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*The Gene Wars: Science, the Law and the Human
Genome*

Omid E. Khalifeh

Sonic Hedgehog, Hunchback, Cactus, Porcupine, Groundhog, and Tiggiwinkle are some of the most controversial figures of the twentieth and twenty first century but you may never have heard of them. They are members of a consequential group that can impact every facet of your life yet you probably don't even know they exist. Who are these exotically named titans of the modern age? They are not the latest superheroes to emerge from the Marvel Comics factory. They are six of the thousands of genes that make up the human genome and the nucleus of debate since the first patent on a genetic sequence was issued.

The origin of gene patents can be traced to a watershed decision that spurred disagreement between scientists, politicians, and activists alike. In *Diamond v. Chakrabarty*, the Supreme Court was asked whether or not a genetically modified microbe that eats up oil spills could be patented.ⁱ The fact that the microbe was a living organism caused an eruption of controversy. At the heart of the matter was whether or not the United States patent laws authorize the United States Patent and Trade Mark Office (PTO) to issue patents on living things.ⁱⁱ The patent office believed organisms that exhibit characteristics of life were inherently products of nature thus not within the purview of the patent statute.ⁱⁱⁱ However, Dr. Chakrabarty argued that the organism originated in a lab therefore it was his invention and not a product of nature.^{iv}

Writing for the Court, Chief Justice Warren Burger famously defined the scope of patentable subject matter as “everything under the sun made by man.”^v The Supreme Court had made its decision and those who thought laboratory-made microbes could not be patented lost by a narrow margin of five to four. Perhaps not aware of the monumental impact this decision would have over the next 20 years, the Chief Justice said even

though the case addressed some big issues, the Court believed that *Chakrabarty* was a narrow decision.^{vi}

Although the scope of patentable subject matter had now been defined, whether gene patents fall within the precise limits of the *Chakrabarty* doctrine remains unclear. Decisions from the Supreme Court and the Court of Appeals for the Federal Circuit have been constantly adjusting the boundaries of patentable subject matter in ways that alter assumptions about what is and is not patentable. These fluctuations have been affecting patent applicants and practitioners in the field of biotechnology since the *Chakrabarty* decision came down in 1981. Biotech patents have been shrouded in uncertainty, which is why it took 7 years following the *Chakrabarty* decision for the PTO to issue a one-sentence decree stating that you can patent anything in the world that's alive except a full birth human being.^{vii}

Ever since the atomic bomb was created, the government's role in pioneering areas of scientific research has been debated. This has led the populous to believe that scientific and technical developments described as "progress" are in fact introducing additional elements of risk into society.^{viii} Like atomic energy and later the susceptibility of the information networks to viruses and hacking, genetics has become perceived as a risk.^{ix}

Gene patents have increasingly faced scrutiny from people who often times don't understand genetics or the complexities of the patent process. A lack of understanding has led them to make emotive and one-sided arguments. In his novels, Michael Crichton warns of dangerous mutated bacteria^x and genetically engineered dinosaurs.^{xi} Similarly, in 1831, Mary Shelley warned of maniacal grave robbing scientists who would use their

gifted minds to bring the dead to life.^{xii} Before his death, Crichton entered the political arena and tried to convince Congress to ban genetic sequence patenting.^{xiii} There were others like him who argued that government should interfere with genetic research.

For the past several years, some members of Congress have been proposing set backs to biotechnology. Bills like Representative Xavier Beccera and Representative Dave Weldon's Genomic Research and Accessibility Act have been roaming the halls of the Capital Building for over 2 decades.^{xiv} These bills represent a government effort to control biotechnology and stifle scientific research by banning gene patents. The harsh reality is that some members of government want to use their power to promote personal agendas while ignoring the scientists behind the innovations.

Just as mechanical engineering did not lead to a race of humanoids clamoring to replace all mankind, it is unlikely that genetics and biotechnology will lead to a race of ape/men subjugated to experimentation. History has taught us that if there is a desire and need for invention it will eventually be made^{xv} and many of the worlds leading thinkers have come out in support of genetics and biotechnology. In 1997, members of the International Academy of Humanism (including the famous biologist Francis Crick and author Kurt Vonnegut, Jr.) issued a statement supporting genetic research.^{xvi} Their reasons for supporting biotech are telling:

Some world religions teach that human beings are fundamentally different from other mammals-that humans have been imbued by a deity with immortal souls, giving them a value that cannot be compared to that of other living things. Human nature is held to be unique and sacred. Scientific advances which pose a

perceived risk of altering this "nature" are angrily opposed. . . . As far as the scientific enterprise can determine, [however] . . . [h]uman capabilities appear to differ in degree, not in kind, from those found among the higher animals. Humanity's rich repertoire of thoughts, feelings, aspirations, and hopes seems to arise from electrochemical brain processes...^{xvii}

In the 17th century mankind witnessed the first scientific revolution where religious mores of a geocentric world had to be set aside in favor of the new vision proposed by Galileo. Today we are undergoing a new scientific revolution of sorts. The intellectuals quoted above have begun to shed old-fashioned religious views of human distinctiveness and have acknowledged the fact that genetics does not insult human dignity any more than recognition of a heliocentric world did. "Humanity's rich repertoire of thoughts, feelings, aspirations, and hopes" are not empty notions simply because they can be understood as "electrochemical brain processes".^{xviii}

Some, opponents of gene patents have protested that genes are naturally occurring substances and therefore do not meet the "made by man" requirement of *Chakrabarty*. Any patent claiming a genetic sequence must be invalid because it is directed to a product of nature. But these objections have failed to prevent gene patents from issuing. To date, over 6,000 gene patents have been allowed and they continue to be an important part of the patent landscape.^{xix}

If a scientist comes across something that already exists in nature but that no one else was aware of, she has made a discovery. Unlike inventions, discoveries cannot be patented. In order for something to be patentable it must be novel to world not just the

applicant or the scientific community. With respect to gene patents, applicants have dealt with this requirement by claiming “isolated and purified” genes instead of the gene as it exists in nature. In nature, every gene is part of a much longer chain of nucleic acids that makes up an organisms genome. The genome can contain tens of thousands of genes performing different functions important to the organism’s survival. It would be amiss to say that the genes, which comprise every genome, are “made by man.” This is why opponents of gene patenting believe that “isolated and purified” language is a legal construct designed to offer inventors patent protection while staying within the confines of *Chakrabarty*.

Put simply, inventors have succeeded by avoiding claims directed specifically to genetic sequences as they exist in the body. Such claims would be considered discoveries and would be rejected by the PTO.^{xx} Instead, inventors have used the “isolated and purified” genetic sequence language to narrow their claims in such away that the PTO will grant them a patent. Take the following 2 patent claims for example:

Claim A. A DNA sequence encoding Sonic Hedgehog.

Claim B. An isolated and purified DNA sequence encoding Sonic Hedgehog.

Claim A could not be allowed. But, by adding three more words, Claim B could.^{xxi} To the average person, and many patent experts no doubt, the 2 claims appear to be going after the same thing. Sonic Hedgehog does exist in nature. But, it only exists as part of a larger strand of DNA that comprises an organism’s genome. Isolated and purified Sonic Hedgehog does not exist in nature. It must be created in a lab using state of

the art technology. Is this a case of substance following form? Or have these applicants really discovered something so novel that they are entitled to patent protection?

Opponents of gene patenting argue that this is a distinction without difference.^{xxii} Based on this logic, you should be able to patent the human brain once you removed it from the body and preserved it.^{xxiii} Opponents feel that, because a human gene is created first in nature, the fact that it is in an isolated and purified form doesn't change the quintessence of its origin.^{xxiv} Are the opponents of a gene patents correct or was Justice Frankfurter when he wrote:

It only confuses the issue, however, to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.^{xxv}

Purified natural products have traditionally been considered patentable subject matter. "Yeast, free from organic germs of disease, as an article of manufacture" was the title of patent that was granted to Louis Pasteur in 1873.^{xxvi} Adrenaline purified from glandular tissues and isolated and purified Vitamin B12 were patents that issued to Takamine, and Merck respectively.^{xxvii} The Merck patent was upheld in court over objections that purified vitamin B12 could not be invented only discovered.^{xxviii} As early as 1957, the patent office issued a patent to Isaacs and Lindenmann for a partially

purified protein that was produced by a virus-infected cell.^{xxx}

The importance of gene patents to the biotechnology industry is unquestionable. Billions of dollars are invested in research and development each year.^{xxx} In 1970, it took about 6 years and cost \$8 million to get a new drug from discovery to market approval.^{xxx} Today, the process takes about 17 years and reportedly costs half a billion dollars.^{xxx} Only about one new drug candidate in every thousand makes it all the way through the drug development process to market approval.^{xxx} Without patent protection, the stakes would be far too high for such commercial development.^{xxx}

As a student of science and the law I was afforded a great opportunity to meet with my science professors at the University of California, Los Angeles (UCLA) and learn more about how scientists felt about the state of the patent law. What they taught me educated by opinions in writing this article.

The perception of my professors was that “isolated and purified” feels like a legal maneuver. This legal device looks bad for the patent system and confuses those inside the patent community as well as outsiders. The time has come for Congress to pass legislation specifically dealing with the patentability of genetic sequences. As research pushes the horizons of knowledge, the patent statute should adapt to the burgeoning needs of the biotech industry and its researchers. An absence of clear patent laws undermines our patent system and may one day have catastrophic results.

This article aims to explore issues surrounding gene patents in the context of one of the most revolutionary discoveries of the modern age. In the early 1990s the biggest project ever undertaken in biology was captivating the world. The human genome is considered one of the most outstanding achievements in the history of mankind. Now the

secrets of life appear to be at our fingertips. Scientists have unraveled the blueprints for making a human being and the expectation is that interpreting the genome will give them an understanding of how the body was put together. Scientists now hope that this discovery will lead them to the genetic cause and cure for every disease.

In 2009, the ban on stem cell research was lifted.^{xxxv} When President Obama signed the \$787 billion stimulus measure in February of 2009, the National Institutes of Health (NIH) saw its budget increase by 36%.^{xxxvi} The law gives the health institute \$10.4 billion in addition to its annual budget of \$29 billion, and the new money must be allocated by September 2010 on grants and other projects that can extend no more than two years.^{xxxvii} The National Science Foundation (NSF), is receiving about \$3 billion; and the Department of Energy (DoE) is receiving \$1.8 billion.^{xxxviii}

The newly approved stimulus package includes \$1.3 billion for cancer research in 2009 and 2010, and the head of the National Cancer Institute says that money will go a long way toward doubling the number of research grants that it approves. Specifically, the NCI plans to increase funding for a project that studies tumor DNA in an effort to find better cancer therapies.^{xxxix} Scientists are promising the end of diseases like cancer, Alzheimer's, Parkinson's, and diabetes within the next 10 years.^{xl} If ever there was a time for the Government to step in and settle the controversy surrounding gene patents, now is that time.

According to current estimates, there are fewer than 30,000 genes in the human genome.^{xli} As different groups scramble to get patents on every gene they discover, we are sure to see a surge in litigation by those who want to challenge the validity of gene patents. With the only thing sustaining the legality of gene patents being one narrowly

decided Supreme Court decision, gene patents and the biotech industry are on shaky ground.

The goal of this article is not to decide whether the use of “isolated and purified” claim language is correct or to argue that the gene patents that have already been issued are valid. The goal of this article is to determine whether Congress should enact new legislation adding genetic sequences to the list of patentable subject matter and thus end the debate on whether gene patents fit within the boundaries of the Patent Act. The Constitution grants Congress the power to enact patent legislation to promote science.^{xliii} This article will discuss whether enacting legislation to specifically allow for gene patents will foster scientific achievement in this country and satisfy this requirement. In other words, will gene patents foster the free flow of ideas and scientific discovery that the patent clause was meant to inspire?

