DNA DILEMMA: A PERSPECTIVE ON CURRENT U.S. PATENT AND TRADEMARK OFFICE PHILOSOPHY CONCERNING LIFE PATENTS

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ABSTRACT

The lack of a solid set of criteria for determining patentability of subject matter—particularly subject matter dealing with life—has recently been of increasing public concern in the United States. Alarm for patent practices related to life systems ranges from patents being granted on biochemical processes and the knowledge of these processes to the patenting of entire organisms. One of the most volatile concerns is the patenting of human genes or parts of genes since this genetic material is the basic informational molecule for all life. Current patent law, legislated in 1952, has been interpreted by the U.S. Supreme Court to allow broad patents of DNA, biochemical processes, and what are generally considered "inventions" of life systems. Several issues are addressed in this paper regarding the unsound reasoning underlying both the interpretation and execution of patent law. Lapses in logic provide a gateway for businesses and individuals to take patenting to an illogical and unworkable extreme. Patent Office disorder of this magnitude is unnecessary and has great potential for harming the mission that the patent office was designed to serve. Recently disclosed patent-granting guidelines suggest the United States Patent and Trademark Office is not upholding its Constitutional responsibility of promoting the progress of science.

"Living organisms are able to reproduce themselves even if they are patented, and in view of this special quality of living organisms, the scope of a patent is difficult to define, which makes it nearly impossible to find a balance between private and public interests."[1]

INTRODUCTION

Patents on life, ranging from DNA fragments to entire organisms, have reached mainstream concern in the past few decades. It is now obvious that several fundamental problems exist with United States patent law and the system that has been established to execute that law. Through the United States Patent and Trademark Office's interpretation of Supreme Court decisions[2], patents on DNA have been deemed grantable. As this paper illustrates, it is now theoretically possible to acquire a patent on any life-related subject matter, whether the subject matter is in essence a duplication of nature or otherwise. Through the current practice of granting life patents, fundamental problems arise because of the distinct differences that exist between life and inanimate objects. At this time, the patent system needs to undergo a significant reevaluation to ensure that it is promoting the best interest of science in a sound and logical manner.

The magnitude of the current challenges facing the patent office is easily seen in the number of pending genetically related patents. Through the end of December 2000, approximately 25,000 DNA-based patents were granted.[2] Several forms of life-related subject matter have been successfully patented: Expressed Sequence Tags (EST), which serve as gene markers along a DNA strand; Single Nucleotide Polymorphisms (SNP), which are single-base variations within DNA that could potentially cause disease; and regulatory sequences—all only gene fragments—have been patented. Entire genes, such as a gene called CCR5 that helps in the process of allowing HIV entrance into immune cells, have also been patented. An entire chromosome of a vertebrate is yet to be patented.[4]

LEGAL JUSTIFICATION FOR DNA PATENTING

To obtain a patent on DNA of any type or scope, the DNA fragment must be isolated and purified from its (thus far) observed natural state, or the fragment must be produced in purified form in a laboratory. More specifically, the following eligibility conditions as stated in the United States Patent and Trademark Office (USPTO) Utility Examination Guidelines, must be met:

> (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.[5]

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Thus, it is not acceptable to patent the exact genes as they exist in an individual.[6] However, several other logical conflicts and practical dilemmas arise from this patent philosophy.

As Condition (1) infers, one method by which DNA patents can be acquired is through patenting DNA that has been extracted from its natural environment. Since DNA is patentable, and by its very nature is part of all living organisms, any organism should be patentable by a similar mechanism to that established for the patenting of DNA. This brings about startling possibilities, the consequences of which the USPTO may have never anticipated or desired.

Entire organisms like plants, bacteria, even mice, have indeed been patented. All such patents, however, have been of an entirely different nature than DNA patents. These organisms have been fundamentally changed in some way by human ingenuity to improve upon their previous functions, abilities, and characteristics. Bacteria were genetically altered for oil-spill bioremediation purposes[7]; numerous plants have been transgenically altered for production purposes and other specific qualities[8]; mice are commonly genetically engineered as in the case of the "knockout" mice[9]: patents have been granted in all of these situations. The purification and isolation of DNA does not resemble such accomplishments. Patented DNA has simply been stripped of some of the critical parts it needs to function in a natural setting, but the base code still remains intact and unchanged by human influence.

