

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
COLLEGE OF AMERICAN PATHOLOGISTS;
HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD;
WENDY CHUNG, MD, PhD; HARRY OSTRER, MD;
DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD;
ELLEN MATLOFF, M.S.; ELSA REICH, M.S.;
BREAST CANCER ACTION; BOSTON WOMEN'S
HEALTH BOOK COLLECTIVE; LISBETH CERIANI;
RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE;
VICKY THOMASON; KATHLEEN RAKER,

Plaintiffs,

v.

UNITED STATES PATENT AND TRADEMARK
OFFICE; MYRIAD GENETICS; LORRIS BETZ,
ROGER BOYER, JACK BRITTAIN, ARNOLD B.
COMBE, RAYMOND GESTELAND, JAMES U.
JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS,
DAVID W. PERSHING, and MICHAEL K. YOUNG,
in their official capacity as Directors of the University
of Utah Research Foundation,

Defendants.
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09 Civ. 4515 (RWS)

ECF Case

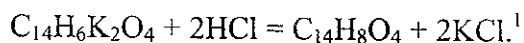
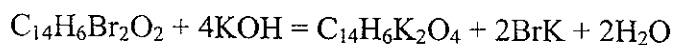
DECLARATION OF
MYLES W. JACKSON

I, Myles W. Jackson, declare under penalty of perjury:

1. I am the Dibner Family Professor of the History and Philosophy of Science and Technology, Chair of Humanities and Social Sciences, and Director of Science and Technology Studies at the Polytechnic Institute of New York University. In addition, I am Professor of the History of Science and Technology of The Gallatin School of Individualized Study at NYU. I teach a course at both Poly and Gallatin, entitled Biology and Society, in which three weeks are dedicated to the Human Genome Project, including the patenting of genes.

2. As an undergraduate at Cornell University, I majored in German literature and minored in biological sciences (with a specific concentration in molecular and cell biology). I was an undergraduate researcher in the Department of Biochemistry for two years. The summer after graduation I received a DAAD Fellowship to be a research assistant at the Institute for Human Genetics at the University of Düsseldorf. I entered graduate school in a Ph.D. program in Biochemistry and Molecular Biology; however, I transferred after one year to the Ph.D. program in the history and philosophy of science at Cambridge University (UK).
3. I received my Ph.D. in the history and philosophy of science in 1991. Over the last three years I have been investigating the history of gene patenting. In particular, I am researching the history of the CCR5 gene. I have published several articles on gene patenting and related topics and am currently working on a monograph on the CCR5 gene. A complete copy of my curriculum vitae is attached.
4. I was asked to compare and contrast the science involved in gene patenting with the science of other legal cases relevant to the patenting of products of nature. In doing so I have reviewed twelve law cases, nine of which were heard by the U.S. Supreme Court. I also reviewed a number of scientific texts, including works on nineteenth-century chemical technology and more recent sources on molecular genetics. I consulted a number of essays, which are also cited in my footnotes, by intellectual property lawyers.
5. I also reviewed the patent claims that are being challenged by the plaintiffs in this case.
6. I am not a lawyer and not qualified to give opinions on legal distinctions made in the cases I reviewed. My sole task was to compare and contrast the scientific principles, materials, and processes in each case to those in this case.

7. One of the earliest Supreme Court cases relevant to the patenting of a natural substance is *Cochrane v. Badische Anilin & Soda Fabrik* (111 U.S. 293 (1884)). The reissued letters patent No. 4321 granted to C. Graebe and C. Liebermann for “an improvement in dyes or coloring matter from anthracine” (293) and “a new and useful improvement in the manufacture of alizarin [a compound found naturally in the root of the madder plant]”, called “artificial alizarin” (294), was deemed to be too broad to cover a dyestuff. The patent details the rather complex organic chemistry by which madder alizarin heated with zinc dust generated anthracine, which was then converted into anthrachinon. Anthrachinon was subsequently heated with bromine and then caustic potash (potassium hydroxide) or soda (sodium hydroxide), producing artificial alizarin:



8. The bromine method was rather difficult to carry out on a commercial scale (301-302). Fortunately artificial alizarin could also be produced by means of anthrachinon sulpho-acids ($\text{C}_{28}\text{H}_{18}\text{SH}_4\text{O}_3$).² Heinrich Caro noticed that anthrachinon would yield sulpho-acids if heated with sulphuric acid between 200 and 260 degrees. Fusing sulpho-acid with potassium hydroxide or sodium hydroxide produced artificial alizarin.
9. No one before had ever created artificial alizarin and as the above recitation indicates, the process was difficult. However, the end product was identical to alizarin produced from the madder root, and the patent was sought over the alizarin, not over the process by which it was made.