Currently, all gene patents are at risk of being invalidated. If this were to happen, the effect on the biotech industry would be catastrophic. Without patent protection, some researchers may be forced to seek shelter under trade secret laws. This would be like erecting a damn on the river of ideas that scientists need to make the discoveries that benefit those suffering from disease.

Genetics is the new frontier of scientific achievement and this article will help to inform it’s readers of the controversy surrounding this consequential issue. The time for intervention is upon us. As the elected representatives of our society, Congress must establish the proper boundaries of patentability. Congress should address certain issues so that there can be certainty for those who rely on gene patents. Congress should decide that gene patents are in the interest of society because these patents hasten the delivery of

life saving technologies. Thus Congress should amend the Patent Act to incorporate a biotechnology specific provision.

This article will attempt to inspire congressional action by providing empirical and statistical data showing how gene patents have benefitted the scientific community and by addressing the most prevalent arguments of gene patent opponents. Section II describes the origins of the gene patent debate. Section III contains information on how gene patents allow the biotech industry to deal with the high cost of doing research. Section IV addresses frequent issues raised by opponents to gene patenting including whether gene patents stifle university research and the “tragedy of the anticommons.” The article concludes with a look at foreign patent statutes and includes suggestions for how Congress can modify the existing United States patent laws to incorporate gene patents.

II. Background - The Origins of a Controversy

The sociopolitical issues surrounding gene patents can be traced back to the first gene patent issued. Alvin Tatenholz was the first patent examiner at the PTO to be presented with a patent application for a genetic sequence. The applicant was the University of California and the application claimed an expression of genes for chorionic somatomammotropin.^{xliii} The year was 1978 and the biotech industry was still in its fledgling stages.^{xliv} Uncertain about what to do with the application, Tatenholz refused to

examine it pending the outcome of a Supreme Court case on the issue of whether a genetically modified bacterium constituted patentable subject matter.^{xlv}

In 1972, Ananda Chakrabarty was a microbiologist working for General Electric Company who had used genetic engineering to create a bacterium that could make cleaning oil spills easier because of how it was able to break down crude oil.^{xlvi} When Chakrabarty applied for a patent on his microbe, the primary examiner refused to approve the application for two reasons: (1) that micro-organisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101.^{xlvii}

Chakrabarty appealed the decision to the Patent Office Board of Appeals and the Board also denied the professors request.^{xlviii} The Board agreed with the examiners finding that the Chakrabarty microbe could not be patented since it was a living organism.^{xlix} However, the Board disagreed with the examiners finding that the microbe was a "product of nature."ⁱ They held that just because something is alive doesn't make it a "product of nature."ⁱⁱ The *Pseudomonas* bacteria that Chakrabarty wanted to patent had characteristics that were not found in nature and therefore Chakrabarty *was* its creator.^{lii} Nevertheless, the microbe was a living organism and that meant it could not be patented.^{liii}

Next, Chakrabarty appealed to the Court of Customs and Patent Appeals. They reversed the decision of the Board and cited to *In re Bergy*, 563 F.2d 1031 (1977) which held "the fact that microorganisms . . . are alive . . . [is] without legal significance" for deciding whether or not something is patentable.

After years of discord in the lower courts, *Chakrabarty* was heard by the Supreme Court.^{liv} Genentech, Inc. (at the time, a relatively small biotech company with only a

handful of researchers) and the University of California (a leader in biotech research) were in favor of patentability. In an amicus curiae brief submitted on behalf of Genentech, Inc., attorney Thomas Kiley argued that the outcome of the case would have a profound impact on future research investments in the biotechnology industry. He explained that confirming the patentability of the microbe would both “encourage a beneficent science and ensure that broad and forward looking incentives remain for those who would pull the next technology.”^{lv}

Jeremy Rifkin was one of amicus curiae opposing patentability of the Chakrabarty microbe. For the past 20 years, Rifkin has been one of the loudest voices against gene patenting. He has written 2 books on the sociopolitical and ethical issues concerning gene patents.^{lvi} He claims that the technology of genetic engineering was not in the public interest, and should not be unduly encouraged by giving unwarranted economic incentives to corporations in the field of genetic research and development through the vehicle of awarding potentially lucrative patents on living organisms.^{lvii}

Rifkin believes that gene patents are a violation of the mandate in Article I Section 8 of the United States Constitution.^{lviii} In what is known as the patent clause, the Constitution grants Congress the power pass legislation that promotes the sciences.^{lix} Congress has used this power to grant inventors limited monopolies on their inventions if these inventions are disclosed to the patent office and survive the rigorous examination process. Jeremy Rifkin argues:

There are tremendous short-term benefits—new plants and animals, new pharmaceuticals and energy sources. But it is naive to believe that these benefits come with no costs. The environmental, social and ethical implications of this

science are chilling. Will the creation of cloned, chimeric and transgenic species mean the end of nature? Will the mass release of genetically engineered organisms into our biosphere mean genetic pollution and irreversible damage to the biosphere in the twenty-first century? What are the risks of making a “perfect” baby?^{lx}

Rifkin’s arguments notwithstanding, the Supreme Court held that the Chakrabarty microbe was patentable in a 5 to 4 decision. In an opinion written by Chief Justice Burger, the holding is described as one of narrow statutory interpretation.^{lxi} The Chief Justice writes:

Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend §101 so as to exclude from patent protection organisms produced by genetic engineering. Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of §101 as it is. The language of that section fairly embraces respondent's invention.

In what is now a famous quote from the opinion, the Court concludes that “anything under the sun made by man” is patentable.^{lxii}

All of the issues surrounding gene patents are far from being resolved. Chakrabarty was not a case about gene patents per se. It was a decision about whether a living organism made in a lab constitutes patentable subject matter.^{lxiii} The Court does not mention gene patenting in its opinion and states that the opinion is one of narrow statutory interpretation. This taken with the fact that *Chakrabarty* was a 5 to 4 decision

means that gene patents are still on shaky ground.^{lxiv} The lack of a rule or clear statement about the patentability of genetic sequences has created numerous administrative difficulties in the patent office and plagues the courts.^{lxv}

The U.C. gene patent was eventually examined and, in 1982, the PTO issued the first gene patent to Regents of the University of California for work carried out on the construction of a plasmid contained in a bacterium and expression of genes for chorionic somatomammotropin.^{lxvi} The advent of gene patenting has paved the way for the economic growth of the biotechnology industry and has proven vital to innovation in the pharmaceutical industry (virtually every new drug has depended on biotechnology). In the U.S., biotechnology patent applications increased to 47,473 in 2002 from 18,695 in 1996 (a 154% increase).^{lxvii}

III. The Cost of Doing Genetic Research and the Effect Gene Patents have had on the Biotech Industry

“Stifling or Stimulating-The Role of Gene Patents in Research and Genetic Testing” was the most recent attempt by Congress to understand the conflicts between those who support and those who oppose gene patents.^{lxviii} This hearing was held before the House Committee on the Judiciary, Subcommittee on the Courts, the Internet, and Intellectual Property chaired by Representative Howard Berman (D-CA) on October 30, 2007. Rep. Berman has been a strong advocate of patent protection for genetic research.^{lxix}

None of the witness who testified before the committee advocated any sort of legislation limiting the patentability of genes or DNA.^{lxx} A Congressional report on the findings of the hearings concluded that developers of research tools "need an income stream from those who use their inventions" and that the "hearing record provides no basis for exempting such tools from patent protection."^{lxxi}

Before a biopharmaceutical can be brought to market it requires on average \$1.2 billion in research and development.^{lxxii} The cost is high for a number of reasons. For every biopharmaceutical that is brought to market, there are approximately 10,000 failed attempts.^{lxxiii}

In addition, the time to go through clinical development and regulatory approval to market for the biopharmaceutical is 97.7 months on average.^{lxxiv} Finally, the cost of the clinical trials is quite high and continues to rise every year. The average cost of research and development went up by 7.5% over the annual rate of inflation throughout the 1990s, the latest years for which figures are available.^{lxxv} In 2005 biotech companies spent \$20 billion on research and development.^{lxxvi} Most studies cost hundreds of millions of dollars and most do not result in a commercial product reaching the market.^{lxxvii}

Historically, gene patents have had a significant role fostering growth in the biotechnology industry. Genentech, Inc. was founded in 1976 by Robert Swanson and Herb Boyer.^{lxxviii} As a biochemist, Swanson could foresee the commercial value of DNA technology.^{lxxix} Together with Boyer, a venture capitalist, they barrowed \$500 and began what would one day be the biggest biotech company in the world.^{lxxx} Their first commercial venture was to try and clone the insulin gene and they gave the University of California a grant to aid in their research.^{lxxxi}

Early on, Swanson recognized the importance of intellectual property protection in genetic research and was quoted saying:

It's been clear for a long time that patents were critical for commercial development. It was really a critical part of this process to get scientists to understand that. It was somewhat in conflict with this idea that we were going to publish, and that was critical to getting the very best scientists and having them and the company be recognized for the quality of their research. So we developed this idea that we are going to publish our work because we think we get more benefit from doing that than we lose by telling our competitors what we're doing. But we're going to patent it beforehand.^{lxxxii}

One issue which concerned scientists was how patenting interfered with their ability to publish their discoveries.^{lxxxiii} Swanson felt that patenting new discoveries did not hamper scientific progress.^{lxxxiv} According to him, patent attorneys were sensitive to the needs of scientists and their desire to publish their discoveries as soon as possible.^{lxxxv} Today, the USPTO publishes every patent application within eighteen months of filing.^{lxxxvi}

In 1979, Genentech filed a patent application for what would eventually become the first-ever FDA approved genetically engineered human therapeutic.^{lxxxvii} The drug, called Protropin, was a human growth hormone drug used to treat dwarfism.^{lxxxviii} Following issuance of the 1979 patent application, Genentech successfully acquired multiple patents related to the human growth hormone.^{lxxxix} Protropin was Genentech's

first marketed drug and has generated \$2 billion in sales to date.^{xc} As of March 2008, Genentech employs more than 11,000 people and Arthur D. Levinson is the Chairman and CEO.^{xc1} The Swiss pharmaceutical conglomerate Hoffmann-La Roche owns the majority of Genentech shares and has offered to buy the remaining.^{xc2}

In the world of biotech, patents are often used as a ‘signaling mechanism’, and the worth of a biotechnology corporation is closely connected to their patent portfolio.^{xc3} These corporations use their portfolios to send messages to both their investors and their rivals.^{xc4} Genentech, Inc. made its first official public offering of stock in October of 1980.^{xc5} The investor’s enthusiasm for biotechnology was evident when stock underwent the most dramatic escalation in the history of the U.S. Stock market.^{xc6} In the first 20 minutes of trading the stock rose from \$35 dollars per share to \$89 dollars per share.^{xc7} That month, Herb Boyer was featured on the cover of Time magazine under the headline: ‘Shaping Life in the Lab: The Boom in Genetic Engineering’.^{xc8}

The biotech industry relies heavily on the patent laws. Perhaps more than any other industry, the people in biotech rely on patents to nurture development.^{xc9} Because of the tremendous amount of time and money that must be invested before a product is ready for market, investors rely on strong patent protection to provide a sense of long-term security. Any change in U.S. patent policy can have a big impact on the biotech industry. In 2000 President Clinton and Prime Minister Blair issued a joint statement regarding the human genome project. They announced that the human “gene map belongs to all.”^c This was interpreted as private companies would no longer be allowed to patent genetic sequences and, that day, stocks for biotech companies went tumbling.^{ci}

IV. 2 Sides of a Long Fought Debate

Patenting genetic discoveries has become one of the most visible and controversial topics in biotechnology.^{cii} For more than 20 years, this area of the patent law has struggled with unresolved issues.^{ciii} Gene patents have ignited controversy and debate amongst scientists, scholars, politicians, and legal academics.^{civ} Notwithstanding the many objections to patenting genetic sequences, the PTO and most patent offices around the world have consistently issued patents on genetic sequences. To date, approximately 20% of the human genome has been patented.^{cv}

The PTO has struggled to make new rules in an effort to keep up with advances in biotechnology. The PTO does this without any legislative assistance. There is little grey area for them since one side of the debate believes that genes are just as patentable as any other invention and the opposition believes that no gene can ever be patented.^{cvi}

Those who oppose gene patents have taken issue with the Federal Circuit's decisions holding that "products of nature" are unpatentable per se, while they continue to uphold patents on isolated and purified gene sequences which do occur in nature.^{cvii} Some opponents do not contest the fact that genetic sequences are patentable but they do disagree with gene patents being issued to inventors who do not disclose the protein that the gene encodes, usually because they do not know what it is. These gene patents include expressed sequence tags (ESTs). ESTs are gene fragments which can be used as probes to locate and characterize complete genes.^{cviii} They are instrumental in gene discovery and gene sequence determination.