CONDITION (1): PATENTING A TREE

Let us now consider patenting a tree by the same process that one would undertake to patent a DNA fragment under the first USPTO-defined condition. Though patenting a tree at first seems completely absurd, it is quite conceivable given current patent law and USPTO guidelines. While attempting to satisfy the requirements for patent approval legislated by Congress and interpreted by the USPTO in its execution of that legislation, the *Metasequoia glyptostroboides*—long thought extinct—will serve as our hypothetical example, though someone has yet to apply for a patent on this tree or any tree by such means. Several criteria need to be met in order to obtain a patent on *Metasequoia*. Formally, these criteria consist of non-obviousness, novelty, utility, and enablement. The first criterion however, and perhaps most logically troublesome, is that the tree must be an invention of human design. At first thought most individuals would believe it impossible for humans to invent the *Metasequoia*; it has already been created by nature. But the USPTO has a different view and exercises its duties accordingly. Patent law states that:

> 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 therefor, subject to the conditions and requirements of this title.[10]

Just as DNA must be removed (purified and isolated) from the environment in which it has been observed, so too must the tree. To "invent" the *Metasequoia* we simply need to take it from central China and plant it in our own backyard. As an extra measure, we will thoroughly clean the tree so that none of the native dirt is attached to its roots, no naturally growing fungi or bacteria indigenous to the region are residing on the tree, and all other foreign material such as birds and their nests are free from the tree's limbs. *Metasequoia* has now been isolated and purified and thus is our own "invention."

The tree must be non-obvious, which is defined by the USPTO to mean that the claimed subject matter must not be obvious to a person of ordinary skill in light of what was previously known.[11] Since *Metasequoia* was thought to be extinct, its existence on Earth today was not common knowledge to those of ordinary skill in the field of botany. Given this, *Metasequoia* would also conform to the novelty requirement as well, which states that a patent cannot be granted for an entity that has already been invented by someone else.[12] While no human invented the tree as it existed in nature, and because we invented the tree as it exists outside of nature, the novelty requirement is satisfied.

Metasequoia must have utility.[13] In other words, it must be useful in at least one way. "The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way."[14] *Metasequoia*, as in the nature of all trees, is useful in any of a number of applications. Thus, our tree fits perfectly with the utility requirement. To meet the final requirement, our *Metasequoia* patent must show enablement.

> The specification shall contain a written description of the invention, and of the manner and process of making and using it…to enable any person skilled in the art to which it pertains…to make and use the same.[15]

To satisfy this requirement, we must simply describe in what fashion the tree was transplanted from its native land to our backyard as well as how to use it to benefit from the previously described utility.

CONDITION (2): PATENTING A PROTON

As formerly alluded to, the second condition—Condition (2)—that makes DNA eligible for patenting is satisfied after the DNA has been "synthesized in a laboratory from chemical starting materials."[16] Hence, biologists must simply prove that they can recreate in a laboratory setting that which has already been created by nature. If patenting practices of this form are adopted by other science disciplines, perplexing and possibly undesirable consequences could result. For example, ever since Einstein proposed his famous equation $E = mc^2$, a result of the Special Theory of Relativity, it has been understood that all matter is simply a form of energy.[17] Today, scientists have the ability to manipulate energy in the vast number of particle accelerators that exist all over the world to create the various elementary particles of nature[18]—particles as common as the proton and as exotic as the Z boson. If DNA can be patented simply by synthetically creating it from more basic materials and meeting the four other conditions and requirements outlined by patent law, a proton or Z boson should theoretically be patentable because it can likewise be created. The ramifications of such patents being granted are incomprehensible.

