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Gene patents: "What God hath wrought!"[1]

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Abstract: Although the U.S. Patent and Trademark Office ("PTO") has granted patents on genes for over 20 years, the prudence of gene patenting continues to stir controversy. Some have questioned the ethics of monopolizing a resource that is so fundamental and basic to all living organisms. It has also been argued that patents unfairly restrict the use of genes, impeding both basic and commercial research. For the biotechnology industry, however, gene patents are the currency it uses to protect its investment in research and development, and eventually, the products it brings to market. This paper examines the eligibility of genes for patenting, and considers whether the policy reasons that have led courts to decide that certain categories of subject matter are unpatentable, apply to the realm of genes. Even if this were the case, this does not mean that biotech companies have no way of protecting their inventions. Methods and processes of using the genes do not invoke the same policy considerations, and may provide a more appropriate way of rewarding industry for the narrow discovery of a gene's specific use.

Introduction

In 1844, the first intercity electronic message was tapped out by telegraph from Washington, D.C. to Baltimore, Maryland, by Samuel F.B. Morse, the man who invented it. The message transmitted for the historic occasion – "What God hath wrought!" – was a biblical quotation intended to express awe at the natural force of electricity used to propel his words over the 37 miles of telegraph wire that stretched between the two cities. While he had not invented the natural phenomenon of electromagnetism, Morse had certainly succeeded in harnessing it to create the world's first intercity internet. Paying homage to nature's role its development was the right thing to do for the son of a pastor, but as it turned out, a doubled-edged sword for a man hoping to reap financial reward from it.

The tension between what belongs to nature, and what belongs to a human, later surfaced in litigation over a patent secured by Morse for his invention. Morse, as many inventors of his time did, sought patent protection for his invention. In preparing the patent application, Morse claimed the invention broadly, covering

not only the particular configuration he had used to carry his message between two cities, but also any innovation using electromagnetism to transmit messages. Then, as now, broad patents found no favor in the public eye, or in the federal courts that decide these matters, and Morse eventually ended up in litigation defending the validity of his patent.

In Morse's case, he described as his invention the use of electromagnetism to produce characters at a distance by any means, whether conceived of by Morse or not. As he put it in his patent: every use of the electromagnetic force "however developed for marking or printing intelligible characters, signals, or letters, at any distances."[2] Although he had invented a particular electromechanical structure for transmitting electronic information through wire, Morse sought to patent much more. Patents confer the owner with the right to exclude all others from carrying out whatever subject matter is claimed as the invention. By making broad claims to the principle of electromagnetism to convey information any distance, he could bar the rest of the world from using it in any later conceived innovation. The Patent Office allowed Morse's claims, but Morse's victory did not last.

Ironically, Morse's own message identifying nature ("God") at the heart of the invention became his poison pill. When challenged in litigation, the broad patent claim to every use of electromagnetism for printing information at a distance was found to be invalid for the reason that, what Morse declared as his own invention, was really the work of nature. In denying its validity, the Supreme Court emphasized that the discovery of a principle of nature was not patentable subject matter until it was reduced to a specific structure in which the principle was used to achieve a tangible result. Morse had only described one such structure. "Nor is this all," the Court wrote, "while he shuts the doors against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men bring to light. For he says he does not confine his claim to the machinery or parts of machinery, which he specifies, but claims for himself a monopoly in its use, however developed, for the purpose of printing at a distance."[3] Restricting an inventor to the specific structures described in the patent was the Court's way of balancing the competing interests in the new technology.

Gene patents

Morse's message, sent on the world's first internet, captured the essence of an issue that continues to echo down Patent Office corridors: What constitutes patentable subject matter? When discoveries and technologies unforeseen when the present Patent Act was adopted in 1952 confront the patent examining group, a threshold question is whether they are within the realm of the patent system. This is what happened in the late 1970's when the first wave of genetically engineered organisms were presented to the Patent Office. General Electric, the owner of a patent application covering a bacterium, which had been genetically altered to make it capable of eating oil, said they were. The Patent

Office disagreed, and turned down the patent. The debate was tossed into the federal courts, and the U.S. Supreme Court answered the question affirmatively. Yes, patent rights could be extended to a living organism made by humans. Relying on the legislative history of the Patent Act, the Court's opinion was heavily influenced by the perception that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)."[4] The Supreme Court was cheering the biotech industry on, telling it that everything was patentable.