Today, approximately 52 million ESTs are available in public databases such as GenBank.^{cix} Corporations such as Incyte, Inc. and Human Genome Sciences, Inc. have filed patent applications on hundreds of thousands of ESTs.^{cx} These applications often contain very broad claims and this has caused concern amongst those who oppose gene patents. Oftentimes, the applicant will claim the EST along with the full gene of which it is a part and future uses of that gene.^{cxii} However, the opponents needn't be too concerned about whether broad claims will in fact be granted because the Federal Circuit's biotechnology jurisprudence suggests that such claims will fail the written description requirement of section 112 of the patent statute.^{cxiii} Still, some worry that recent EST patents such as those granted to Incyte Pharmaceuticals do not clearly describe whether the patent is limited only to the EST fragment or if it conveys broader rights.^{cxiii}

Another concern for those who oppose gene patents are patent applications for single nucleotide polymorphisms (SNPs). SNPs are the areas in a genome which differ from person to person by just a single base pair. The human genome is thought to contain approximately 300,000 SNPs.^{cxiv} Scientists believe that these small variations in an individual's genome can be useful for analyzing polygenic diseases, which are diseases that have more than one gene as the cause. Such diseases include cancer, diabetes, asthma, and Alzheimer's disease.^{cxv} Because the study of SNPs is still in the very early stages of development, most SNPs have not been tied to any particular disease. Like with ESTs, the lack of sufficient disclosure leads to rejections by patent examiners who cite to section 112 of the Patent Act.^{cxvi}

Those who oppose gene patents often cite applications with overly broad claims as a reason for concern. However, filing a patent application with broad claims is not

specific to the area of biotechnology. Filing broad claims is common practice in all areas of invention and oppositionist should not be concerned with what applicants are filing but with what examiners are allowing.

The PTO does not issue patents that do not meet the strict requirements of section 112 of the patent statute. Dr. Craig Venter is well known in the field of genetics research. He made news in 1999 when he filed 6,500 provisional patent applications over human genes.^{cxvii} To some, filing many patent applications are a necessary response to the growing costs of biotechnology and the increased innovations in the area.^{cxviii} To others, these filings represent legal gamesmanship to maneuver and corner an important field.^{cxix}

Dr. Venter filed patent applications on various ESTs of unknown function and the PTO rejected all of his claims under section 112.^{cxx} In his applications, Dr. Venter did not disclose any specific utility for his inventions but instead relied on speculation as to a variety of uses that the claimed inventions could possibly have. The PTO concluded that “the mere mention of possible uses is not sufficient to establish a definite utility” and thereby meet the requirements of the Patent Act.^{cxxi}

The initial standard for utility was set by Justice Joseph Story.^{cxxii} The standard was that an invention had to have some type of beneficial use, and not be detrimental or amoral.^{cxxiii} This standard was created in the early 19th century when the majority of patent applications were for mechanical devices and lacked the intricacies of modern day inventions.^{cxxiv} Most courts still apply this standard today in almost every field of technology.^{cxxv} However, the advent of chemical inventions brought with it a higher standard that is now being applied to gene patents.^{cxxvi} The Supreme Court in *Brenner v. Manson* set that standard.^{cxxvii} Under the new standard for chemical applications, the

application passes the utility threshold only if it has both substantial utility, and carries a specific benefit in "currently available form."^{cxxviii}

The patent office grappled with whether or not ESTs could meet this requirement for several years until, in 1995, they announced new guidelines that lowered the threshold utility requirement. However, without any guidance from the legislature, they continued to change course in the following years.^{cxxix} In 1997, they announced that they would require patent applications to assert more than the “mere allegation of utility...as a probe” and “significant utility” would have to be demonstrated before a patent on an EST would issue.^{cxx} The patent office began issuing patents to applicants who could meet this vague requirement.^{cxxi} In November 1998, Incyte Pharmaceuticals was granted a patent on an application which claimed an EST.^{cxxii} This, however, does not mean that such patents would survive the gauntlet of litigation. Thus, even if an inventor does file a patent application and shoulders the expense of patent prosecution, she really would not know what her patent was worth until she sued someone on it.

In 2005 case *In re Fisher*, 2 scientists from the Monsanto Corporation challenged a new set of EST guidelines set by the PTO in 2001.^{cxxiii} The scientists appealed the rejection of their patent application by both the PTO examiner and the Board of Appeals and Patent Interferences for failure to show sufficient utility.^{cxxiv} The Fischer application claimed thousands of EST sequences derived from pooled leaf tissue of the maize plant.^{cxxv}

The court affirmed the Board’s decision and compared the facts in *Fisher* to those in *Brenner*, which was decided by the Supreme Court almost 4 decades earlier.^{cxxvi} The court compared ESTs to chemical intermediates and analogized them to research

tools.^{cxxxvii} The court emphasized the discord between the patent laws when it explained that one reason for using the *Brenner* standard was that the PTO utility guidelines were not binding on the court.^{cxxxviii}

Because *Brenner* had not established a specific test for either substantial or specific utility, the court fashioned such a test.^{cxxxix} The *Fisher* court held that for an invention to have substantial utility, it "must show that the claimed invention has a significant and presently available benefit to the public."^{cxl} Furthermore, specific utility must provide "an immediate well-defined, real world benefit to the public" and also requires applicant "disclose a use which is not so vague as to be meaningless."^{cxli} *Fisher* was hailed as a major victory against the patenting of ESTs. Those in favor of gene patents have argued that gene patents are necessary to promote outside investment and to counterbalance the substantial amount of risk that is involved in genetic research.^{cxlii}

Despite all of these challenges, the United States continues to make the largest commitment to basic research in biological sciences worldwide.^{cxliii} By 1990, the single largest source of funding for research and development for biotech in the United States was private industry.^{cxliv} In a recent series of studies, the National Research Council attributed the rapid growth of biotechnology in the United States to the country's intellectual property laws.^{cxlv} The study found that these laws fostered a link between industry and academic science that did not exist in other countries.^{cxlvi} Researchers and industrialists alike attribute the United States dominance in biotechnology to the patent laws.^{cxlvii} While a director of the National Institutes of Health, Dr. William Raub said "many biological scientists, perhaps most, regard the patent process as a means of institutionalized secrecy, whereas it is in fact a time-tested way to assure broad and ready

access to proprietary information.^{cxlviii}

The U.S. biotechnology industry is dependent on patent protection to maintain its leadership in world markets. The gene patent issue is no longer merely an academic one. Patents allow for the biotech industry to receive funding and resources from a variety of different sources.^{cxlix} There is a lot at stake and supporters of the biotech industry are working tirelessly to ensure those who oppose gene patents do not succeed.

i. Are Infringement Suits Interrupting Research?

While the discussion above focuses on economic growth attributable to gene patents, some oppositionists argue that the true victims of the gene patents are the university researchers. The opponents to genetic patenting contend that gene patents impede progress by creating a lot of red tape and fees to utilize research that is patented.^{cl}

In the world of academia there are two categories of researchers: the general scientists and the inventors.^{cli} The general scientist does not engage in research for the purpose of finding a commercial application. She has a general goal of providing useful innovations to society through the discovery of scientific truths. Commercial gain does not factor into her concept of success. Most of the time, these scientists do not seek patents on their discoveries. They share their inventions openly in scientific journals.

The modern university researcher often falls into the second category. She may be both a traditional researcher during the day and the head of her own biotech start-up company in the afternoon.^{clii} In biotechnology, the melding of basic scientific research and technological innovation is a common occurrence.^{cliii} These researchers are after

scientific truths but utilize the patent system to protect the utilitarian tools that they may develop along the way.^{cliv}

Opponents of gene patenting argue that gene patents stifle academic research by creating patent thickets. A patent thicket is a dense web of overlapping intellectual property rights that a scientist must hack her way through in order to conduct research.^{clv} They constrain researchers and limit their ability to make meaningful discoveries. This effect has come to be known as the tragedy of the anticommons.

The tragedy of the commons is a theory by Garrett Hardin that describes what happens when people overuse shared resources.^{clvi} In his article, *The Tragedy of the Commons*, Hardin describes a group of herders and the plot of land on which they can all allow their cows to graze.^{clvii} In Hardin's view, a rational Herder should put as many of his cows as he can onto the common parcel of land to graze.^{clviii} Even if the excessive number of cows damages the land, the herder receives all of the benefit while all the other herders who can no longer use the common parcel for their cows split the cost. In this situation, a single person gains a lot while everyone else is hurt a little.^{clix}

An "anticommon" is a metaphor for what happens when the herders can block one another from using the commons.^{clx} If each herder has the power to prevent the others from using the common parcel, they will do so and the scarce resource gets underused instead of being overused.^{clxi} In an article published in 1998 Heller and Eisenberg argued that the tragedy of the anticommons is what happens when over-patenting blocks advances in the biotechnology industry.^{clxii} They felt that patents in the biotech industry would lead to an inability to conduct research without infringing someone else's patent.^{clxiii}

Although patents are not the only example of the tragedy of the anticommons, they are one of the most cited. This has to do with the fact that certain areas of research involve the use of many different techniques or substances which are patented by different people or corporations. According to the *Tragedy of the Anticommons*, researchers avoid doing work in these areas because they are afraid that they may infringe somebody else's patent. Heller and Eisenberg felt another problem with granting patents in the area of genetic research is that researchers may have to pay so many licensing fees that the research becomes prohibitively expensive.^{clxiv} As a result of the high cost, certain discoveries will never be made.