THE DENIAL OF EXAMPLE PATENT APPLICATION IDEAS

Would the patent office ever grant a patent on *Metasequoia* or a proton in the manner that has been suggested, even though the application would comply with all of the outlined requirements in the same way DNA patent applications do? Since the patent office has yet to encounter a patent on a tree or a proton, one can only speculate upon the outcome. It inherently seems absurd to any rational person for a patent to be granted on a tree. In all probability, the patent office would reject a patent application on a tree not because of the apparent absurdity, but because of the size scale on which the patent is being proposed. The USPTO would likely not see the isolation and purification process used with *Metasequoia* as comparable to the isolation and purification that is undergone with DNA. The isolation and purification of the tree as described above is a fully tangible and visually understandable process, unlike the isolation and purification of DNA, which by its technical nature is more abstract. This dichotomy would almost certainly be enough to sway the patent office's view on the purification of the tree and thus reject the patent for not meeting the standard criteria. With the application of simple logic one can see that purification processes differing in physical size and technological scale can otherwise be quite similar. Given this, the USPTO seems to unwittingly hold a standard for patentability based on size and technological level.

Such a patent system based ultimately on size is inherently ambiguous. Size, like most any continuous system, presents natural difficulties when trying to establish arbitrary boundaries within the system. At what size does an object move from the non-patentable realm into the patentable? If DNA is patentable, then is an entire cell patentable? If an entire cell is patentable, then certainly a free-living, single-celled organism would be patentable material. If a single celled organism is patentable, then why not a multi-celled organism? Though, as mentioned earlier, patents have been granted on multi-celled organisms, all patented organisms have, to this day, been in some way genetically altered by humans and not simply the product of nature.

Similarly, it would probably be considered equally absurd to grant a patent on the proton. Protons are basic building blocks of all matter. But it follows that DNA is a basic structure of all life. For DNA to be patentable, all entities on Earth, whether devised by the creativity of humans or otherwise, must be in essence patentable. This certainly defies Congress's original intention when writing current patent law in 1952 that "anything under the sun that is *made by man*"[19] (emphasis added) be patentable subject matter.

PLAGIARIZING NATURE'S WORK

Another fundamental problem exists with the patenting of DNA. Historically, patents have been granted for inventions of an original mechanical nature or process. Plows, automobiles, and oil refinement processes have all been patented. More recently, computer chip designs and biological processes such as the polymerase chain reaction have been patented. Those patents are intrinsically different from patents on DNA fragments since they are processes or creations of humanity and not extant physical entities in nature.

Traditional patents encourage further innovation and ingenuity because it is physically possible to *invent around* the patented subject matter with a new and novel idea. However, DNA was not a human innovation, but a manifestation of nature that has undergone millions of years of evolution. By purifying and isolating DNA to patent it, humans are simply plagiarizing nature's work. Because of the innate characteristics of DNA, it is inherently impossible to re-invent it or even invent around it. Thus a patent on DNA has power above and beyond that of a typical patent.

In this regard the USPTO seems confused. The USPTO likens DNA patenting to patents on television sets and the picture tubes therein, as explained by the USPTO Director of Biotechnology Examination.

> "The USPTO views this situation as analogous to having a patent on a picture tube. The picture tube patent does not preclude someone else from obtaining a patent on a television set. However, the holder of the picture tube patent could sue the television set makers for patent infringement if they use the patented picture tube without obtaining a license."[20]

A dissection of this analogy is revealing. A Single Nucleotide Polymorphism (SNP) would be analogous to the picture tube, and a cure for a disease is analogous to the television set. Consequently an SNP patent does not preclude someone else from obtaining a patent on a cure for a disease, which is attributable to that SNP. However, the holder of the SNP patent could sue the "disease-cure" manufacturer for patent infringement if that manufacturer uses the patented SNP without obtaining a license.