In the 1990's, as internet companies struggled to protect their innovations in the electronic medium, the question again resurfaced, this time in the guise of whether business methods implemented on a computer system could be patented. Signature Financial Group was the owner of a patent directed to a data processing system for managing an investment portfolio. The patented system contained a computer processor, a storage medium (computer disc), and software instructions (referred to as "means for" in the patent) for calculating asset value and share price. State Street initially tried to license the patent, but when negotiations broke down, they filed suit, arguing that a business method was improper subject matter for a patent. But once again, the federal courts construed the Patent Act broadly, rejecting State Street's arguments. The court held there was no business method exception, and that a process of transforming data by a computer, through a series of mathematical calculations, to produce a final share price constituted a "useful, concrete, and tangible result," satisfying the requirements of the patent statutes. The fact that these steps were performed in an electronic milieu and for the purpose of doing business was no bar to patentability.[5]

Now, as a surge of gene applications floods the patent examining group, the patentability question is back. It is clear from reading federal court decisions that limitations on statutory subject matter are rarely read into the patent statutes where the legislative history indicates the Congress intended no such limits. This is consistent with the very broad purpose of patents to foster progress by offering inventors exclusive rights to their invention for limited periods of time. But, as indicated in *Morse*, there are also categories to which patent protection can not be extended. Namely, "laws of nature, natural phenomena, and abstract ideas."[6] Figuring out what occupies this neverworld of invention can be a patent attorney's nightmare.

Genes are troublesome for the patent system because of their dual nature. As chemical compounds comprised up repeating units of nucleotides, they fall squarely into subject matter that is well-established as being patentable. In recognition of this, federal courts apply chemical patent law to genes. As one federal judge wrote, "A gene is a chemical compound, albeit a complex one..."[7]

But genes are also informational, defining fundamental natural processes that can aptly be described as "wrought" by nature. A gene contains the informational code that the cell utilizes to manufacture a protein. In this way, a gene is not only a conglomeration of atoms bonded together, but also serves as the cell's bible, providing the instructions to implement the basic process of making the protein it encodes. This distinguishes genes from proteins, and other chemical compounds.

Yet, genes have been patented for over 20 years. One of the earliest gene patents, U.S. Pat. No. 4,322,499, was granted in 1982 to the University of California and covered the human endorphin gene. At first, progress was very slow. The technology to clone genes was tedious, and new genes were identified at a snail's pace. This changed in about 1991, when DNA sequencing strategies enabled scientists to rapidly sequence through the human genome, discovering new genes at a surprisingly fast rate.[8] A biotechnology industry sprung up around DNA sequencing, and gene patenting became its standard approach to protect new gene discoveries. Since that time, the number of issued gene patents has grown exponentially, and an even greater number have been filed on, but have yet to mature into granted patents. As patent filings on genes piled up at the Patent Office, concerns surfaced that the human genome was being gobbled up and patented by the biotech industry. Academics and public watch groups following the industry were troubled, warning that gene patents were impeding basic research and extorting high royalties when used in the field of diagnostics.[9]

In countering these concerns, the U.S. Patent Office (the "PTO") began to raise the patentability bar for getting a gene patent. To be granted a patent, an inventor must show that the invention is new, not obvious to a skilled scientist, and useful. The PTO focused on the question of whether a gene was useful[10] – the so-called "utility requirement." Since many of the discovered genes were selected by brute force sequencing of the human genome, no precise function had been identified for them at the time the applications were filed. Companies rushing to patent genes had no time to actually perform research on them. As gene sequences poured out from DNA sequencing machines, patent departments literally grabbed the sequences, crafting patent applications based almost solely on the DNA sequence and the corresponding deduced polypeptide. Many of the genomic companies use templates and automated processes that facilitate and expedite the journey from sequencing machine to patent application. With these sophisticated tools, gene patents are spun out as fast their nucleotide sequences can be read.

According to current PTO policy, a claim to a gene can not satisfy the utility requirement unless the inventor can define a precise use for it – in the PTO's words: a substantial, specific, and credible use. Training materials prepared by the Patent Office provide guidance on the type of uses considered to comply with the utility requirement. *Revised Interim Utility Guidelines Training Materials*,

1999.[11] In these materials, the PTO takes the position that a protein whose function is only generally known is not considered to be an adequate disclosure for utility purposes. For example, the knowledge that a DNA codes for a transmembrane receptor protein – without knowing whether it is associated with a disease or condition, or has some other "real world" application which is specific to it – is simply not enough in the PTO's eyes to get a patent. This is serious challenge to the industry's holy trinity of patent law: deducing polypeptide sequence from a DNA, categorizing the structure into a basic functional class of proteins – receptor, secreted molecule, transcription factor, etc. – and then filing it as a patent application. Whether the "deduce, classify, and file" approach will stand up in court has yet to be decided.