¹ Johannes Rudolf Wagner, translated by William Crookes, *A Handbook of Chemical Technology*, (N.Y.: D. Appleton Co., 1872), p. 584.

² *Ibid.*, p. 585.

10. Similarly, in this case, the patent claims are over the genes, not over the process by which genes are taken out of the body and analyzed.
11. The patent claims in *Cochrane* were denied because the end product was identical to the end product created by other methods. As discussed in more detail below, the same is essentially true of the gene claims in this case. The end product, or “isolated” DNA is functionally identical to the DNA in the body, as is its information.
12. There is a broader point to be made from the application of *Cochrane* to this case. Some people have argued that DNA or genes are just chemicals and should be analyzed for patent purposes in the same manner as other chemicals. That argument is incorrect.
13. Even though the science behind the synthetic manufacture of alizarin is very different from the science of gene patenting, it is critical to note that the case of alizarin is emblematic for the dye industry: there are numerous ways of synthetically producing a natural substance, or slight variations thereof. Indeed, the history of the chemical industry is littered with examples of how companies would attempt to invent around a patent by creating either a slightly different method of synthesis or a minor variation of the patented (or natural) substance. Inventing around a patent often leads to further innovation. The same unfortunately is impossible with genes. One cannot invent around a gene, potentially allowing patent holders to enjoy a monopoly, thereby hampering further downstream diagnostic and therapeutic research.
14. The problem of the inability to invent around a patent potentially deterring innovation becomes particularly salient when DNA sequences are treated like chemicals.³ Composition of matter patents on chemicals cover all properties of the patented substances, regardless of

³ “A gene is a chemical, albeit a complex one” *Genetics Institute v. Amgen*, 502 U.S. 856 (1991). See also *Amgen v. Chugai Pharmaceutical Co.* 927 F.2d 1200, 1206 (Fed. Cir.)

whether or not they are described in the patent specification. Only one single commercial application needs to be stated in order to receive exclusive control of the substance and all of its properties.

15. As Human Genome Sciences' intellectual property attorney Jorge A. Goldstein remarked, "Whoever is the first to patent a DNA sequence- for any use- can lock up subsequent uses. The chemical patent law has been the same for over 100 years, everywhere in the world: if you discover a compound that has any use, even a marginal one, you are entitled to a patent on the compound. [...] Biotech hasn't changed anything."⁴ Stanford intellectual property lawyer John Barton concurs: "This is a result of applying traditional chemical patent law principles to biotechnology. Under chemical patent principles, a patent on a novel chemical covers all uses of that chemical, whether or not discovered by the original patent holder. The discoverer of a new use may have a right to file a further patent, claiming use of the chemical for the particular new purpose, but will still have to obtain a license from the initial patent holder using the chemical for the new purpose."⁵ In short, the threat of the patentee locking up a substance and all of its uses is far greater with gene patents than with chemicals due to the science of genes.
16. But you cannot invent a slightly different gene that includes the sequences created by nature, whether natural or mutated, in the way you can invent a slightly different chemical. Nature has created the sequences and the variants, and it is the sequence created by nature that is the entire point of the gene.

⁴ Jacobs and Gosselin, "Profiteering & Shoddy Science," *LA Times*, 21 March 2000.

⁵ John H Barton, "Patents, Genomics Research, and Diagnostics," in *Journal of Medical Education* 72 (12, Part 2) (December 2002): 1339-1347, here p. 1341.

17. Cochrane was pre-figured by The Wood-Paper Patent, (90 U.S. (23 Wall.) 566 (1874)), which deals with a patent for paper pulp (cellulose) extracted from wood via chemical processes and from vegetable substance by means of chemical and mechanical processes. The mechanical process involves a machine that shreds the wood or vegetable substance into shavings. The chemical processes involve a myriad of reactions, including boiling in a strong alkali solution under high temperature and pressure, chlorination, and washing with hydrochloric acid.
18. Again, the patent was a patent on the paper that was the end product, not the process by which the paper was made. And the patent was denied on the grounds that even if the end product were slightly more pure, it had the same function as paper produced by other means.
19. The process of extracting genes is roughly similar. DNA is separated from the cells by precipitation and centrifugation. A particular gene is excised via restriction endonucleases, separated from other pieces of DNA via pulse-field gel electrophoresis, and then placed into plasmid vectors, which in turn are added to bacteria, thereby generating many copies.⁶
20. The crucial distinction between cellulose and a gene is that a gene carries information and instructions for its replication and translation into proteins. It is not merely a chemical, as cellulose clearly is. In addition, whereas pulp can be obtained from various substances (such as wood, straw, and vegetable material), the gene can only be found in a genome. One can neither find other sources of it,⁷ nor can one invent around it.