If true, the tragedy of the anticommons can have disastrous results in the area of biomedical research. Discoveries in this area of research are directly related to human health and people may die if certain life saving studies are blocked. This phenomenon is a form of market failure.^{clxv} This is a situation where an individuals' pursuit of pure self-interest produces results that hurt the rest of society.^{clxvi} Heller and Eisenberg fear that the "rational" patent holder will attempt to maximize her own self-interest by excluding others from doing research using their patented inventions. Or, the patent holder may charge exorbitant licensing fees which make the research prohibitively expensive. If the costs are sufficiently high, the patent holder may end up receiving nothing and society as a whole loses the fruits of the scientist's research.^{clxvii}

In 2009, National Institutes of Health (NIH) task force released a draft report on its findings on the effects of gene patenting on medicine, research and business.^{clxviii} The NIH is the primary government agency responsible for biomedical research.^{clxix} Their report states that patents covering genetic tests and related licensing practices do not

appear to be hampering clinical access to the tests.^{clxx} The report also showed no “widespread overpricing” of genetic diagnostic supplies that were patented versus those that were not patented.^{clxxi}

Furthermore, Genentech, Inc. addressed concerns about their litigations policies by making a declaration that they would not sue academic researchers in respect of research uses of genomics information.^{clxxii} Dennis Henner, speaking on behalf of Genentech, Inc., made the following statement:

I note that patents on research tools used to discover genes are not especially valuable in our view, and we do not make a priority out of pursuing patent protection for most of the research tools that Genentech scientists invent. We do not believe that enforcing patents on research tools represents sound policy, as it tends to discourage the open research environment that we believe is so important to scientific advancement and the biotechnology industry.^{clxxiii}

Most industries, however, require manufacturers to negotiate multiple licenses in order to create a product. When Apple, Inc. developed the iPhone in 2007, it was not the only holder of proprietary technology used in the device. An iPhone contains multiple devices that were patented by multiple companies. A single microchip may be protected by thousands of patents. Accordingly, the iPhone would never have been developed without agreements by the patent holders to license their inventions to Apple, Inc.

Cross-licensing agreements are also very common in all areas of technology. Here, one manufacturer allows the use of its patented technology in exchange for

permission to use another's patented technology. Licensing can also be done for a fee that allows the end product to be affordable to the average consumer.

With different companies holding patents for different components, developing new technologies can be difficult.^{clxxiv} Under such circumstances infringements, lawsuits, and the concomitant gridlock are almost inevitable.^{clxxv} The history of the electronics industry, however, tells us that such obstacles can be overcome.^{clxxvi} In this industry, the Institute of Electrical and Electronics Engineers (IEEE) has helped to foster licensing of patented technology to encourage electronics manufacturers to share their patented technologies. Groups like the Biotechnology Council have begun to perform a similar role in the biotechnology industry.^{clxxvii} Such organizations are dedicated to advancing cutting edge research by fostering collaborations to further research at the intersection of medicine and bioengineering.^{clxxviii}

These groups have been helping to create information "commons" via collaborations in professional organizations such as the Association of University Technology Managers and the Licensing Executives Society.^{clxxix} These organizations have assisted academic institutions in bettering their negotiation stance with the commercial biotechnology industry.^{clxxx} In July 2003, a group of leading research institutions (Cornell, the University of California, the University of Florida, Michigan State, Rutgers, and the University of Wisconsin) announced that, with support from the Rockefeller Foundation, they had joined forces to share proprietary information and foster growth in biotechnology research.^{clxxxi}

Those in favor of gene patents believe that the right to exclude given by a patents is essential to avoiding underuse.^{clxxxii} They believe that a rational individual with

ownership rights in a parcel of land will maximize the value of her parcel by putting the parcel to higher and better uses. Simply erecting a fence to keep others out does not give the owner anything but the land. But, if she permits others to share her land for a fee, she would still own the land and get to enjoy the added benefit of the revenue that it generates for her. Just like the licensors who shared their innovations with Apple, Inc., the rational parcel owner can enjoy gains while allowing others to benefit from what is legally hers.

Even though the Heller/Eisenberg article cited no empirical data, *The Tragedy of the Anticommons* still managed to stimulate a lot of discussion amongst academics in the field of biotechnology and patents. So much controversy surrounded this issue that the National Academy of Sciences commissioned a study to examine the issue.^{clxxxiii}

At the “Stifling or Stimulating” hearing, Jeffrey Kushan, an attorney appearing on behalf of the Biotechnology Industry Organization (BIO) presented Congress with testimony on the importance of biotechnology to the economy and the role of patents in securing investment capital in this remarkably expensive area of research.^{clxxxiv}

Mr. Kushan explained some of the important ways in which gene patents are used in the biotechnology industry.^{clxxxv} In particular, he rejected the argument that gene patents interfere with academic research, pointing out the close relationship between the biotechnology industry and the academic community, and the lack of any evidence of infringement actions against university researchers engaged in noncommercial research.^{clxxxvi} He also sought to debunk the patent thicket theory, pointing to the lack of evidence that patents are inhibiting research and development activities in either the public or private sectors.^{clxxxvii} With regard to the fear that patents impede access to

genetic diagnostic testing, he pointed out that very few disputes of this type have materialized, in his view, confirming that the vast majority of gene patents do not significantly impede clinical diagnostic testing.^{clxxxviii}

Walsh *et al* conducted a survey of 414 academic researchers from universities, non-profits and government labs to determine what impact patents had on their research.^{clxxxix} The results indicated that only 1% of the academic respondents stated that they had experienced delays on their projects of more than one month and none of the academics reported abandoning a line of research due to patents.^{cx} When I returned to UCLA to interview some of my professors, what they told me matched the findings of the Walsh study.^{cxci} None of my professors had experienced any interference by patent holders when they conducted their research.^{cxcii} Moreover, none of them had ever been faced with a lawsuit brought by the holder of a gene patent.^{cxci} When I asked if this was a consideration when deciding what type of research to conduct, the answer was always no.^{cxci}

ii. University v. Biotech – recent suits involving biotech patents

To determine if there was any support for the claims that university researchers fear lawsuits by biotechs, I conducted LexisNexis, Westlaw, and Google searches on infringement actions against universities or researchers engaged in noncommercial research. When I searched the internet for lawsuits between biotechs and universities, some of the search terms I used included “university patent infringement” and “biotech company sues university.” The results surprised me. Although opponents of gene

patenting claim that lawsuits brought by biotech corporations are stifling university research, in the majority of cases I found, the university was the claimant in the infringement suit.

The most well known conflict between a university and a biotech company involved the University of California and Genentech, Inc. and arose just before *Diamond v. Chakrabarty*. In 1978, 3 researchers working for the University of California were the first to identify a DNA sequence encoding the human growth hormone.^{cxv} An application was filed naming Howard M. Goodman, John Shine, Peter H. Seeburg as the inventors and, in 1982, the University of California received a patent on “recombinant DNA transfer vectors containing codons for human somatomammotropin and for human growth hormone.”^{cxvi} During the same time, Genentech, Inc. was making a substantial amount of money through the sale of Protropin. As discussed earlier, Protropin is a human growth hormone drug that is used to treat dwarfism.

In 1990, the University of California accused Genentech, Inc. of infringing the Seeburg patent while making and selling Proptropin.^{cxvii} The result was a long and drawn out legal battle between the university and Genentech, Inc. that included an 8 week trial ending with a hung jury.^{cxviii} Just before the case was to be retried and 9 years after the initial complaint had been filed, the parties settled.^{cxix}

The terms of the settlement required Genentech, Inc. to pay the University \$150 million and contribute another \$50 million dollars to the development of the first biological sciences research building at Mission Bay in San Francisco.^{cc} Genentech Hall was completed in 2003 and contains 60 state of the art research laboratories. The research

that takes place in Genentech Hall is centered around the biomedical sciences and it currently houses the Molecular Design Institute and the Center for Advanced Technology as well as programs in structural and chemical biology; molecular, cell and developmental biology; and advanced microscopy.^{cci}

It is worth mentioning that Genentech, Inc. and the University of California have collaborated with one another since 1979 and did so all throughout the patent dispute.^{ccii} They have remained strong partners in the area of biomedical research.

However, many still believe that university research has been negatively impacted by gene patents. In a Science Week article entitled *Academia vs. Industry: A US \$1 Billion Hormone Patent Battle* one journalist writing about the lawsuit between Genentech and the University of California said: “a legal battle concerning the patent rights to a synthetic human growth hormone has just been completed, and the details of the conflict are an instructive illustration of how the push for huge profits from research in molecular biology may be corrupting the practice of basic science by both industrial and academic researchers.”^{cciii}

Those who share this view claim that the commercial motivations of the large biotech companies are corrupting science done on the university level.^{cciv} Opponents of gene patents insist that gene patents interfere with academic research while those who support the patents refer to a close relationship between the biotechnology industry and the scientific community.

In 1990, The Regents of the University of California also filed claims against Eli Lilly & Co. alleging infringement of a patent for a “DNA Transfer vector and transformed microorganism containing human proinsulin and pre-proinsulin genes.”^{ccv} At

the time, Eli Lilly was manufacturing insulin using recombinant DNA methods using a gene that encodes proinsulin. The case made it up to the Court of Appeals for the Federal Circuit. In 1997, the court issued a ruling invalidating the UC patent for failure to satisfy the written description requirement of 35 U.S.C. § 112. The courts opinion led to stricter PTO guidelines that made gene patents more difficult to issue. Throughout the lawsuit, the university and Eli Lilly continued to collaborate on various research projects and they have remained partners in the area of biomedical research.^{ccvi}

More recently, in 2003, several of the biggest biotechnology companies in the world, Amgen, Biogen, Genzyme and a subsidiary of Abbott Laboratories, filed a lawsuit against Columbia University accusing it of trying to prolong the term of a patent beyond what is allowed under the patent act.^{ccvii} The patent at issue had brought the institution hundreds of millions of dollars in annual revenue.^{ccviii} The claimants alleged that Columbia abused the patent system when it was awarded a new patent covering the same subject matter of a patent that had expired 3 years earlier.^{ccix} The patent act only allows the PTO to issue 1 patent for every new invention.^{ccx} The plaintiffs alleged double patenting by the university and sought a ruling that would prohibit Columbia from collecting licensing fees.^{ccxi}

The patent involved a method invented by Nobel Prize Winner Richard Axel, which helped scientists genetically engineering animal cells to produce biotech drugs used to treat various diseases such as cancer and arthritis.^{ccxii} Axel received a patent on his invention in 1983.^{ccxiii} Afterwards, it was licensed by biotech companies who paid up to \$100 million per year in royalties.^{ccxiv} This made it one of the most lucrative discoveries in the Columbia's history.^{ccxv} In August 2000, just before the patent was

going to expire, the university sent representatives to Capital Hill to ask Congress for a 14 to 18 month extension to their patent term.^{ccxvi} Their request was denied and the biotech companies stopped paying Columbia royalties for use of the Axel patent.^{ccxvii}

In September 2003, the PTO issued Columbia another patent on a similar invention and the university began requesting royalties from the biotech companies again.^{ccxviii} They claimed that the newly issued patent gave them the right to charge companies for the use of their invention until 2020.^{ccxix} In 2004, a U.S. District Court Judge granted Columbia's motion to dismiss the claims when they agreed not to assert certain claims against the biotech companies or try to recover royalty payments for use of the newly patented invention.^{ccxx}

Another lawsuit that garnered a lot of attention arose in September 2008 when the University of Iowa sued Amgen, the largest biotechnology company in the world, for infringing multiple patents.^{ccxxi} The 2 patented inventions, both conceived by Mark Stinski, were titled "Transfer Vectors and Microorganisms Containing Human Cytomegalovirus Immediate-Early Promoter-Regulator DNA Sequence."^{ccxxii} Amgen was accused of infringing the universities patents every time they made the colon cancer treatment Vectibix and the arthritis drug Enbrel.^{ccxxiii} In particular, the biotech company was accused of making these drugs using techniques that had been patented by the university.^{ccxxiv} The 2 drugs accounted for nearly \$2 billion in sales for Amgen in the first half of 2008.^{ccxxv} This case is still pending.^{ccxxvi}

In May 2007, the Iowa State University Research Foundation sued biotech giant Monsanto in the U.S. District Court for the Southern District of Iowa.^{ccxxvii} The patents involved a low-linolenic acid content soybean, which was considered to be healthier than

conventional soybeans.^{ccxxviii} The university, which held multiple patents covering methods for breeding and manufacturing such soybeans, was seeking an injunction as well as treble damages.^{ccxxix} This case is also pending.