So why are genes so interesting to the biotechnology industry? There are three major uses of genes: (1) to make recombinant proteins that have therapeutic value (e.g., insulin, Factor VIII, hepatitis B vaccine, etc.); (2) as a diagnostic probes to determine whether a patient has a genetic disease; and (3) as tools in basic research and drug discovery ("research tools"). The use of genes for therapeutic and diagnostic purposes is well-established in the industry. Utility as research tools is not new either, but with the rapid identification of new genes over the past few years, this has become a significant focus of the industry. With so many new genes, and so little information about their function, companies have turned to high throughput methods of analyzing genes and discovering their role in the body and disease. It is either like digging in a gold mine, or finding a needle in the haystack. Using a wide array of technologies – from gene chips (arrays of genes or gene fragments on solid substrates) to cellular based assays where individual genes are introduced into cells – there is a continuous search to define functional roles for genes. Although the methods utilized to identify gene and protein function differ widely, genes are often utilized at some point in the assay method. Thus, a discovery program may push as many as possible genes through the technology in the hope that an activity for at least one will be discovered. Genes have become the currency of the industry, and gene patents have become the sword. A patent on a gene can block its use for any purpose and in any environment, including in the generalized discovery methods that have become the industry staple.

Discoveries and principles of nature

The Court spelled out clearly in the *Morse* case that principles of nature are not by themselves patentable, until they have been used to achieve a constructive result. If a gene is a natural principle, analogously, it could be argued that it can not be patented. The gist of invention would lie in the use of the gene to accomplish a useful outcome, not in the gene *per se*.

According to Article I, Section 8 of the Constitution:

The Congress shall have Power … [8] 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.

Although the term "Discoveries" would appear to cover any principle of nature revealed by a scientist – like gravity, relativity, and other laws of physics – it has never been given this broad interpretation. Instead, the right to discovery conferred by the constitution has been limited to a category of human endeavor called "invention."

Several reasons underlie this restraint on the patent system. In its earliest rendition, this concept appears to reach back to John Locke's eighteen century idea that the earth in its natural state belongs to all humankind until a person's labor has taken it out of the hands of nature. Discovering a tree full of apples is not enough to give the observer ownership over the apples. "Whatsoever, then, he removes out of the state that nature hath provided and left it in, he hath mixed his labour with it, and joined to it something that is his own, and thereby makes it his property. It being by him removed from the common state nature placed it in, it has by this labour annexed to it that excludes the common right of other men."[12]

The early patent cases reflected this view. For example, in *In re Kemper* (1841), 14 F. Cas. 286 (Circuit Court, D.C., 1841), the court wrote: "Every patent is a monopoly; and nothing can justify it but the natural right of property which a man has in the products of his own labor and ingenuity. With this exception, it is in derogation of common right, and it should be strictly confined to the case excepted."

The distinction between what is a discovery and what is the product of a person's labor is difficult, if not a fiction.[13] The person who "discovered" the tree full of apples may have expended a great deal of labor – both mental and physical – in identifying a particular tree loaded with ripe apples, but the system would not reward him with ownership until he picked those apples from the tree. Even though human ingenuity was a necessary element of its discovery, the conventional Lockean approach would not have recognized the acquisition of personal property until physically removed from its natural state.

The policy reason for this requirement is evident: when private rights have the potential of interfering with the public's right of way to a substantial resource, it is in the public's best interest to restrain them. The danger of a "monopoly of knowledge" according to the Supreme Court in *Brenner, Commissioner of Patents v. Manson*, 383 U.S. 519, 535 (1966) was that "Such a patent may confer power to block of whole areas of scientific development, without compensating benefit to the public." The Morse case is illustrative. A patent covering any use of electromagnetism to transmit messages would have given

Morse a virtual monopoly over the industry. For public policy reasons, this was considered too excessive.