⁶ Since the late 1980s, many copies of a DNA sequence are rapidly produced by using a technique called polymerase chain reaction, or PCR, rather than the plasmid-vector technique.

⁷ Other mammalian species have genes corresponding to their human counterparts, but my point is that one cannot find genes outside of a genome. It is now possible to synthesize genes in a laboratory.

21. Two key considerations of the Court in this case were the nature and patentability of an extract, namely pulp. Justice William Strong argued that

... in cases of chemical inventions, that when, as in the present case, the manufacture claimed as novel is not a new composition of matter, but an extract obtained by the decomposition or disintegration of material substances, it cannot be of importance from what it has been extracted. There are many things well known and valuable in medicine or in the arts[,] which may be extracted from divers substances. *But the extract is the same no matter from what it was been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.* [my italics, page 90 U.S. 593]

22. In applying the paragraph to genes, the isolated gene, which could very well have diagnostic value, is extracted from the DNA of a somatic cell, which contains all of the DNA. The process of extraction may be patentable, but the extract (or in this case, the gene itself) is neither a new composition of matter, nor can it be considered a new manufacture.

23. As Strong famously states in the ensuing paragraph,

Thus, if one should discover a mode or contrive a process by which prussic acid could be obtained from a subject in which it not now known to exist, he might have a patent for a process, but not for prussic acid. If, then, the Watt & Burgess patent for a product is sustainable it must be because the product claimed, namely, 'a pulp suitable for the manufacture of paper, made from wood or other vegetable substances,' was unknown prior to their alleged invention." [ibid.]

24. Unfortunately for Watt and Burgess, this was not the case, as pulp had been used in the manufacture of paper much earlier than 1853. In short, since cellulose was used routinely in

that manufacturing process before the time of the patent, and because the claimed manufacture and the prior art differed only in degree of purity, not of kind, the Court decided that it was not patentable. The message of the case: isolated and purified substances are in principle patentable if the claimed substance differs from the natural product in more than just degree of purity.⁸

25. How does this case compare to genes in general and to the BRCA 1 and 2 genes in particular? The “isolated” genes, whether in their natural form or in a mutated or variant form, are the same functionally as the genes in the body, and their information is identical to those in the body. Just as the new form of paper, even though more “pure” was not a new composition, so too the “isolated” gene is not a new composition.
26. *Parke-Davis & Co. v. H. K. Mulford Co.* (28 April 1911, 189 F. 95), though not a Supreme Court case, is a patent-infringement case that also raises the issue of patentability of biological entities. Indeed, it is often referred to as the precedent for the patenting of genes.⁹ The case commences with the affirmation of the patentability of a “substance extracted from animal tissue for medicinal use, which is new, practically and therapeutically may be patentable, although it differs from the previous preparations only in its degree of purity from other portions of the tissue.” (Thomas Reuters/Westlaw, p. 1) Takamine’s purification of adrenaline was the first to make it available commercially for use by removing it from the gland tissues and by partially ridding it of its impurities: “it became for every practical

⁸ Lauren M. Nowierski, “A Defense of Patenting Human Gene Sequences under U.S. Law,” in *Cardozo Arts and Entertainment* 26 (2009): 473 -508, here p. 481. Available at <http://docs.google.com/gview?a=v&q=cache%3AGoahCHV9JKEJ%3Awww.cardozoaelj.net%2Fissues%2F09%2FNowierski.pdf+%22The+assertion+founded+in+the+American+Wood-Paper&hl=en&gl=us&pli=1>, last downloaded on 7 August 2009.

⁹ Lori B. Andrews, “Genes and Patent Policy: Rethinking Intellectual Property Rights,” in *Nature Reviews: Genetics* 3 (2002): 803-807, here p. 804, and J. Doll, “The Patenting of DNA,” in *Science* 280 (1998): 689-690.

purpose a new thing commercially and therapeutically.” (ibid., p. 6) The key was that purification of adrenaline was necessary; injected unpurified adrenaline could have serious deleterious effects on the patient.

