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Abstract
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Breaking Bioethics

Disease Genes Are Not Patentable: A Rebuttal of McGee

JON F. MERZ and MILDRED K. CHO

Dr. McGee presents a cogent argument for the patentability of the diagnosis of gene forms that are found to be associated with disease or other phenotypic manifestations. We're convinced he's wrong. An analogy will help explain why.

Some years ago, in the Black Forest, people hunted down the elusive truffle, that culinary delight, with pigs learned in the art of rooting around in, you guessed it, tree roots. People and pigs had been collaborating in the search for truffles for thousands of years. Among the truffles collected in the forest, none was as highly prized—or as rare—as the White Truffle. It would reward its finder with 10 times the price of other truffles at market. But the White Truffle was much more elusive than other truffles, and a day in the forest would yield an average 1 White Truffle for every 100 regular truffles.

After 20 years of truffle trifles (and meticulous notekeeping), one Franz Statistiner did make an interesting (and, as we shall see, valuable) observation: 9 of every 10 White Truffles that he had gathered over the years were found on the roots of red oak trees, and, overall, 20% of truffles found on red oaks were White!

Franz contemplated keeping his finding secret and simply targeting his pigs on their daily jaunts to search only red oaks, thereby increasing his yield of White Truffles. He was worried, however, that other truffle hunters would soon note his success in the market and figure out his secret. Instead, he went to a patent lawyer.

A good patent lawyer. She wrote and got an imaginary patent with the following claims:

I Claim:

1. A method of detecting an increased chance of having White Truffles under a tree comprising directly or indirectly:
   detecting whether or not a tree is a Red Oak Tree;
   and
   observing whether or not the tree is more likely to have White Truffles growing under it, wherein Red Oak Trees have an increased likelihood of having White Truffles thereunder.

2. The method of claim 1, wherein said detecting step comprises looking for trees having at least one Red Oak Tree Leaf growing thereon.

Franz then was able to collect royalties from all other hunters who focused their search on red oak trees, making him wildly wealthy. Franz bought the forest.

Sound reasonable? Dr. McGee apparently agrees with us: neither the discovery nor the act of looking at red oak trees for the purpose of diagnosing the increased likelihood of finding White Truffles is patentable subject mat-

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ter. What has been discovered is a mere phenomenon of nature, an (as yet unexplained) association between an observation of a particular type of tree in the forest and the empirical fact that such trees have a "natural" propensity for White Truffles. It is no more than an observation of a thing and the mental step of understanding the informational value of that thing.

The truffle patent is not only analogous to a disease gene patent, but has been craftily drafted directly from U.S. Patent No. 5,508,167, entitled Methods of Screening for Alzheimer's Disease, which reads:

> What is claimed is:
>
> 1. A method of detecting if a subject is at increased risk of developing late onset Alzheimer's disease (AD) comprising directly or indirectly:
> detecting the presence or absence or an apolipoprotein E type 4 isoform (ApoE4) in the subject; and
> observing whether or not the subject is at increased risk of developing late onset AD by observing if the presence of ApoE4 is or is not detected, wherein the presence of ApoE4 indicates said subject is at increased risk of developing late onset AD.

This invention, Dr. McGee and the U.S. Patent and Trademark Office agree, is patentable. What differs? The act of "detecting" in the truffle patent requires one's eyes and knowledge of any unique characteristics of the red oak tree, such as the leaf specified in claim 2. Detecting in the AD patent requires use of PCR, Southern analysis, sequencing, or one of numerous other previously established means of looking at the chemical structure known as DNA. Each entails steps that are obvious to anyone skilled in the pertinent art. The act of looking at trees or genes, respectively, comprises normal knowledge and skill of those trained in their respective arts. Any one device or method for looking might itself be a patentable innovation (such as a microscope, telescope, or PCR), but the special protections afforded by patenting should not be extended to all specific acts of looking.

What else differs? The "invention" underlying the truffle patent is the association of red oak trees with an increased chance of finding White Truffles thereunder. The "invention" underlying the AD patent is the association of a particular allele with an increased chance of disease occurrence. Both are empirical observations; both are simply epidemiologic discoveries about (albeit within our current understanding of) naturally occurring phenomena.

Dr. McGee's argument is based on two false premises. The first is that the difficulty and effort involved in making a discovery, the "immensely difficult epidemiological task of purifying otherwise diffuse relationships between particular environments and genes, and between particular groups and genes," make the discovery patentable.

Everyone agrees that a basic scientific or statistical discovery, regardless of how difficult it was to make or how much effort and money went into it, is not patentable subject matter. As the U.S. Supreme Court stated in a case in which it invalidated claims for a mixture of bacteria, "[P]atents cannot issue for the discovery of the phenomena of nature. . . . 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 exclusively to none."[1] The Supreme Court more recently reiterated that "[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable. . . . Thus a new mineral discovered in the earth or a

new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity."[2] The work Einstein and Newton put into these discoveries was synthetic and novel, but their genius and remarkable efforts do not make their observations of associations between physical entities patentable.