The judicial solution to policing whether an invention has the ability to unduly limit public access has been to require that the invention be placed in a tangible form, apart from simply being an idea or principle of nature. "A discovery may be brilliant and useful, and not patentable. No matter through what long, solitary vigils, or by what importanate efforts, the secret may have been wrung from the bosom of Nature, or to what purpose it may be applied. Something more is necessary. The new force or principle brought to light must be embodied and set to work, and can be patented only in connection or combination with the means by which, or the medium through which, it operates."[14]

The important consideration here is what type of activity entitles a party to remove a good from public domain, and claim it as his own. Although labor may have been expended in making a discovery, it does not become patentable until cast into a particular tangible embodiment that is distinct from its place in nature. The policy reasons are well established. Too broad a grip on a technology "would discourage arts and manufacture, against the avowed policy of the patent laws."[15] The restriction on patenting "principles of nature" was simply the court's attempt to articulate a bright line test for determining the boundaries of patentability.

Funk Brothers v. Chakrabarty

The sentiments set forth in *Morse* are echoed in a line of established federal court decisions. In *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948), the Supreme Court found a patent claim to a combination of bacteria unpatentable. Inventor Bond, employed by Funk Brothers, had been issued a patent on a bacterial inoculant for leguminous plants that contained a mixture of "mutually non-inhibitive strains of different species of bacteria of the genus Rhizobium." Rhizobium had been sold for many years to colonize the roots of leguminous plants. Each plant type hosted its own unique bacterial strain. Mixtures of different strains of bacteria had been unsatisfactory since they had an inhibitory effect on each other. As a result, farmers were required to purchase separate inoculant strains for each type of plant sown. Bond discovered strains which did not exert the inhibitory effect, and thus were compatible in mixed cultures. A farmer could use one inoculant, containing multiple bacterial strains, for all types of leguminous plants. He patented the combination. In a suit for infringement, the infringer Kalo Inoculant argued that bacterial cultures were not patentable subject matter. The Court agreed: "Their qualities are the work of nature. These qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. See *Le Roy v. Tatham*, 14 How. 156, 175. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved to exclusively

none. … If there be an invention from such discovery, it must come from the application of the law of nature to a new and useful end."

Funk Brothers was not overruled by *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), a case often cited in favor of the patentability of genes ("anything under the sun that is made by man" is patentable). In *Chakrabarty*, the Supreme Court reversed a Patent Office decision not to grant a patent on a bacterium which had been genetically engineered by the introduction of a piece of DNA – a plasmid – from another bacterial strain. The plasmid contained genes which coded for proteins ("enzymes") that, when produced in the bacterium, enabled it to degrade crude oil. In his patent application, later granted as U.S. Pat. No. 4,259,444, Chakrabarty described how the engineered bacteria had acquired the ability to digest oil, making them useful in cleaning up oil spills and disposing of spent automobile oil. Thus, Chakrabarty's microorganism, unlike Bond's, had not simply been captured from nature. Instead, it had been manipulated genetically and endowed with new genetic characteristics conferring a phenotype which it had not previously possessed.

At about the same time as *Chakrabarty*, the Patent Office had denied Bergy a patent on an antibiotic-producing bacteria which had been isolated from soil, but which had not been manipulated genetically in any way. For purposes of appeal, Bergy had been consolidated with Chakrabarty since both cases raised related questions about the patentability of living organisms.[16] Although the lower court decided in favor of both parties, when the decision was appealed by the Patent Office to the Supreme Court, Bergy dropped out and gave up his patent application. Because Bergy's microorganism had not been genetically altered like Chakrabarty's, Upjohn Co., the owner of the patent application, was afraid that the Supreme Court in view of the *Funk* decision might put a roadblock in the way of patenting bacteria, and related biotechnology inventions, which had not been modified by gene technology.[17] *Funk* is still the law when it comes to unaltered life forms. An isolated, unmodified human gene seems akin to Bond's unmodified bacteria, not Chakrabarty's artificially constructed bacterium.

Mathematical formula

Morse and *Funk Brothers* are not alone in placing restrictions on what can be divined from nature and patented. The U.S. Supreme Court has long held that algorithms and mathematical formulas are not patentable unless they are embodied in a novel and useful structure or process. A formula for determining how radio waves are projected from an antenna could not be patented, but the antenna made from applying such formula could.[18] The policy reason for this exemption was to prevent a patent from pre-empting the use of an equation by the public.[19] The federal patent power stems from principle that innovation should be encouraged, but at not at the expense blocking off entire areas of scientific research.[20] The restriction on mathematical formula is an extension of the prohibition on patenting natural principles.