27. Genes here are in some respects analogous. As briefly discussed above, the patentee isolates and extracts them from the genome (found in a somatic cell); however, *in vivo*, humans have a cadre of enzymes, which specifically target, isolate and interact with a single gene or groups of genes. Often patented genes are in the form of complementary DNA (cDNA), which does not contain introns, or the nucleotide sequences that do not get translated into the protein. cDNA copies are created in the laboratory by a series of steps. First, a DNA primer is annealed to the messenger RNA (mRNA). An enzyme, reverse transcriptase, is added *in vitro*, which produces cDNA using mRNA as a template. The double-stranded DNA-RNA duplex is treated with alkali to remove the RNA. DNA polymerase is then added to make a double-stranded DNA molecule. Finally S₁ nuclease is added to clip the hook at the 3' end of the initial DNA strand.¹⁰
28. Although humans do not possess reverse transcriptase, pre-mRNA is generated by RNA polymerase, which pairs bases of the substrate ribonucleotides with DNA and catalyzes the creation of phosphodiester bonds between them.¹¹ Spliceosomes, which splice specific segments of pre-mRNA, produce mRNA. The mRNA is then translated into proteins.
29. The example of the genetic technique of purification performed by molecular biologists is not quite the same as the purification of adrenaline. Adrenaline obtained from suprarenal glands needs to be purified by human intervention in order to be taken safely. The human body does not possess a natural process for purifying adrenaline as it does for isolating and

¹⁰ Benjamin Lewin, *Genes* (New York: John Wiley and Sons, 1983) pp. 306-7.

¹¹ *Ibid.*, p. 166.

splicing together genes. Genes and their splicing occur naturally, without human intervention; purified adrenaline does not.

30. *In re Merz*, 97 F.2d 599, 601 (1938), states that “[If] the process produces an article of such purity that it differs not only in degree but in kind it may be patentable. If it differs in kind, it may have a new utility in which the invention may rest.” Where the utility of isolated and purified substance differed substantially from the natural state (as determined by someone skilled in the art), a patent could be granted.¹²
31. Laboratory-isolated and purified genes code for the same protein product as they do *in vivo* and the sequence is functionally and informationally identical. Hence, it strikes me that in these respects, isolated and purified genes are not analogous to purified adrenaline. Once again, the analogy between ordinary chemicals and DNA breaks down. The genes represented in the patents in this case do not have an entirely new function, whereas purified adrenalin’s function was enabled by human intervention. They have the same function and information and that function and information was dictated by nature, not by scientists.
32. In 1948 the Funk Brothers were denied a patent of strains of bacteria. They found a previously unknown way of combining several species of bacteria that resulted in a far more universally effective weed killer; however, as the Court argued:

The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each specifies has the same effect it always had. The bacteria perform in their natural way. Their use in combination

¹² Lauren M. Nowierski, “A Defense of Patenting Human Gene Sequences under U.S. Law,” in *Cardozo Arts and Entertainment* 26 (2009): 473 -508, here p. 484. Available at <http://docs.google.com/gview?a=v&q=cache%3AGoahCHV9JKEJ%3Awww.cardozoaelj.net%2Fissues%2F09%2FNowierski.pdf+%22The+assertion+founder+in+the+American+Wood-Paper&hl=en&gl=us&pli=1>, last downloaded on 7 August 2009.

does not improve in any way their natural functioning. They serve the ends nature originally provided, and act quite independently of any effort of the patentee. [Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), Page 333 U.S. 131]

33. What little science that exists in this case strikes me as different from that involved in gene patenting. There is more human intervention in the process of isolating and patenting a gene than in combining bacteria.
34. However, this case reinforces the theme that I believe applies to the science in all of the cases discussed thus far. If the product over which the patent is sought is altered by humans to create a product that has new functions, then it falls into one category. If the product has been structurally altered but retains the same function that it had previously, especially if that function was created by nature, then it falls into the same category as the merged bacterial product in Funk Brothers. Patented genes can, and normally do, serve the ends nature originally provided.¹³
35. The first major court case tried after the Patent Act of 1952 involving the patentability of a natural substance was, Merck & Co., Inc. v. Olin Mathieson Chemical Corporation in 1958 [253 F.2d 156; 253 F.2d 156 116 U.S.P.Q. 484]. The District Court initially rejected the defendant's claim that the plaintiff's patent of vitamin B₁₂ extract was invalid since it was a product of nature.
36. In the reversing of the decision and granting of the patent, however, the Federal Court did stress that "[t]he claims of [the] patent do not reach pure, crystalline vitamin B₁₂, for they are restricted to compositions having a maximum LLD activity which is less than that of the pure