Carnegie Mellon sued Hoffman-La Roche, Inc. in 2001 alleging patent infringement. This case involved recombinant plasmids containing a gene that encodes the useful enzyme DNA polymerase I.^{ccxxx} The case made it all the way to the Federal Circuit where on September 8, 2008, the court sided with La Roche by affirming the district court's finding of no infringement. The court used the same reasoning as in *UC Regents v. Eli Lilly* to invalidate claims in the universities patents. The claims failed to meet the written description requirement of § 112 of the patent act:

"To satisfy the written description requirement in the case of a chemical or biotechnological genus, more than a statement of the genus is normally required. One must show that one has possession, as described in the application, of sufficient species to show that he or she invented and disclosed the totality of the genus. . . . [W]e conclude that that requirement was not met here."^{ccxxxi}

Tulane is currently suing Ipsen and subsidiaries Biomeasure and SCRAS for, among other things, alleged breach of contract, breach of fiduciary duty, and correction of inventorship in relation to patents surrounding a diabetes drug currently being shepherded through Phase III clinical trials by pharmaceutical giant Roche.^{ccxxxii} Roche licensed rights to the drug from Ipsen in 2006.^{ccxxxiii}

V. How some other Countries are Facing Gene Patents

The U.S. has had a tremendous influence on gene patents around the globe. This is partially because the majority of biotech research is conducted in the U.S., the most venture capital for biotech research originates in this country, and the biggest commercial market for biotech is also the U.S.^{ccxxxiv} More gene patents are filed in the U.S. than in any other country and of all the gene patents filed between 1996 and 1999, 62% were filed by Americans, 20% by people living in the European Union, and 10% were by Japanese applicants.^{ccxxxv} These statistics concerned America's trading partners who are now increasing their intellectual property protection to surpass the amount of protection granted in this country.^{ccxxxvi}

The United States, India, Canada, China, Korea, Germany, Holland, Britain, Australia, Japan, all allow patent applications claiming genetic sequences.^{ccxxxvii} In Britain, these patents are allowed under the "new chemical substances" provision of their Patent Act. The British are facing issues similar to those in the U.S. because their Act states such claims did not extend to the substance "when found in Nature". The UK Patent Office interpreted the statute to mean "as found in Nature." i.e in its natural state. Thus, the first to discover and isolate the substance could claim it without restriction.^{ccxxxviii}

In July 1998, the European Parliament enacted Directive 98/44/EC on the Legal Protection of Biotechnological Inventions.^{ccxxxix} A directive is a type of E.U. legislation that targets Member States^{ccxl} and binds them with respect to the end to be achieved,

while allowing each Member State some choice as to the method, and, sometimes, the extent, of implementation. It is distinguishable from a regulation, which is binding upon all Member States and mandates a particular means of attaining the stated goal. Thus, directives are more flexible and accommodating to national law, making them particularly useful in order to harmonize the laws within a certain area.^{ccxli}

The directive had two major purposes.^{ccxlii} The first was to foster effective and harmonized patent protection for biotechnological inventions throughout the Member States of the European Union (E.U.)^{ccxliii} with intent to stimulate investment in the European biotechnology industry and thus become more competitive with countries such as the United States and Japan.^{ccxliv} The second objective was preserving the ethical dimension of biotechnological invention when determining whether or not a patent should be granted.^{ccxlv} This second objective was particular to European patent law and had no corollary in American patent law.

In the first of its 5 chapters, the Directive describes “biological material” as patentable so long as the usual requirements for patenting are met.^{ccxlvii} In other words, the invention is novel, contains an inventive step, and has an industrial application. The term “biological material is defined as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.”^{ccxlviii}

According to Article 3.2 of the Directive “biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”^{ccxlviii} This provision makes clear isolated and purified genetic sequences are patentable subject matter under the Directive. Allowing patents for isolated and purified genes is justified by declaring

they are inventions and not merely discoveries.^{ccxlix} The directive acknowledges the efforts of man as a required step in the purification of genetic sequences and that isolation cannot be accomplished by nature alone.

Article 5 of the directive further elaborates on this point. According to Article 5.1, patent protection will not be granted to "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene."^{cccl} Article 5.2 explains that there shall, however, be patent protection granted to "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."^{cccli} This confirms that gene sequences may be patented, if they meet the other requirement of industrial usefulness.^{ccclii}

Unpatentable subject matter is described in Articles 4, 5, and 6 of the Directive. The human body at various stages of development^{cccliii} and certain "essentially biological" processes which "consist entirely of natural phenomena"^{cccliv} are barred from patent protection. Article 6 contains a catch all exception termed the "morality provision."^{ccclv} This section provides: "inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation."^{ccclvi}

The "morality provision" of the Directive is meant to accomplish the Directive's second objective of preserving the ethical dimension of biotechnological invention when determining whether or not a patent should be granted.^{ccclvii} This section of the Directive

may be utilized by Member States who do not wish to provide patent protection for certain types of inventions. For instance, the French Intellectual Property Code provides “the human body, its parts and products, and the knowledge of the entire or partial structure of the human gene” are unpatentable.^{cclviii}

Some have referred to the fact that genetic testing is cheaper in France to support their arguments against gene patenting.^{cclix} However, what these people fail to recognize is that although the tests may cost less to administer in France, they were not developed there.^{cclx} The vast majority of genetic tests originate in the U.S.^{cclxi} The lack of patent protection in France has caused French companies to avoid doing research in the area of genetics. In the U.S., researchers can conduct experiments and get the economic support needed to take a scientific discovery and turn it into something beneficial to the public.^{cclxii} This is so because of patent protection. The role of the French in biotech research is similar to a parent that does not have her child vaccinated and hopes that every other parent will.^{cclxiii} They are seeking the benefit without having to pay for it. This has resulted in reliance on foreign innovation and a biotech sector that is outdated and far below the curve.^{cclxiv}

In 2004, the Australian Law Reform Commission (ALRC), an independent body established to conduct reviews of Australian law and advocate options for statutory reform, completed a major inquiry into the controversial subject of gene patents. The Commission produced a 700-page report called *Genes and Ingenuity: Gene Patents and Human Health* (ALRC 99).^{cclxv} Prof David Weisbrot, the ALRC President, made this statement following the release of the report:

“extra flexibility must be built into the patent system to accommodate genetic technology or there could be a ‘chilling effect’ on research and development— and the commercialization of that research—with adverse implications for advances in healthcare”^{cclxvi}. He went on to say, “Australia needs to promote investment in research and development—biotechnology is hugely expensive and patent rights are the main way of rewarding innovation and investment”.^{cclxvii}

Advances in biotechnology have also led Canadians to call for patent reform.^{cclxviii} In 2002, the Ontario government’s Report to the Premiers’ Conference (adopted by all premiers at a Premiers’ Conference in Vancouver) recommended clarifying several statutory requirements related to gene patenting.^{cclxix} The report suggests that clearer laws will encourage research, invention, and innovation while ensuring a better balance between public and private interests with appropriate transparency and rigour.^{cclxx}

Janet Lambert, President of BIOTECCanada, the national association of biotechnology researchers and practitioners, summarizes the Canadian biotech industries stance on gene patents:

Intellectual property is often the most valued asset for biotechnology researchers and companies, particularly those who have yet to commercialize a product. The majority of Canadian biotechnology companies do not have revenues, are spending their capital on research, are small to medium sized businesses and are faced with increased international competition for funding and human resource skills. It is by ensuring Canada is internationally competitive in

our protection of IP, that our voice as a society is heard in the vital social and ethical debates needed to define the boundaries of biotechnology.^{cclxxi}

Juan Enriquez, founding director of the Life Sciences Project at Harvard Business School and recognized as one of the world's leading authorities on the economic and political impacts of life sciences, has suggested that a countries economic worth can be measured by the patents it produces.^{cclxxii} He sees patents as a window on which countries may succeed over the next two decades and argues "What matters in a modern economy is knowledge. It is what you live off. It is what powers growth. And from patents in the last 20 years it is not hard to predict who gets rich and who gets poor"^{cclxxiii}

VI. Now is the Time for Statutory Reform

Section 101, the part of the Patent Act that describes patentable subject matter, has only been changed once since it was written by Thomas Jefferson in 1793.^{cclxxiv} The statute currently reads "Whoever 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 therefore, subject to the conditions and requirements of this title."^{cclxxv} The one and only time it was amended was by the 82nd Congress just prior to Watson and Crick's discovery of the double helix.^{cclxxvi} The amendment merely replaced the word "art" with the word "process." Could the amenders have envisioned the advances in biotechnology that have taken place since 1952? Surely, they could not have foreseen a world where technology could be used to create 2 genetically identical human beings.

Who is to say what Congress intended when they made this change in 1952? The answer is the courts, the PTO, and patent lawyers have shouldered this burden. The law must constantly evolve in order to keep up with technology, commerce, and the public interest. When the legislative branch does not react quickly enough, the judicial and executive branch's must pick up the slack. However, neither of the two has the benefit of inputs from neutral disinterested parties who have the public interest in mind. They must make due with creating law by listening to 2 feuding parties with their interests and not the public's in mind.

1990 marked the start of an international science research project with the primary goal of mapping the human genome.^{cclxxvii} The Human Genome Project, as it was called, was completed over 2 years ahead of schedule in 2003.^{cclxxviii} In response to the thousands of gene patents that were being filed in conjunction with the Human Genome Project and uncertainty by the PTO as to how to deal with these applications, the Federal Circuit was forced to grapple with these issues.^{cclxxix}

Attempts by Federal Circuit to create new written specification requirements for gene patents have been received with mixed reactions. Those who agree with the court feel that the new restrictions are a reasonable response to the explosion of biotech patents.^{cclxxx} These people fear that without a heightened written description requirement, the patent office could be opening "Pandora's Box" and issuing patents for sequences that the inventor never actually worked on.^{cclxxxi}

Those who oppose the Federal Circuit's approach to gene patenting have called it "Ineffective legal patchwork to stem the uncomfortable tide of biotech patents."^{cclxxxii} These people argue that the judicially created written description required is too rigid to

be commensurate with the patent act.^{cclxxxiii} The patent act requires only the amount of disclosure that would enable one of ordinary skill in the art to practice the invention. This is a unique characteristic of the patent law that allows it to adapt to rapidly advancing technologies.^{cclxxxiv} The court's willingness to make such drastic changes highlights how serious a problem the flood of gene patents has created and how a solution is desperately needed.^{cclxxxv}

The patent office issued a series of administrative guidelines outlining the new requirements for gene patent applications.^{cclxxxvi} These new guidelines required inventors to explicitly to identify, unless already well established, a specific, substantial and credible utility for all inventions. The effect on applicants was that many patent applications were being rejected for failing to demonstrate 'real world' utility.^{cclxxxvii}

Arthur Levinson, the chief executive officer of Genentech, Inc. wrote in support of the new utility requirements of the PTO:

Patents are the lifeblood of the biotech industry and are crucial to spurring innovation and incenting companies to make the necessary significant investments to bring drugs to market. We support the PTO's guideline on utility, which creates an appropriately higher bar for biotechnology companies in requiring demonstration of biological function and use. We believe that this is the surest way to provide important incentives for the further pursuit of new innovative therapies by the biotechnology industry and to reward those that are successful in that pursuit.^{cclxxxviii}

The Senior Vice President of Research at Genentech, Dennis Henner, also approved of the new administrative guidelines but expressed some concerns about how

they would be applied by patent examiners. Ultimately, the guidelines would require some scientific assumptions on the part of examiners. Traditionally, the utility requirement of the patent act has been interpreted to mean that applicant's invention must be operable or demonstrate some sort of practical or beneficial utility.^{cclxxxix} For the majority of patent applicants this requirement has been de minimus and usually presumed. However this requirement has been emphasized in the area of biotechnology "because inventions in these fields can produce new compounds with unknown utility for which patent protection may be sought. An invention that lacks utility is consonant with a disclosure that does not teach how to use the invention; the enablement requirement and the utility standard thus overlap."^{ccxc}

VII. Conclusion

Biotechnology is redefining the frontiers of scientific research. But, without proper protection for the fruits of their costly research, biotech companies will have little reason to continue investing billions of dollars into genetic research. This article has referenced the various issues surrounding gene patents and addressed some of the critics who would like to see them banned. The history of gene patenting has been loaded with controversy and the biotech industry has had to overcome many obstacles in order to bring about new and beneficial innovations each year. These obstacles stifle advances in research because of how much time and resources lawyers, the courts, and the PTO have to spend trying to create guidelines when Congress will not.