The USPTO analogy is confusing, though a simple conclusion results. It is entirely possible for the television set maker to choose any of a number of picture tubes that have already been patented to use in a television set. More importantly, the television set maker can opt to design its own picture tube because it is physically possible to invent around patented picture tube innovations. Conversely, a competitor of the "inventor" of the SNP cannot pick and choose among other SNPs for a cure for the same disease since the originally patented SNP was the natural cause for that disease. Furthermore, DNA is wholly unique to this planet not because of human invention and action, but because of the forces that allowed it to evolve. Inventing around DNA therefore is entirely impossible without redesigning billions of years of evolution and "remaking" life systems altogether.

THE ROLE OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

In addition to current patent guidelines seeming illogical, strong potential exists for the hindrance of the advancement of science and engineering innovation. The United States Constitution provides:

> The Congress shall have Power…To promote the Progress of Science and useful Arts, by securing for limited Times to Authors, and Inventors the exclusive Right to their respective Writings and Discoveries.[21]

The USPTO was established to execute this Constitutional mandate. Keen observers may deduce that it is the current position of the USPTO to interpret this statement with emphasis on "securing for limited Times…exclusive Right to…Discoveries." However, the purpose of the patent office is not to simply impart patents without regard for the objectives it was created to serve. The USPTO should take special care to fulfill its first and foremost duty, which is "To promote the Progress of Science and useful Arts." Strong economic and scientific advancement arguments exist on both sides of the DNA patenting issue; individuals in the scientific, academic, research, economic, and law communities are heavily divided. Through all of the controversy, it appears that the patent office is not seeking the avenue that will truly yield the most success for accomplishing its purpose, but is simply upholding previously established patent precedent. The USPTO should be more forthright about fighting to uphold its constitutional obligation of promoting the state of science. Even though "it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents,"[22] precedent should not supersede purpose.

That the patent woes of other nations might be just as daunting as those of the United States was recently illustrated by John Keogh who successfully applied for and received a patent in Australia for…the wheel. He does not expect to make money from the patent but did receive worldwide attention and the 2001 Ig Nobel Award in Technology.[23]

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REFERENCES

1 Committee on Agriculture and Rural Development, Parliamentary Assembly - Council of Europe, Biotechnology and Intellectual Property Doc. 8459, July 1999.

2 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

3 Cook-Deegan, R. M., & McCormack, S. J. "Patents, Secrecy, and DNA." Science, 293, (2001, July 13) 217.

4 Root, M. J., & Kay, M. S., & Kim, P. S. "Protein Design of an HIV-1 Entry Inhibitor." Science, 291, (2001, February 1) 884-888.

5 Utility Examination Guidelines, 66 Fed. Reg. 1,093 (2001)

6 Utility Examination Guidelines, 66 Fed. Reg. 1,093-1,094 (2001)

7 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

8 "Sixty-Five Years of the U.S. Plant Patent Act." ETC Group. http://www.etcgroup.org/article.asp?newsid=204

9 National Research Council. "Sharing Laboratory Resouirces: Genetically Altered Mice." National Academy of Sciences, (1993, March 23-34) 19. http://www.nap.edu/html/mice/

10 35 U.S.C. § 101

11 35 U.S.C. § 103

12 35 U.S.C. § 102

13 35 U.S.C. § 101

14 Utility Examination Guidelines, 66 Fed. Reg. 1,094 (2001)

15 35 U.S.C. § 112

16 Thorton, S.T., Rex, A., *Modern Physics for Scientists and Engineers.* Forth Worth: Saunders College Publishing (2000) 63.

17 "The Science of Matter, Space, and Time: How to Find the Smallest Particles." Fermi National Accelerator Laboratory, (2001, Oct. 24) http://www.fnal.gov/pub/inquiring/matter/smallest/

18 Utility Examination Guidelines, 66 Fed. Reg. 1,093 (2001)

19 S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)

20 Doll, J. J. "The patenting of DNA." Science, 280, (1998, May 1) 689-690.

21 United States Constitution, Article 1, Section 8, Clause 8

22 Utility Examination Guidelines, 66 Fed. Reg. 1,093 (2001)

23 "Scientific Prizes." Science, 294 (2001, Oct. 12) 285.