¹³ Short sequences of DNA, expressed sequence tags (ESTs), can be used as probes to find other genes. Although they are more difficult to patent now, that was not the case back in the mid-1990s.

substance. The claims do not cover vitamin B₁₂ compositions derived from liver or any source other than the specified fermentates.” Dr. Wood was able to isolate vitamin B₁₂ from a number of fermentation products of *Streptomyces griseus*. Grisein, a substance produced by *Streptomyces griseus*, was adsorbed from an acidic broth upon an activated carbon (Norit). After removal, a residue was present with ‘spent Norit’, which could be extracted with ethanol or acetone. This residue was then diluted, and the requisite level of LLD activity was obtained.

37. There are two differences between the chemical at issue in Merck and the genes at issue in this case. First, as the court emphasized, the patent in that case did not cover all forms of the vitamin. For example, it did not cover the vitamin as derived from some natural sources. Scientists could invent around it and create new and useful forms. Second, the form patented had a function that was different from that found in nature. Indeed, the court described the natural form as “useless” and the patented form as valuable.
38. The eligibility of patenting products of nature arose in *General Electric Co. v. De Forest Radio Co. et al.* (28 F.2d 641) The Circuit Court of Appeals, Third Circuit, reiterated that “a patent cannot be awarded for a discovery or for a product of nature, or for a chemical.” [Westlaw, Thomas Reuters, 2009, p. 2. See also *United States Industrial Chemical Co. v. Theroz Co.* (C.C.A.) 25 F.(2d).387)] Coolidge, the inventor, referred to his material as a new metal, a pure tungsten and he applied for a patent. His process consisted of converting WO₃ (tungsten III oxide) into pure tungsten. First, WO₃ is heated in a gas furnace in order to liberate oxygen, carbon, and chemical impurities. The resulting product was then heated electrically changing the substance from the yellow oxide to the blue oxide to the bronze

oxide and then finally to pure tungsten. These various oxides of tungsten are different, with distinct properties from pure tungsten.

39. However, the court denied his patents on the so-called pure tungsten saying “who created the pure tungsten. Coolidge? No. It existed in nature and doubtless has existed there for centuries. The fact that no one before Coolidge found it there does not negative its origin or its existence.” Similarly, genes have existed in nature for centuries and the fact that Myriad found these genes does not negate their origin.
40. The court further noted that the Coolidge tungsten had “ductility and a high tensile strength. Did Coolidge give those qualities to ‘substantially pure tungsten? We think not for it is now conceded that tungsten pure is ductile cold. If it possesses that quality now, it is certain that it possessed it always.” Similarly, it is indisputable that the gene that Myriad has patented possessed its qualities always. The sequence of the gene, the sequence of variants, and the significance of the variants were always there.
41. *Diamond v. Chakrabarty* (447 U.S. 303 (1980)) is often cited as the precedent for the patenting of genes. I find this rather surprising, since there is no mention of the patenting of genes in the patent application or its judgment. While working at General Electric, the microbiologist A. M. Chakrabarty created a new bacterium of the *Pseudomonas* genus. This bacterium possessed the coveted attribute of being able to break down crude oil into biodegradable materials. Clearly such a quality was applicable to oil spills. At the time of his patent application, there were four known species of bacteria that could metabolize oil. These species, however, competed with each other, thereby limiting the amount of oil they could convert. Chakrabarty took the genes coding for the proteins that degrade the oil and cloned them in bacterial vectors. Irradiating the bacteria with ultraviolet light after introducing the

genes into the recombinant DNA vectors, he discovered a method for cross-linking that resulted in all four genes being present in one bacterium. This newly created bacterium could degrade two times more oil than the four original species of bacteria. We are speaking here of a bacterium, which clearly is the product of human hands, as it did not exist before Chakrabarty's invention. The genes encoding the proteins that metabolized oil were *not* a part of the patent; therefore, while it could be argued that *Diamond v. Chakrabarty* set the milieu for the patenting of genes, it cannot serve as the legal precedent.