Gene patents nurture developments in genetic research. Because of the high cost of doing research, and the low probability of return on any particular study, investors rely on strong patent protection to provide a sense of long-term security. There is hardly any evidence to support the theory that these patents deter scientists from making new and useful inventions. Even through the most well known dispute between a biotech company and a university, the two parties continued to work with one another. The end result was a state of the art research facility on the campus of U.C.S.F. and hundreds of millions of dollars in grant money for the University of California. Moreover, the two parties continue to have a productive professional relationship conducting research in the area of biotechnology.

Studies conducted by neutral disinterested parties have shown that gene patents do lead to exorbitant licensing fees nor have they produced a “patent thicket” eclipsing scientists who would otherwise be adding to public knowledge. Other countries are working hard to create laws that fuel genetic research by providing greater protection than the U.S. They are making these laws to attract some of the American biotech industry. The U.S. patent act is outdated in an area where we cannot afford to fall behind.

This brings us full circle to the mandate of Article I Section 8 of the Constitution. 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.^{ccxc} If allowing gene patents will promote science, Congress is allowed to enact legislation clearly defining their patentability. Not passing such legislation is stifling scientific research in this country. As advances continue to be made in genetics, inventors will rely more and more on the patent system for protection and to foster their growth.

As the elected representatives of or society, Congress should define boundaries of patentability that benefit all of society. The evidence shows it is likely that the patentability of genes hastens the delivery of life-saving medicines or treatments. If this delivery is deemed a social good and there is virtually no evidence to show gene patents have had a negative impact, then Congress should amend the Patent Act to create a new biotechnology specific provision.

Endnotes

ⁱ See 447 US 303

ⁱⁱ *Id.*

ⁱⁱⁱ *Id.*

^{iv} *Id.*

^v *Id.*

^{vi} See Rifkin, J. *The Biotech Century*. New York: JP Tarcher, 1998.

^{vii} *Id.*

^{viii} See Sandra Braman (Ed.), *Biotechnology and communication: The meta-technologies of information*, pp. 3-36. Mahwah, NJ: Lawrence Erlbaum Associates, 2004.

^{ix} See Paul Berg and Maxine F. Singer. "The recombinant DNA controversy: Twenty years later". *Proc. Natl. Acad. Sci.* Vol 92, pp. 9011-9013, (Sept. 1995): 9011.

^x See Michael Crichton, *The Andromeda Strain* (Avon Books 2003) (1971).

^{xi} See Michael Crichton, *Jurassic Park* (Ballantine Books 1993) (1991).

^{xii} See Mary Shelley, *Frankenstein* (Signet Classic ed., 1983) (3d ed. 1831)

^{xiii} See Michael Crichton, [Essays](#), February 2007, 17 April 2009 <nytimes.com>.

^{xiv} See REPS, BECERRA & WELDON INTRODUCE BILL TO BAN THE PRACTICE OF GENE PATENTING, 7 February 2007, 14 April 2009
<<http://becerra.house.gov/HoR/CA31/News/Press+Releases/2007/02-09-07+REPS+BECERRA+WELDON+INTRODUCE+BILL+TO+BAN+THE+PRACTICE+OF+GENE+PATENTING.htm>>.

^{xv} *Id.*

^{xvi} See International Academy of Humanism, "Statement in Defense of Cloning and the Integrity of Scientific Research," May 16, 1997.

^{xvii} *Id.*

^{xviii} See 45 Am. J. Juris. 1

^{xix} The basic requirements of patent law are found in 35 U.S.C. §§ 101-03 (2000). For a review of statutory and policy arguments for and against gene patents see generally, Rebecca S. Eisenberg, *Genetics and the Law. Patenting the Human Genome*, 39 Emory L.J. 721 (1992), and Linda J. Demaine & Aaron Xavier Fellmuth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 Stan. L. Rev. 303, 374 (2002).

^{xx} *Id.*

^{xxi} *Id.*

^{xxii} See Barbara A. Caulfield, Why We Hate Gene Patents, 2002 30 December <<http://www.law.com/jsp/article.jsp?id=1039054490790>>

^{xxiii} *Id.*

^{xxiv} *Id.*

^{xxv} See *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972).

^{xxvi} See U.S. Patent No. 141,072

^{xxvii} <http://www.capmag.com/article.asp?ID=1534>

^{xxviii} *Id.*

^{xxix} R. Stephen Crespi, Patents on Genes do they have a Future

<http://www.law.ed.ac.uk/ahrc/files/81_crespipatentsongenes00.pdf>

^{xxx} See Bio.org

^{xxxi} See Gene Patents and Global Competition Issues
<<http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0>>

^{xxxii} *Id.*

^{xxxiii} *Id.*

^{xxxiv} *Id.*

^{xxxv} *Id.*

^{xxxvi} See US: Research body warns universities on stimulus money, 2009 01 March
<<http://www.universityworldnews.com/article.php?story=20090226170630254>>

^{xxxvii} *Id.*

^{xxxviii} See Mendy Fisch, Stimulus package may bolster U. science research March 2nd, 2009 <<http://www.dailyprincetonian.com/2009/03/02/22941/>>.

^{xxxix} See John Carroll, Stimulus money to double cancer research grants, April 21, 2009 <<http://www.fiercebioresercher.com/story/stimulus-money-double-cancer-research-grants/2009-04-21>>

^{xl} *Id.*

^{xli} See Gary Marcus, The Birth of the Mind: From 30,000 Genes to 20 Billion Neurons New York University, Department of Psychology

^{xlii} See U.S. Const. art. I, § 8, cl. 8.

^{xliii} See Gene Patents and Global Competition Issues

<<http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0>>

^{xliv} Rimmer, Matthew, Genentech and the Stolen Gene: Patent Law and Pioneer Inventions. Bio-Science Law Review, Vol. 5, No. 6, pp. 198-211, 2002/2003.

^{xlv} *Id.*

^{xlvi} See Diamond v Chakrabarty (1980) 447 US 303

^{xlvii} *Id.*

xlvi *Id.*

xlix *Id.*

¹ *Id.*

li *Id.*

lii *Id.*

liii *Id.*

liv *Id.*

lv See Amicus Curiae Brief of Genentech Inc.

lvi See Rifkin, J. *The Biotech Century*. New York: JP Tarcher, 1998.

lvii See Rimmer, Matthew, *Genentech and the Stolen Gene: Patent Law and Pioneer Inventions*. *Bio-Science Law Review*, Vol. 5, No. 6, pp. 198-211, 2002/2003. Available at SSRN: <http://ssrn.com/abstract=603221>

lviii See Amy Otchet, [Jeremy Rifkin: fears of a brave new world](http://www.unesco.org/courier/1998_09/uk/dires/txt1.htm), 2009 15 April <http://www.unesco.org/courier/1998_09/uk/dires/txt1.htm>.

lix See U.S. Const. Art. 1 Sec. 8 Cl. 8

lx See Otchet, *supra* note 70.

lxi See *Diamond v Chakrabarty* (1980) 447 US 303.

lxii *Id.*

lxiii *Id.*

lxiv *Id.*

lxv See 3.1 PTO Utility Guidelines

lxvi *Id.*

lxvii See *Gene Patents and Global Competition Issues*
<http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0>

lxviii See <http://judiciary.house.gov/oversight.aspx?ID=390> (last visited Feb. 7, 2008)

^{lxi} See <http://ipcenter.bna.com/pic2/ip.nsf/id/BNAP-59GSX9?OpenDocument>

^{lxx} *Id.*

^{lxxi} See FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, executive summary, at 3-4, ch. 3, at 18-20, ch. 4, at 34-36 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

^{lxxii} See DiMasi, Joseph A. and Henry G. Grabowski. “The Cost of Biopharmaceutical R&D: Is Biotech Different?” *Managerial and Decision Economics*. Forthcoming.

^{lxxiii} *Id.*

^{lxxiv} Note: This does not include pre-clinical time of development.

^{lxxv} See DiMasi, J. A., Hansen, R. W. and Grabowski, H. G. “The price of innovation: new estimates of drug development costs.” *Journal of Health Economics* 22 (2003).

^{lxxvi} <http://www.bio.org/ip/domestic/TheMythoftheAnticommons.pdf>

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^{lxxviii} *Id.*

^{lxxix} *Id.*

^{lxxx} See Rimmer, Matthew, Genentech and the Stolen Gene: Patent Law and Pioneer Inventions. *Bio-Science Law Review*, Vol. 5, No. 6, pp. 198-211, 2002/2003. Available at SSRN: <http://ssrn.com/abstract=603221>

^{lxxxi} *Id.*

^{lxxxii} See Swanson, R, 'An oral history conducted by Sally Smith Hughes', *Bioscience and Biotechnology Archives and Oral Histories*, Bancroft Library, 1996-1997, http://sunsite.berkeley.edu:2020/dynaweb/teiproj/oh/science/swanson/@Generic_Book_View

^{lxxxiii} *Id.*

^{lxxxiv} *Id.*

^{lxxxv} *Id.*

lxxxvi *Id.*

lxxxvii See Genentech <<http://www.absoluteastronomy.com/topics/Genentech>>

lxxxviii *Id.*

lxxxix See Goeddel, et al. United States Patent 4,634,677; Plasmid capable of expressing human growth hormone (6/1/1987) United States Patent 4,658,021 Methionyl human growth hormone (14/4/1987); United States Patent 4,898,830. Human growth hormone DNA (6/2/1990)

xc *Id.*

xcii *Id.*

xciii See Goeddel, et al. United States Patent 4,634,677; Plasmid capable of expressing human growth hormone (6/1/1987) United States Patent 4,658,021 Methionyl human growth hormone (14/4/1987); United States Patent 4,898,830. Human growth hormone DNA (6/2/1990)

xciv *Id.*

xcv See Long, C. 'Patent Signals', The University Of Chicago Law Review, 2002, Vol. 69 (2), p. 625.

xcvi *Id.*

xcvii *Id.*

xcviii See Rifkin, J. The Biotech Century. New York: JP Tarcher, 1998, p 43.

xcix See Bancroft Library, <<http://bancroft.berkeley.edu/Exhibits/Biotech/25.html>>

cx See Robert Mullan Cook-Deegan & S.J. McCormack, "Patents, Secrecy and DNA" (2001) 293 Science 217; and Joseph Straus, "Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions" (1998) 9 Duke J. Comp. & Int'l L. 91.

^c See Brad Evenson "Gene Map Belongs to All" (15 March 2000) *National Post* A1 at A1.

^{ci} See Robert Schehr & Jeff Fox, "Human Genome Bombshell," (2000) 18 Nat. Biotechnol. 365.

