United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE 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, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant,

and

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-Appellants.

Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515, Senior Judge Robert W. Sweet.

BRIEF OF AMICI CURIAE E. RICHARD GOLD, JAMES P. EVANS, AND TANIA BUBELA IN SUPPORT OF APPELLEES AND AFFIRMANCE

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FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Association for Molecular Pathology et al. v. United States Patent and Trademark Office and Myriad Genetics, Inc. et al

No. 2010-1406

CERTIFICATE OF INTEREST

Counsel for the ~~(petitioner) (appellant) (respondent) (appellee)~~ (amicus) ~~(name of party)~~ E. Richard Gold certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

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Nov 29, 2010
Date

Signature of counsel

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Please Note: All questions must be answered

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FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Association for Molecular Pathology et al v. USPTO, Myriad Genetics, Inc. et al

No. 2010-1406

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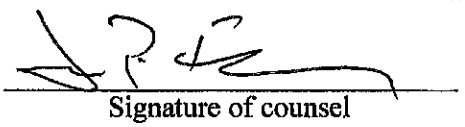
Date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Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

The Association for Molecular Pathology et al v. USPTO, Myriad Genetics, Inc et al

No. 2010-1406

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are academics who have written and provided advice about gene patent law and policy. Richard Gold, law professor, has an S.J.D. from the University of Michigan. He has authored an extensive case study of Myriad Genetics and its patenting policies and many articles on patent law and policy. As consultant to the Organisation for Economic Co-operation and Development, he was lead author of the *Guidelines on the Licensing of Genetic Inventions* (2006). James P. Evans, MD, Ph.D is a board certified Medical Geneticist and Internist with extensive clinical and research expertise in the area of genetics and genetic testing, including the analysis of the BRCA1/2 genes in the research and clinical setting. He chaired a Federal task force for the Secretary's Advisory Committee on Genetics, Health and Society that evaluated the impact of gene patents on patient access to genetic testing and resulted in a series of recommendations to the U.S. Secretary of Health and Human Services in 2010. Dr. Tania Bubela, Ph.D., LLB is a professor of health and intellectual property. She has written and consulted on the commercialization of biomedical research and technology transfer.

We provide affiliations in Appendix A solely for the purpose of identification. No part of this brief was authored by counsel for any party, person, or organization besides *amici.* Our interest is to assist the Court. Counsel of Record for the Parties have consented to the filing of this brief.

SUMMARY OF ARGUMENT

The law relating to patentable subject-matter applies equally to DNA-based inventions as to inventions in other fields. For the last 150 years, courts have held that abstract inventions are not patentable subject-matter.

A claim to an invention is abstract and, therefore, not patentable subject-matter, if it over-generalizes the inventive concept beyond the specific contribution that the inventor made to the art. *Bilski v. Kappos*, 130 S. Ct. 3218, 3221 (2010) ("The concept of hedging ... is an unpatentable abstract idea. . . . Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.").

While information is abstract in the above sense, claims to information recorded in a particular medium may be more specific, and thus constitute patentable subject-matter where the recording of the information on that medium provides a function that the information in any other form does not. For example, a claim to a series of increasing numbers printed on a tape (a tape-measure) would constitute patentable subject-matter where the tape could be used to measure length. This function constrains the scope of the invention to the inventor's contribution and provides a better basis for determining whether the invention is non-obvious, useful, described and enabled. Where such a specific function is

absent, the embodiment of the information on the particular medium of recording does not render it patent-eligible.

As DNA acts both biochemically and as an information-storage medium, claims reading on it are subject to the above analysis. Where neither a particular claim reading on DNA nor its accompanying specification discloses a function of the information stored on the DNA beyond the function of the information itself, the claim is abstract and does not constitute patentable subject-matter. Such is the case of the impugned composition of matter claims insofar as they claim isolated but unaltered genomic DNA without specifying a function beyond its information storage capacity. These claims could have been saved by having adopted a narrower definition of DNA or by having provided a specific function for each form of DNA included within that definition.

Similarly, where a claim is to a method involving the comparison of information stored on DNA but does not provide steps that must follow that comparison, the invention is claimed too abstractly. This is particularly true of methods of comparing an individual's genetic sequence against a wild type where the inventor does not contribute to the method of conducting the comparison and fails to instruct on any specific actions that follow from the comparison.