42. There are three cases that concern not the patenting of a thing, such as adrenaline or DNA, but of information or thought. As Rebecca Eisenberg, Professor of Law at the University of Michigan argues, "DNA sequences are not simply molecules, they are also information. Patent claims to information- even useful information- represent a fundamental departure from the traditional patent bargain."¹⁴ Since DNA is not simply a chemical, but also a purveyor of information, a number of relevant court cases involving the patenting of information need to be compared and contrasted with the patenting of genes.
43. In addition, the patent claims in this case are not limited to claims on things, to the extent DNA is a product. They include processes by which one compares two genes to see if they are the same or different. The processes by which genes are removed from the body and sequenced are well known in science and have been for some time. The claims in this case do not purport to describe particular processes. They appear to claim comparison of two genes no matter the process used to make them comparable. The only unique feature is, after looking at the two, reaching a conclusion as to their similarity and, if they are different, the significance of that difference.

¹⁴ Rebecca Eisenberg, "Reexamining the role of patents in appropriating the value of DNA sequences," *Emory Law Journal* 48 (2000): 783-800.

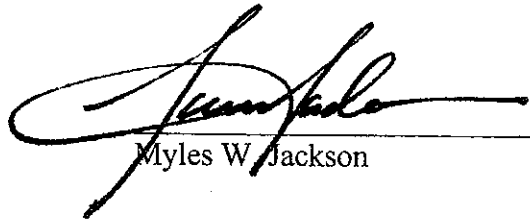
44. *Parker v. Flook* of 1978 (437 U.S. 584) dealt with a patent for a "Method for Updating Alarm Limits." The patent contained a mathematical algorithm, which of course carries information. It provides instructions by performing a series of operations. The Court ruled that the process patent claim did not have an inventive step. "Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application." [Page 437 U.S. 594] Because this patent sought to patent all uses of the formula and because mathematical formula are representations of nature, not creations of scientists, this patent was invalid.
45. Much along the same lines of argumentation as *Funk Bros. v. Kalo Inoculant*, the Court found in *Gottschalk v. Benson*, 409 U.S. 63 (1972) the implementation of the algorithm trivial, denying a process claim for a numerical algorithm arguing that it would be equivalent to patenting an abstract idea.
46. By contrast, in *Diamond v. Diehr* (450 US 175 (1981)), the Court found that a physical process that used a mathematical algorithm to control the process for curing rubber was patentable because the algorithm could still be used for other purposes. The algorithm was being patented for one purpose only, not as an abstract idea.
47. Genes are similar to mathematical algorithms, as they carry information. They offer a blueprint for their replication and the coding of proteins; hence, their code contains information that carries out a sequence of processes. Such information, however, is the handiwork of nature, not scientists. In addition, the informational chart linking the genetic information of the nucleic acid's codon to its corresponding amino acid has been well known for over forty years; any textbook in biochemistry or molecular biology contains that

information. Unlike the precision of a mathematical algorithm, one cannot determine with total certainty the function of a protein from its nucleic acid sequence. Indeed, another major drawback to applying intellectual property law from chemistry to biotechnology deals with the imprecision of such information.

48. In addition, the claims in this case do purport to be over all uses of information or in other words all uses of abstract ideas. The claims over the genes cover all use of the genes and the information in them. The claims over the mutations include all uses of the mutations and the information in them. The claims that involve processes for determining if the genes cover variants and if those variants have significance claim all methods of examining the genes and drawing conclusions. In each instance, nature has created the gene's information, the information of the mutations, and the relationship between the mutation and disease and in each instance, Myriad has claimed all uses of the abstract ideas or natural laws. The claims in this case thus are far more analogous to the claims in *Gottschalk and Parker* than *Diehr*.
49. In conclusion, the uncritical and indiscriminate application of chemistry intellectual property law to genes is rather inappropriate for several reasons. First, the science differs in rather critical ways. Often patented genes are the same ones existing in nature. Second, much of the history of chemistry and chemical engineering over the past 125 years proffers numerous examples of the inventions around patented materials or techniques. One cannot do this with a gene. Third, broad gene patent applications for all use of a gene, such as that in this case, were granted throughout the 1980s and 90s. These two last factors can lead, indeed some would say have led, to a hindrance of further development in research, diagnosis, and therapies. Such impediment is anathema to the spirit and purpose of patents.

I declare, pursuant to 28 U.S.C. § 1746, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and belief.

18 Aug 2009
Executed _____, 2009


Myles W. Jackson