementary nucleotide sequences in long strands of DNA (In re Fisher). EST tags (a type of probe) can be used to determine the nucleotide sequence of a gene fragment (see figure 4.1).

Figure 4.1: Expression Sequence Tags (ESTs)

a) A schematic diagram of DNA replication. Each tick mark represents a nucleic acid. The shorter arrows along the DNA backbone within the replication bubble denote newly synthesized fragments of DNA. These fragments may contain EST tags.
b) Here, the upper portion of the DNA molecule consists of an EST comprising three amino acid residues. These residues are radio-labelled.

Sources: GEENOR: Genetic Engineering Organization; DNA Sequencing Service.

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49 “Nucleic Acid Molecules and Other Molecules Associated with Plants” (In re Fisher).
Fisher claimed ESTs that corresponded to genes expressed in maize leaf tissue without knowing the precise structure or function of the genes or the proteins encoded for by those genes (In re Fisher). In September of 2001, the PTO examiner of the ‘643 patent rejected Fisher’s application, citing lack of utility under § 101 of title 35 U.S.C. Fisher appealed this finding to the Board of Patent Appeals, and subsequently to the Federal Circuit Court.

4.3.2. Federal Circuit Ruling

The Court, along with the Board, agreed with the patent examiner’s initial rejection of patent ‘643, affirming lack of utility under § 101, and also claiming lack of enablement under § 112. Like the Federal Circuit’s enablement ruling in Amgen, the court’s finding concerning the Fisher patent’s utility is of great significance to the biotech industry. The Court denied patentability to expressed sequence tags (ESTs) because they were “only tools to be used along the way in the search for a practical utility” and therefore lacked an immediate real world benefit (In re Fisher).50

4.3.3. Strengthening of the Utility Requirement

In hopes of fulfilling the utility requirement, Fisher identified several potential uses for his ESTs, including use for the identification of polymorphisms51 and use as DNA probes. The court explained that the detection of a polymorphism would only serve to elucidate the genetic heritage of a particular species, a “use” of little practical utility.

50 The court relied upon the Supreme Court’s classic ruling in Brenner v. Manson for support (see chapter 3, section 3.2.1).
51 Polymorphisms are multiple phenotypic morphs of one trait in a particular species (Berg et. al., 2007, p.137b). Polymorphisms are heritable but serve little purpose beyond genomic mapping purposes.
As for the use of ESTs as genetic probes, the court stated that using the ESTs “to isolate nucleic acid molecules of other plants and organisms, which themselves had no known utility, is not a substantial utility” (In re Fisher). The court looked to the Utility Guidelines set forth by the PTO in its treatment of Fisher’s ESTs as a “useful” research tool:

utilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not substantial utilities…[a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact ‘useful’ in a patent sense. [The PTO] must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. (In re Fisher).

According to the courts, allowing EST patents without proof of utility would discourage research and innovation as these patents are considered junk patents until some identifiable use for them can be named.

Fisher’s claims concerning utility merely represent hypothetical possibilities lacking substantial empirical evidence. His claims are not specific- any EST from any gene in the maize plant has “the potential to perform any one of [Fisher’s] alleged uses” – thus his claims are not precise enough to truly describe his invention (In re Fisher). Here (again) the Federal Circuit seems to take the problem of uncertainty in biotechnology into account. US Patent Law is evolving to reduce uncertainty in the biotech market. This reduction in uncertainty will, in turn, reduce transaction costs. The ruling on Fisher’s ESTs set a strong precedent for similar cases in biotechnology. Shortly after the ruling, Pamela A. MacLean wrote in the National Law Journal that “[t]here are probably more than 100 pending patent cases of pure EST applications that are likely to be thrown out” because of the court’s ruling in Fisher (MacLean, 2005). Fisher strengthened the utility requirement, signifying the evolution of the common law.
As we have seen through the analysis of these two cases, both the utility and the disclosure requirements of U.S. patent law have evolved to accommodate the unique conditions of the biotech industry. Recalling chapter 3, we know that both utility and disclosure eliminate junk patents and reduce transaction costs, thus avoiding – or alleviating – anticommons problems.

5. Conclusion

The Federal Circuit Court’s treatment of genomic patents in *Amgen v. Chugai* and *In re Fisher* seems to indicate that although the process is not instantaneous, the law is groping towards economic efficiency. High transaction costs associated with genomic patents prevent the invisible hand of the market from internalizing externalities, but they do little to impede the invisible hand of the law. Although the biotech market is plagued with uncertainty, patent laws can develop to encourage both upstream patent applications and downstream follow-on research.

The changes in U.S. patent law stemming from *Amgen v. Chugai* and *In re Fisher* reinforce Harold Demsetz’ (1967) hypothesis that property rights evolve to internalize market externalities. Demsetz applies his hypothesis to an example of land ownership rights resulting from over-hunting in a commons situation, but implies that the theory may be applicable to intellectual property rights as well:

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52 See footnote 2, chapter 1.
Consider the problems of copyright and patents. If a new idea is freely appropriable by all... [t]he benefits derivable from these ideas will not be concentrated on their originators. If we extend some degree of private rights to the originators, these ideas will come forth at a more rapid pace. But the existence of the private rights does not mean that their effects on the property of others will be directly taken into account. (Demsetz, 1967, p.359)

Demsetz is correct in his assertion that intellectual property right owners may not be concerned with the effects that privatization has on the property of others; the advent of the anticommons problem in the biotech industry confirms this. Happily, Demsetz’ theory on the evolution of efficient property rights seems to apply to the anticommons problem: U.S. patent law is changing to accommodate the technicalities of genomic patents.

Suggested remedies to the anticommons problem involving patent pools, compulsory licensing, and systems of rewards may be overly reactionary; if the law assures that each patent is correctly and rightfully assigned, such complicated measures may be unnecessary. Unfortunately, non-market solutions (i.e., changes in the interpretation of the law) take time to develop. The law must keep pace with technological development, which is no easy feat in the realm of genomic patents. However, over time, the biotech industry will equilibrate, and so will the law.

The extent of the changes in the efficiency of U.S. patent law remains to be seen; economists must pay close attention to Federal Circuit decisions dealing with patents in biotechnology. If laws are unable to develop at a sufficient pace, or if the technology of the biotech industry continues to change rapidly, other solutions must be found to eliminate anticommons externalities. These solutions must address the problem of high transaction costs (uncertainty) in the market for biotechnology, as well as the problem of complementary genomic patents.
6. References


Cochrane v. Deener, 94 U.S. 780 (1876).


Fiers v. Revel, 984 F.2d 1164, 1170-1171 (Fed. Cir. 1993).


In re Bell, 991 F.2d 781, 785 (Fed. Cir. 1993).

In re Dane K. Fisher and Raghunath V. Lalgudi, 421 F.3d 1365 (Fed. Cir. 2005).

In re O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988).