The origin of the mathematical formula exception was in an early case in which an improvement had been made in manufacturing pipe. The inventors had discovered that, under heat and extreme pressure, lead could be shaped into a tube, superior in quality from any other previously known. The Court emphasized that while the machinery, itself, used to produce the lead pipe was patentable, the principle upon which the machine was based was not. The Justices reasoned that a patent on the scientific law of heat and pressure, stripped of any structural limitation, "would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufacture, against the avowed policy of the patent laws."[21]

Naturally-occurring products

Patents are only granted when the subject matter of a patent application satisfies the statutory requirements set forth in the Patent Act, including 35 U.S.C. §101, which authorizes patents on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[22] To get a patent, the subject matter claimed as the invention must be new. This reflects the basic principle in property law that ownership of a thing is acquired by being the first in time to possess it. When a scientist discovers the existence of a new compound or element in nature, he can not obtain a patent on it because the form as it exists in nature is not new. To translate the discovery into patentable subject matter, the discovered compound must be changed into a form in which it does not occur in nature, or incorporated into a process that achieves a useful result. Either way, the scientist must demonstrate possession of the discovered compound by transforming its place in nature ("natural state") to a status that is human-made.

In the vitamin B12 cases, scientists at Merck pharmaceutical company had succeeded in isolating vitamin B12 from a natural source for the first time.[23] It had been known that liver extract contained a substance that was useful for treating anemia, but the agent responsible for the therapeutic effect had not been isolated or even identified. In a series of experiments, Merck scientists succeeded in separating out the agent from liver and characterizing its structure. By removing the B vitamin from its natural environment, they satisfied a key threshold for patentability – putting it into a form that was not previously known – isolated or substantially pure. It was free of the other materials that are normally present in an extract of liver tissue. This same principle has permitted many newly discovered biological molecules to be patented by their discoverers.[24]

Are genes patentable?

The preceding rules suggest that the mere discovery that a particular gene is present in the human genome is insufficient to satisfy the requirements for patentability. First, a gene as it exists in the chromosomal milieu is not new. Until it is extracted, a gene can not be claimed as a new and useful composition of matter. By pulling the gene out from the cell nucleus – cloning it – the U.S. Patent Office has taken the position that the scientist then acquires the right to

patent it because he has dug it out from its naturally-occurring state in the chromatin, and reconstituted into an artificial human-made form.

This extraction principle echoes from the basic principle of acquiring property by capture. Things like wild animals, running water, and minerals are public property until ownership is acquired by a party exerting control and domination over it. Once possession of it has been established, the party is entitled to own it. Similarly, once a naturally-occurring compound is removed from the environment in which it normally exists, it becomes the property of the possessor. In this analogy, the gene is indistinguishable from the wild animal or mineral.[25]

But even if the extraction principle is not a bar to a gene's eligibility for patenting (i.e., after obtained in its isolated and cloned form), there are still impediments that require serious consideration. Patents extend ownership to not only the specific copy of the substance that has been captured, but to all copies of it – whether in the hands of the possessor or not. The capture of a single gene becomes the proxy to all genes. This important distinction permits the single act of capture to interfere with the ability of anyone else to capture a copy of a like gene. The scientist who plucked out the first copy of BRCA1 (or any other gene) grabs hold of every single copy of it that exists in the human gene pool for the limited period of patent exclusivity. One act of capture can remove all genes from the public property. Instead of just taking the captured copy away, upon grant of a patent, it essentially removes it entirely from public hands. The same policy rationale that curbs patents when they exercise too much control over the public pie could readily be applied to the gene ownership question.

A gene's duality is unusual, having attributes of a chemical compound in being comprised of atoms, but also of a natural principle or mathematical algorithm in that it is an information molecule in which the instructions to make proteins are embedded. This informational quality distinguishes a gene from other classes of chemical compounds. While other compounds found in living organism (including polypeptides, such as hormones and neurotransmitters) have the ability to convey signals, and hence information, in a cell, no other encodes information at such a high level and in distinct form.