Furthermore, the fact that several research groups independently clone and sequence genes associated with diseases, often within weeks of each other, suggests that the effort is not that innovative to those skilled in the arts. If the entire coding sequence of the human genome is sequenced at the end of the Human Genome Project, it will become even less of an effort to correlate the presence of sequences with disease. At some point, by Dr. McGee's argument, associations between genes and diseases will not be patentable because of the ease—a simple computer search—of finding these (as well as far more complex multigene and gene-environment) relationships. To say that these associations are patentable is "genetic exceptionalism": allowing oneself to be unduly dazzled, nay, mesmerized, by the novelty of biotechnology compared to other technologies. It is genetic exceptionalism to say that finding associations between red oak trees and White Truffles using the well-established method of shoveling is not patentable, but that finding associations between a gene and a disease using well-established methods of mapping, cloning, and sequencing genes, and of identifying people with mutations is patentable.

Dr. McGee's second false premise is that he predicates patentability on the usefulness of the discovery. However, market potential is not a necessary, much less a satisfactory, condition to determining whether something comprises patentable subject matter. It is simply irrelevant. Gold and diamonds, while valuable, are not patentable subject matter, regardless of who first discovered them or how difficult those discoveries were. McGee's arguments show how easy it is to segue from an inquiry about whether something is patentable subject matter to questions about whether that something satisfies the tests for patentability; that is, it must be new, useful, and nonobvious. Under U.S. patent law, however, these are separate issues, and confounding them muddles the underlying question.

Arguing that correlating discoveries with "human life for the purpose of creating a diagnostic process is innovation" as does McGee sets us on a slippery slope that would wreak havoc with healthcare. By this argument, tests used in performing physical examinations (including asking patients questions, feeling their thyroid glands, and listening to their lungs and heart with stethoscopes) as methods of detecting abnormalities should be patentable. Many of the methods used in routine physicals took years of clinical observations and effort, resulted from a synthetic and creative process, and are undoubtedly useful. Yet are they patentable?

At bottom, the "detection" involved in the truffle and disease gene patents itself is not patentable. Everyone is free to look at those things—be they trees or genes—that exist independent of the ingenuity, innovation, and manufacture of humans. The fact that someone discovers a reason for looking does not change that basic premise. The scientific reason itself is not patentable, and it does not render the act of looking in the specific case patentable.

Independent of the foregoing, we believe there are substantive arguments against disease gene patenting based not on patentability of the sub–

ject matter but on public policy and ethics. As we have asserted elsewhere, the risks to patient health and access to care, to physician-patient relations, and to the biomedical research enterprise far outweigh the possible benefits that could be attributed to disease gene patents.[3] While we believe the courts should invalidate these broad diagnosis methods patents under the product of nature doctrine, we firmly believe that the unethical patenting practices reflected in these patents should be more firmly enjoined by the medical profession and by healthcare institutions. Unfortunately, the ethical proscriptions have been emasculated by financial pressures, by increasing commercialism of academic medicine, and by profiteering. The profession must clean up its act, or Congress may intervene.

Because of perceived abuse of patents of surgical methods, Congress enacted a law in late 1996 that holds physicians not liable for infringement of "pure process" patents.[4] That law does not apply to "biotechnology patents" (perhaps reflecting Congress's love affair with things biotechnic, and perhaps reflecting the acknowledged assistance of the biotechnology industry in drafting the law),[5] and does not protect laboratories approved under the Clinical Laboratories Improvement Act.[6] That law was a stopgap against more drastic legislation prohibiting medical process patents; if methods patenting continues to burgeon (and diagnostics comprises the largest share of biotechnology patents being issued),[7] Congress should expand the law's protections. Already, the human chorionic gonadotropin patent, a similarly broad diagnostic patent, has led to the abandonment of prenatal testing that had been the standard of care.[8] This is simply unacceptable. These patents are contrary to good medical practice, and must be prohibited.

Notes

1. Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).
2. Diamond v. Chakrabarty, 447 U.S. 303, 308–9 (1980).
3. Merz JF, Cho MK, Robertson MJ, Leonard, DGB. Disease gene patenting is a bad innovation. *Molecular Diagnosis* 1997;2(4):299–304.
4. Public Law 104-208, §101(a), 110 Stat 3009-67, 104th Congress, 2nd term, 1996, codified at U.S. Code Title 35 §287(c) (1997).
5. Congressional Record S12023-4 (30 September 1996).
6. Clinical Laboratories Improvement Act, codified at U.S. Code Title 42 §263a (1997).
7. Thomas SM, Birtwistle NJ, Brady M, Burke JF. Public-sector patents on human DNA. *Nature* 1997;388:709.
8. Eichenwald K. Push for royalties threatens use of Down Syndrome test. *New York Times* 1997;May 23:A1.