^{cii} See 41 U.C. Davis L. Rev. 177

^{ciii} Compare Arti K. Rai, Regulating Science Research: Intellectual Property Rights and the Norms of Science, 94 Nw. U.L. Rev. 77, 104-109 (1999) (opposing patentability of gene discoveries), with F. Scott Kieff, Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai and Eisenberg, 95 Nw. U. L. Rev. 691, 699-700 (2001) (arguing gene discoveries should be patentable).

^{civ} See, e.g., Michael Crichton, *Next* (2006); Michael Crichton, Patenting Life, N.Y. Times, Feb. 13, 2007, at A2

^{cv} See Kyle Jensen & Fiona Murray, Intellectual Property Landscape of the Human Genome, 310 Sci. 239, 239 (2005)

^{cvi} See 41 U.C. Davis L. Rev. 177

^{cvii} See, e.g., Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1558 (Fed. Cir. 1994) (discussing patent on purified form of tissue plasminogen activator (t-PA), a naturally occurring protein that helps dissolve fibrin clots in human body); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991) (patent on highly purified form of Factor VIII:C, a naturally occurring factor involved in human blood clotting process).

^{cviii} See 94 Nw. U.L. Rev. 77

^{cix} See Adams MD, Kelley JM, Gocayne JD, *et al* (Jun 1991). "Complementary DNA sequencing: expressed sequence tags and human genome project". *Science* **252** (5013): 1651–6. PMID 2047873.

^{cx} See Eliot Marshall, Patent Office Faces 90-Year Backlog, 272 Science 643 (1996) (noting that, according to Incyte's chief scientific officer, the company has filed applications on over 400,000 sequences).

^{cxii} See Christopher Anderson, A New Model for Gene Patents, 260 Science 23 (1993).

^{cxii} The PTO has indicated that precisely this type of blocking patent situation might arise with respect to full gene sequences and ESTs. See John J. Doll, The Patenting of DNA, 280 Science 689, 690 (1998) (statement by PTO's Biotechnology Examination director that PTO might grant patent application for full gene sequence even if sequence included an EST on which there was a patent). Blocking patents could not arise if the EST patent application had broadly claimed not only the EST but also the full gene and such a claim were upheld. In that case, the full gene would be obvious in light of the prior art and the

bargaining situation for the researcher with the full-length gene would be very difficult indeed. However, given the CAFC's strict interpretation of the written description requirement, it is unlikely that broad claims on ESTs would be upheld. Moreover, the PTO has recently indicated some reluctance to grant broad claims on ESTs. See *id.* (noting that, in the context of EST patent applications, "the granting of comprehensive claims to downstream DNA products such as full-length genes or to ultimate proteins is unlikely in the absence of a significant amount of information about the gene and protein being disclosed in the patent application."). Thus, for example, the scope of Incyte's EST patent is not entirely clear, see *supra* note 150, even though Incyte's patent application did reveal quite a bit of information regarding the gene with which the ESTs were associated. See *supra* note 166.

^{cxiii} See NIH Finds Incyte EST Patent "Disturbing": Venter Sounds Database Concerns, *The Blue Sheet*, Dec. 9, 1998 [hereinafter *Incyte Patent*].

^{cxiv} See Stephen D. Moore, *Staying Ahead: Genset Scientist Bets on Dense Mapping for Firm's Future*, *Wall St. J. Eur.*, Jan. 27, 1999, at 1.

^{cxv} See Francis Collins et al., *Variations on a Theme: Cataloging Human DNA Sequence Variation*, 278 *Science* 1580 (1997). As the authors of this article point out, SNP association studies "should be particularly efficient for identification of genes with relatively common variants that confer a modest or small effect on disease risk - precisely the type of gene expected in most complex disorders." *Id.* at 1581. The issue of SNP patentability has become particularly urgent because recent approaches to assessing DNA sequence differences between individuals are expected to reduce the cost and increase the rate at which SNPs can be discovered. *Id.*

^{cxvi} 94 *Nw. U.L. Rev.* 77

^{cxvii} See Richard F. Harris, *Patenting Genes: Is it Necessary and is it Evil?*, 10 *CURRENT BIOLOGY* R174, R174 (2000).

^{cxviii} See, e.g., OECD Science, Technology and Industry Scoreboard, <http://www.oecd.org/publications/e-book/92-2003-04-1-7294/execsumm.htm> (last visited Jan. 29, 2007) (presuming that patenting is a measure of innovation).

^{cxix} See NAT'L RESEARCH COUNCIL, *REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH* 62-64 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006), available at <http://newton.nap.edu/openbook/0309100674/html/62.html> (noting that "in many cases patenting activity has departed from its traditional role and has become strategic. Some firms are building large patent portfolios to gain access to others' technologies and reduce their vulnerability to infringement litigation."); *id.* at 37 (noting that "patenting can be an important strategic tool for firms without being either a significant direct stimulus to

R&D or a source of technical information on the direction of R&D or other activities of competitors."); see also *infra* note 342 and accompanying text.

^{cxx} Academics widely discussed Dr. Venter's bid for patents. See, e.g., Christopher Anderson, NIH Drops Bid for Gene Patents, 263 *Science* 909 (1994); Smith & Kettelberger, *supra* note 1; Paul J. Riley, Comment, Patenting Dr. Venter's Genetic Findings: Is the National Institutes of Health Creating Hurdles or Clearing the Path for Biotechnology's Voyage into the Twenty-First Century, 10 J. Contemp. Health L. & Pol'y 309 (1994).

^{cxxi} Rebecca S. Eisenberg & Robert P. Merges, Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences, 23 *AIPLA Q.J.* 1 (1995)

^{cxxii} See 1 Donald S. Chisum, *Chisum on Patents* §1 (2005).

^{cxxiii} *Id.*

^{cxxiv} *Id.*

^{cxxv} *Id.*

^{cxxvi} See generally Brenner v. Manson, 383 U.S. 519 (1966).

^{cxxvii} *Id.*

^{cxxviii} *Id.*

^{cxxix} See PTO Utility Examination Guidelines, 60 Fed. Reg. 36, 263 (1995) (asserting that rejection for lack of utility is inappropriate if the applicant makes an assertion of utility that would be credible to a person of ordinary skill in the field or if the invention has a well-established utility). See also Eric C. Woglom & Margaret A. Pierri, U.S. is Unifying Utility Requirements, *Nat'l J.*, Feb. 20, 1995, at C37-38.

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^{cxixi} Lynn Pasahow & Andrew Kumamoto, Human Genome Project Raises Patenting Issues, *Nat'l Law J.*, Oct. 20, 1997 at C31 (quoting PTO announcement).

^{cxixii} See Christopher Anderson, A New Model for Gene Patents, 260 *Science* 23 (1993).

^{cxixiii} See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

^{cxixiv} See In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

^{cxxxv} *Id.*

^{cxxxvi} *Id.*

^{cxxxvii} *Id.*

^{cxxxviii} *Id.*

^{cxxxix} *Id.*

^{cxl} *Id.*

^{cxli} *Id.*

^{cxlii} See F. Scott Kieff, Property Rights and Property Rules for Commercializing Inventions, 85 Minn. L. Rev. 697, (showing how a patent right to exclude those who have not shared in the commercialization costs provides incentives for the patentee and other players in the complex process of technological progress to come together and incur such commercialization costs, thereby facilitating the social ordering and bargaining around inventions that are necessary to generate output in the form of information about the invention, a product of the invention, or a useful embodiment of the invention).

^{cxliii} See generally Office of Technology Assessment, *Biotechnology in a Global Economy* 1-33 (U.S. Government Printing Office, OTA-BA-495, Washington, DC, 1991) [hereinafter *Biotechnology in a Global Economy*] (reviewing changes in biotechnology, defined to be only the "new biotechnology," which refers to the recombinant DNA, cell fusion, and bio-processing techniques that did not come into regular use until around 1980, or thereafter); see also *infra* notes 54-59 and accompanying text.

^{cxliv} See generally Office of Technology Assessment, *Biotechnology in a Global Economy* 1-33

^{cxlv} *Id.*

^{cxlvi} See Ian Cockburn et al., *Pharmaceuticals and Biotechnology*, in *U.S. Industry in 2000 Studies in Competitive Performance* 389-92 (David C. Mowery ed., 1999) (reviewing relative performance of the United States biotechnology industry).

^{cxlvii} See *Europe Lags Behind in Biotech Commercialization?*, *Biotech. Bus. News*, Jan. 17, 1992; see also Reid Adler, *Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization*, 257 *Science* 908, 909 (1992) (noting that the United States biotechnology industry is critically dependent on patent protection to maintain its leadership in world markets).

^{cxlviii} Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology, 97th Cong. 79 (1981) (testimony of Dr. William Raub).

^{cxlix} See 95 Nw. U.L. Rev. 691

^{cl} See Ben Butkus, US Universities' Patent Policies Retard Plant Biology Research, Survey Suggests, January 28, 2009
<<http://www.genomeweb.com/biotechtransferweek/us-universities-patent-policies-retard-plant-biology-research-survey-suggests>>

^{cli} Interview with Ellen Carpenter, Ph.D. and Jay Phelan Ph.D., Professors, University of California Los Angeles March 10 and March 28, Respectively 2009 (Hereafter “Interview”)

^{clii} See 41 U.C. Davis L. Rev. 177, 238

^{cliii} See Janice M. Mueller, No "Dilletante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 Wash. L. Rev. 1, 10 (2001) (defining research tools).

^{cliv} See, e.g., Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered ... are not patentable, as they are the basic tools of scientific and technological work.").

^{clv} Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, 2001, *Innovation Policy and the Economy* (Vol. I) (Jaffe, Adam B. et al., eds), pp. 119–150, MIT Press. 2

^{clvi} See Garrett Hardin, "The Tragedy of the Commons", *Science*, Vol. 162, No. 3859 (December 13, 1968), pp. 1243-1248.

^{clvii} *Id.*

^{clviii} *Id.*

^{clix} *Id.*

^{clx} *Id.*

^{clxi} *Id.*

^{clxii} See Heller, M.A. and Eisenberg, R.S. “Can Patents Deter Innovations? The Anticommons in Biomedical Research.” *Science* Vol 280. 1 May 1998.

clxiii *Id.*

clxiv <http://www.sciencemag.org/cgi/content/full/280/5364/698>

clxv *id.*

clxvi Krugman, Paul, Wells, Robin, *Economics*, Worth Publishers, New York, (2006)

clxvii *Id.*

clxviii GenomeWeb Staff Reporter: HHS Committee Opens Public Comment on Gene Patents (March 2009).
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clxx *Id.*

clxxi *Id.*

clxxii *Id.*

clxxiii See Rimmer, Matthew, Genentech and the Stolen Gene: Patent Law and Pioneer Inventions. *Bio-Science Law Review*, Vol. 5, No. 6, pp. 198-211, 2002/2003. Available at SSRN: <http://ssrn.com/abstract=603221>

clxxiv See 4 B.U. J. SCI. & TECH. L. 2

clxxv *Id.*

clxxvi *Id.*

clxxvii See Biotech Council, <<http://www.google.com/search?client=safari&rls=en-us&q=ieee+and+biotech&ie=UTF-8&oe=UTF-8>>

clxxviii *Id.*

clxxix See **33 J.L. Med. & Ethics 54**

clxxx *Id.*

clxxxi *Id.*

^{clxxxii} See F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - A Response to Rai and Eisenberg*,

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^{clxxxvi} *Id.*

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^{clxxxviii} *Id.*

^{clxxxix} *Id.*

^{exc} *Id.*

^{exci} *Id.*

^{excii} *Id.*

^{exciii} *Id.*

^{exciv} *Id.*

^{excv} See Science Week. 'Academia vs. Industry: A US\$1 Billion Hormone Patent Battle', Science Week, <http://scienceweek.com>, 11 June 1999.