But is it reasonable to call a gene a "principle of nature," and thereby prohibit its patenting? According to the *Webster's II New College Dictionary*,[26] a "principle" is "1. A basic truth, law, or assumption." Indeed, the rules that govern the role of genes in heredity are called "Mendel's Laws" after their discoverer[27], and are taught in biology classrooms all over the world as such.[28] The fourth entry under "principle" in Webster's is even more fitting: "4. A basic or essential quality or element determining intrinsic nature or characteristic behavior." Genes are the initial determinant of an organism's phenotype (outward appearance) and govern its "characteristic behavior." Analogously to how the law of electromagnetism determines the behavior of electrons in a magnetic field, genes determine the behavior of an organism in its environment. Certainly, given the limited number

and importance of genes in all of biology, it is not unjustified to treat genes as principles of nature for the purpose of patentability.

Striking the balance

If genes are unpatentable, does this mean that the biotech industry has no way of protecting their discoveries? Intellectual property rights are valuable assets, important for industry financial health and development. Depriving biotechnology companies of patent protection undermines the patent system whose express intent is to provide incentive and reward for new innovations. Protein drugs like erythropoietin (sold commercially as Epogen or Procrit) were advanced to market under the expected exclusivity of gene patent coverage. With a significant period during which competitors could be excluded, the sellers of these drugs have been able to collect adequate economic reward from the marketplace to finance their effort, and continue discovery and research. Eliminate patents on genes, and it is likely that the reverberations will have a profound economic impact on the industry as a whole. An appropriate balance must be struck.

One approach that has been suggested is to establish compulsory licensing for DNA sequences modeled on the statutory licensing scheme under the Copyright Act.[29] This could include the requirement that the sequence be in actual use in the industry, analogous to the use requirement for trademark registration. Another suggestion proposed by the U.S. Patent Office and others was the idea of a patent pool, where all owners of gene patents would collect their patents into a common pool that would then be available for licensing.[30]

Laws of nature can't be patented, but their application can be. Samuel Morse lost his broad claim to the use of electromagnetism for making or printing intelligible characters, signs or letters at any distances, but the other seven claims of the patent to specific embodiments of the telegraph were held valid and enforceable. For the realm of gene patents, this suggests another approach: extend patent protection for a specific use of gene, but not to the gene, itself. This is consistent with the PTO's present policy on awarding gene patents only when a "real-world" use has been discovered, but goes one step further by limiting the inventor to that discovered use. Scientists would be able to freely use genes to discover new functions, but would be restricted from using them in the specific ways that have been patented.

Section 101 of the Patent Act sets forth the different classes of invention that may be patented: processes, machines, manufacture, or composition of matter. When a gene is patented as a chemical structure comprising a long string of nucleotides, it is called a composition of matter patent since it covers the gene as a compound. For example, the gene for erythropoietin was patented by Amgen in U.S. Pat. No. 4,703,008 as "A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."

To patent a composition of matter, an inventor is required to describe only one specific use of it in the a patent application, but can still block third parties from any undisclosed use of it. Consider a patent on aspirin where the inventor had discovered that it was useful for treating headaches. The patent would claim the invention broadly as "a pharmaceutical composition containing aspirin." Any time that pharmaceutical composition was used – for treating headaches or any other condition – the patent would be infringed and its owner could stop it. A later innovator who discovered that aspirin could be used to prevent heart attacks would be precluded from selling aspirin for that purpose, despite the fact that the original patentee had no knowledge of it.

A process patent has a narrower scope than a composition patent. It only covers the patented process. A process patent is distinguished from a composition of matter patent by reciting specific steps that must be performed to infringe the patent. Say the heart innovator had patented his discovery in the following form: "A process of preventing heart attacks, having the step of administering aspirin to a patient in need of it." In this example, the innovator can only block the sale of aspirin for heart attack prophylaxis, but any later discovered use is unfettered. The original patentee, in contrast, can block any use of aspirin, including its administration for heart attacks.

Patenting genes as compositions of matter could also be considered repugnant to the federal policy prohibiting the monopolization of laws of nature. *Morse*, *LeRoy v. Tatum*, *Funk*, and many other cases handed down by the federal courts have never softened their stance when it comes to this. The policy reasons are the same: a patent awarded on a gene appropriates every human-driven use under the sun for that gene, giving its owner control over a discovery that has the eerie ring of a law of nature.

When confronted with tough issues like these, the Supreme Court has repeatedly struck down far-ranging patents. In *Brenner, Comr. Pats. v. Manson*, the case relied upon by the Patent Office for their toughened stance on gene patents, the Supreme Court condemned patents that would confer "a monopoly on knowledge," and choke off whole areas of scientific endeavor. For this reason, the Patent Office imposed the strict utility standard, requiring that, for a patent to issue on a gene, it must have a "real-world" use that is specific to the particular gene which has been identified, rather than characteristic of all genes. A logical corollary of this is to recognize that the gene, itself, can not be patented, but only its real-world practical use.