^{excvi} See US patent no. 4363877

^{excvii} See Science Week. 'Academia vs. Industry: A US\$1 Billion Hormone Patent Battle', Science Week, <http://scienceweek.com>, 11 June 1999.

^{excviii} See **Marcia Barinaga Genentech, UC Settle Suit for \$200 Million**, 26 November 1999 http://209.85.173.132/search?q=cache:k_aJY_Fl19UJ:www.biology.iupui.edu/biocoourses/biol540/2006pdf/UCSFvsGenetech.pdf+University+of+California+Genentech+suite&cd=16&hl=en&ct=clnk&gl=us&client=safari

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^{cc} *Id.*

^{cc}_i See **Genentech Hall** *landmark for a new era* <
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^{cc}_v Regents of Univ. of Cal. v. Eli Lilly & Co., 777 F. Supp. 779

^{cc}_{vi} See Chetan NARAIN U. sues lab over cancer drug patent infringement
<http://www.dailyprincetonian.com/2009/05/11/23681/>

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^{cc}_{viii} *Id.*

^{cc}_{ix} *Id.*

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^{cc}_{xi} See *THEO EMERY, Biotech Firms Sue Columbia University* Jul 17, 2003<<http://cmbi.bjmu.edu.cn/news/0307/81.htm>>

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http://www.boston.com/business/technology/biotechnology/articles/2004/11/09/judge_ha_its_patent_suits_against_columbia/

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^{cc}_{xiv} *Id.*

^{cc}_{xv} *Id.*

^{cc}_{xvi} *Id.*

ccxvii *Id.*
ccxviii *Id.*

ccxix *Id.*

ccxx *Id.*

ccxxi See Amgen sued by University of Iowa over patent, September 10, 2008,
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ccxxiv *Id.*

ccxxv *Id.*

ccxxvi *Id.*

ccxxvii See University group sues Monsanto over soybean patent
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ccxxviii *Id.*

ccxxix *Id.*

ccxxx See Carnegie Mellon Univ. v. Hoffman-La Roche, Inc., 2004 U.S. Dist. LEXIS 4975

ccxxxi *Id.*

ccxxxii *Id.*

ccxxxiii See Ben Butkus Tulane University Sues French Drug Maker Ipsen Over Rights to Diabetes Drug Patents, December 10, 2008
<<http://www.genomeweb.com/biotechtransferweek/tulane-university-sues-french-drug-maker-ipsen-over-rights-diabetes-drug-patents>>

^{ccxxxiv} See Elisa M. Buctuanon, "Globalization of Biotechnology" (2001) 20 *New Genetics and Society* 25 at 26: "it appears that although the flow of biotechnology across national borders has grown, increasingly in recent years, there is a tendency for this to agglomerate in developed countries, particularly the U.S., where the socio-economic and politico-institutional environment facilitates their development and commercial exploitation." Later, the author notes that "[a] close examination on the direction of firms in the forming strategic R&D partnerships reveals that they are headed toward the U.S. for insourcing biotechnologies"

^{ccxxxv} See Sandy Thomas, Michael Hopkins & Max Brady, "Shares in the Human Genome -- The Future of patenting DNA" (2002) 20 *Nat. Biotechnol.* 1185 at 1185, who claims that "between 1996 and 1999, 6786 patents were filed" in the U.S., Europe and Japan.

^{ccxxxvi} See 41 *Alberta L. Rev.* 713

^{ccxxxvii} See *Genetic Patent Law and Strategy*, Sep 26th, 2007
<<http://www.articlesbase.com/patents-articles/genetic-patent-law-and-strategy-220823.html>>

^{ccxxxviii} R. Stephen Crespi, Patents on Genes do they have a Future

^{ccxxxix} 1998 O.J. (L 213) 13 [hereinafter Directive]. A directive is a type of E.U. legislation that targets one or more specific Member States, see *infra* note 4, and binds them with respect to the end to be achieved, while allowing each Member State some choice as to the method, and, sometimes, the extent, of implementation. It is distinguishable from a regulation, which is binding upon all Member States and mandates a particular means of attaining the stated goal. Thus, directives are more flexible and accommodating to national law, making them particularly useful in order to harmonize the laws within a certain area. See W. R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* 20-21 (3d ed. 1996).

^{ccxl} See Thomas C. Vinje, *Harmonising Intellectual Property Laws in the European Union: Past, Present and Future*, 8 *Eur. Intell. Prop. Rev.* 361, 361 n.2 (1995).

^{ccxli} See 19 *Berkeley J. Int'l L.* 1

^{ccxlii} *Id.*

^{ccxliii} See Directive, *supra* note 3, PP 1 to 7, at 13. Although the Recitals in the Directive are not operative, they serve to elucidate the intent of the drafters. See Nott, *supra* note 1, at 347.

^{ccxliv} According to a 1998 report, approximately 65% of all biotech patents originate from the U.S., and only about 15% from European nations. See Sean Milmo, *EU Biotech*

Industry Wins Major Battle, Chemical Market Rep., May 18, 1998, at 5. Moreover, in 1997, the biotechnology sector employed some 140,000 people in the U.S., compared with only 39,000 in the E.U. U.S. biotech companies had revenues of \$ 17.4 billion in 1997, and invested \$ 9 billion in research and development, while European biotechnology sector revenues were only \$ 2.9 billion and research and development expenditures totaled less than \$ 2.1 billion. See Ernst & Young, European Life Sciences 98, at 11, tbl. 3 (1998) [hereinafter European Life Sciences].

^{ccxlv} See Directive, supra note 107, PP 37 to 45, at 16.

^{ccxlvi} *Id.*

^{ccxlvii} *Id.* art. 2.1, at 18.

^{ccxlviii} Directive, supra note 107, art. 3.2, at 18.

^{ccclix} *Id.* P 21, at 15.

^{cccl} *Id.* art. 5.1, at 18.

^{cccli} *Id.* art. 5.2, at 18.

^{ccclii} Specifically, Article 5.3 of the Directive provides that "the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application." *Id.* art. 5.3, at 18.

^{cccliii} See Directive, supra. art. 5.1, at 18.

^{cccliv} *Id.* art. 2.2, at 18.

^{ccclv} *Id.*

^{ccclvi} *Id.* art. 6.1, at 18.

^{ccclvii} See Directive, supra note 107, PP 37 to 45, at 16.

^{ccclviii} Joseph Straus, Patenting Human Genes in Europe - Past Developments and Prospects for the Future, 26 Int'l Rev. Indus. Prop. & Copyright L. 920, 922 n.8 (1995)

^{ccclix} See Kevin Noonan, [In Support of Gene Patents, December 07, 2006](http://patentdocs.typepad.com/patent_docs/2006/12/by_kevin_noonan.html)
<http://patentdocs.typepad.com/patent_docs/2006/12/by_kevin_noonan.html>

^{ccclx} *Id.*

^{ccclxi} *Id.*

cclxii *Id.*

cclxiii *Id.*

cclxiv *Id.*

cclxv See Australian Law Reform Commission (ALRC): Genes and Ingenuity: Gene Patents and Human Health (ALRC 99), 2004.

cclxvi See Australia Law Reform Commission – Media release of 31st August 2004. <http://www.alrc.gov.au/media/2004/mr3108.html>

cclxvii *Id.*

cclxviii See 41 Alberta L. Rev. 713

cclxix *Id.*

cclxx See Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (London: Nuffield Council on Bioethics, 2002) at xi-xii, online: Nuffield Council on Bioethics <www.nuffieldbioethics.org/patentingdna/index.asp> [*Ethics of Patenting*]; see also Royal Society (U.K.), *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (London: The Royal Society, 2003) online: The Royal Society <www.royalsoc.ac.uk> at 3.19

cclxxi See Canada NewsWire, "BIOTEC Canada responds to Supreme Court Decision on Harvard Mouse Case" (5 December 2002) online: Canada News Wire <www.newswire.ca/en/releases/archive/December_2002/05/c0202.html>.

cclxxii See *As the Future Catches You* (New York: Crown Business, 2001) at 138.

cclxxiii See *As the Future Catches You* (New York: Crown Business, 2001) at 138.

cclxxiv See John Hammond, Patent- Limited Monopoly, http://www.patenteducation.com/images/200706_Limited_Monopoly_-_35_USC_101.pdf

cclxxv See Title 35, Chapter 10, Section 101.

cclxxvi See Watson JD, Crick FH (April 1953). "Molecular structure of nucleic acids; a structure for deoxyribose nucleic acid". *Nature* **171** (4356): 737–8. [doi:10.1038/171737a0](https://doi.org/10.1038/171737a0). PMID 13054692.

^{cclxxvii} See Barnhart, Benjamin J. (1989). "DOE Human Genome Program". *Human Genome Quarterly* 1: 1. Retrieved 2005-02-03.

^{cclxxviii} *Id.*

^{cclxxix} See USPTO. 'Revised Interim Utility Examination Guidelines' in the Federal Register on December 21, 1999 (Volume 64, Number 244), <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>

^{cclxxx} See, e.g., Scott A. Chambers, Written Description and Patent Examination Under the US Patent and Trademark Office Guidelines, 6 IP LITIGATOR 9, 10 (Sept.-Oct. 2000)

^{cclxxxi} See, e.g., Scott A. Chambers, Written Description and Patent Examination Under the US Patent and Trademark Office Guidelines, 6 IP LITIGATOR 9, 10 (Sept.-Oct. 2000)

^{cclxxxii} See, e.g., Janice M. Mueller, The Evolving Application of the Written Description Requirement to Biotechnological Inventions, [13 BERKELEY TECH. L.J. 615, 617 \(1998\)](#)

^{cclxxxiii} See Lawrence T. Kass & Michael N. Nitabach, A Roadmap for Biotechnology Patents? Federal Circuit Precedent and the PTO's New Examination Guidelines, 30 AIPLA Q.J. 233, 248-61 (2002) (reviewing the revised utility and written description guidelines).

^{cclxxxiv} See [Enzo Biochem Inc. v. Gen-Probe Inc., 323 F.3d 956, 982 \(Fed. Cir. 2002\)](#) (Rader, J., dissenting)

^{cclxxxv} See 47 IDEA 659

^{cclxxxvi} See USPTO. 'Revised Interim Utility Examination Guidelines' in the Federal Register on December 21, 1999 (Volume 64, Number 244), <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf>

^{cclxxxvii} See Rimmer, Matthew, Genentech and the Stolen Gene: Patent Law and Pioneer Inventions. *Bio-Science Law Review*, Vol. 5, No. 6, pp. 198-211, 2002/2003. Available at SSRN: <http://ssrn.com/abstract=603221>

^{cclxxxviii} See Levinson, A. 'Genentech CEO Says Amgen/TKT Trial Outcome Not A Bellwether For Biotech - Broader Issue of Gene Patents Addressed at Congressional Hearings This Week', Genentech Press Release, San Francisco And South San Francisco, California, 13 July 2000, <http://www.gene.com/gene/news/detail.jsp?detail=4624&pNo=9>

^{ccxxxix} Although 35 U.S.C. § 101 simply requires an invention to be "useful," this attribute has been judicially interpreted to have these dimensions. Robert Patrick Merges & John Fitzgerald Duffy, *Patent Law and Policy: Cases and Materials* 212 (3d ed. 2002).

^{ccxc} See 71 Tenn. L. Rev. 707

^{ccxci} *Id.*