A human gene is a resource that is so universal and unique that permitting exclusive domination over it has considerable implications for biomedical research and discovery. One of the purposes of the Human Genome project was to identify all human genes and "make them accessible for further biological study."[31] Genes, after all, are the primary substrates for disease and drug discovery. When a company is engaged in basic research on human disease, a

cloned gene may be a critical component in their research program. Under the current patent law regime, a patent on that gene as a composition of matter could end all third party use of it, impeding scientific discovery – the precise opposite of what the patent laws were meant to accomplish. When the patent owner may have yet to discover why this gene is useful, such a broad sweeping patent may not be in the best interest of any of the players. Limiting gene patents to the specific uses found by an inventor is consistent with patent policy by rewarding him with exclusivity for his discovery, while not blocking others from learning more of a gene's natural secrets.

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[2] O'Reilly et al. v Samuel F.B. Morse et al., 56 U.S. 62 (1853).
[3] Ibid.
[4] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[5] State Street Bank & Trust v. Signature Financial Group, 149 F.3d 1368, 47 U.S.P.Q.2d 1596 (Fed. Cir. 1998).
[6] State Street at 1600.
[7] Lourie, Circuit Judge in Amgen v. Chugai and Genetics Institute, 927 F.2d 1200 (Fed. Cir. 1991).
[8] See, e.g., Adams et al., Science, 252(5013):1651-6, 1991.
[9] See, e.g., Mertz, J.F., In Who Owns Life?, ed., Magnus et al., Prometheus Books, 2002, Pages 99-116.
[10] 35 U.S.C. Section 101.
[11] http://www.uspto.gov/web/menu/utility.pdf.
[12] Locke, J., Second Treatise of Government, Hackett Publishing Company, 1980 (originally published in 1690), Page 27.
[13] For a discussion of the discovery issue, see D. Resnik in Who owns Life?, ed., Magnus et al., Prometheus Books, 2002, Pages 135-159.
[14] Morton v. New York Eye Infirmary, 17 F. Cas. 879 (Circuit Court, S.D. N.Y. 1862).
[15] LeRoy Tatham, 55 U.S. 156 (1852).
[16] In The Matter Of The Application Of Malcolm E. Bergy et al.; In The Matter Of The Application Of Ananda M. Chakrabarty, 596 F.2d 952 (CCPA 1979).
[17] Saliwanchik, pers. comm.
[18] Mackay Radio and Telegraph Co., Inc. v. Radio Corporation of America, 40 USPQ 199 (1939).
[19] Gottschalk, Comr. Pats. v. Benson et al., 175 USPQ 673 (1972); Parker, Acting Comr. Pats. v. Flook, 198 USPQ 193 (1978); Diamond, Comr. Pats. v. Diehr et al., 209 USPQ 1 (1981).
[20] Brenner, Comr. Pats. v. Manson, 148 USPQ 689 (1966).
[21] LeRoy v. Tatham, 55 U.S. 156 (1852).
[22] U.S. Patent Office Manual of Patent Examination and Procedure, §706.03(a).
[23] Merck & Co. v. Olin Mathieson Chemical Company, 253 F.2d 156 (4th Cir., 1958); Merck & Co. v. Chase Chemical Co., 273 F. Supp. 68 (Dis. Ct. NJ, 1967).
[24] See, also, In re Kratz, 201 U.S.P.Q. 71 (C.C.P.A. 1979).
[25] Lebovitz, R.M., Nature, 328:17, 1996.
[26] Houghton Mifflin Company, 2001.
[27] It could be argued that while Mendel's laws are principles of nature, the genes are merely the particles that mediate the effect and therefore patentable. If the principle of electromagnetism is not patentable, could an electron be patented, or another newly isolated subatomic particle?

[28] "Mendel's laws are truly scientific laws – they apply as much to the traits he studied in peas as they do to human families with inherited disease." Lewis et al., Life, 4th edition, McGraw-Hill, 2002, Page176-177.
[29] Lebovitz, Science, 254, 1276, 1991.
[30] Resnik, J. Philos. Sci. Law, 3, January 2003.
[31] See, http://www.ornl.gov/ hgmis/project/hgp.html.