ARGUMENT

I. Introduction

The district court held the impugned claims not to be eligible subject-matter under 35 U.S.C. § 101 since neither the act of "purification" nor of "isolation" altered DNA's essential characteristic as a product of nature, A195-A196 and A225-A228, and further that the method claims were mental processes that failed to pass a "machine or transformation" test. A237-A238.

The effect of the district court's decision is too wide. Taken literally, it implies that isolated and purified DNA, cDNA, human proteins and other natural products would *per se* constitute unpatentable products of nature. While we agree that the district court properly invalidated the impugned claims (although we make no arguments regarding Claim 20 of U.S. Patent No. 5,747,282 (the '282 patent)), we do so on the basis that the *particular* claims—and not all claims reading on DNA, proteins or natural products in general—are "abstract" in the sense that the inventors failed to attribute a specific function for part of the class of DNA molecules included in their definition of "DNA." Similarly, the inventors failed to attribute a specific function for the comparison between an individual's DNA and reference DNA since the inventors only stated that that individual should "consider" the test results in determining future conduct rather than suggesting a particular course of action that the individual ought to follow.

II. "Abstract" subject-matter is excluded from patentable subject-matter and means the opposite of "specific" rather than of "tangible".

The goal of patent law is to promote technological progress. To accomplish this, patent law offers inventors a *quid pro quo*: in return for limited term rights to exclude, an inventor must set out his or her specific contribution to science and technology.

The need to be specific arises out of the consistent stand of the courts that only applications of knowledge, and not basic scientific knowledge—whether in the form of "phenomena of nature", "mental processes," or "abstract intellectual processes,"—can be patented. *Gottschalk v Benson*, 409 U.S. 63, 67 (1972); *Diamond v. Chakrabarty,* 447 U.S. 303 at 309 (1980) ("Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'").

Since at least *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853), the Supreme Court has recognized that one cannot claim an invention in the abstract but only in specific form: "Neither could the man who first discovered that steam might, by a proper arrangement of machinery, be used as a motive power to grind corn or spin cotton claim the right to the exclusive use of steam as a motive power for the purpose of producing such effects." Permitting broad, or abstract, claims

would, according to the Court, impede, rather than promote, technological progress. *Id.* ("If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know, some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification.").

O'Reilly provides the clue to understanding the boundary between unacceptable abstraction and required specificity: Morse's claim to "the use of the motive power of the electric or galvanic current . . . however developed for marking or printing intelligible characters, signs, or letters, at any distances" was not sufficiently restricted to his specific contribution. *Id.* at 139. That is, Morse's invention was "abstract" in the sense that it was "disassociated from any specific instance." *Merriam-Webster Collegiate Dictionary* (2003) ("*Merriam-Webster*")). The problem with Morse's patent was not that it was intangible (*see In re Nuijten*, 500 F.3d 1346, 1358 (Fed. Cir. 2007) (Linn. J., concurring in part and dissenting in part)) but that Morse did not restrict himself to what he invented: a process carried out on a specific set of machinery.

The term "abstract," as used in the case law depends on whether the inventor has, in setting out his or her claims in light of the specifications, made the invention sufficiently specific. *See, e.g., Chakrabarty*, 447 U.S. at 309*; Diamond*

v. Diehr, 450 U.S. 175, 185 (1981); *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk*, 409 U.S. at 67. This involves not a *per se* exclusion of any category of process, machine, manufacture, or composition of matter, but a claim-by-claim analysis. "The Court [in *Diehr*] distinguished a claim that would cover all uses of a mathematical formula and thus is an abstract construct, as in *Benson*, from a claim that applies a mathematical calculation for a specified purpose, as in *Diehr*." *In re Bilski*, 545 F.3d 943, 981 (Fed. Cir. 2008) (Newman, J., dissenting).

Abstraction concerns the failure of the applicant to restrict him or herself to what he or she contributed to the art rather than the broad potential of the principle underlying the invention. "The more abstract the context . . . and, thus, the broader the scope of the claim, the more likely the claim is to recite unpatentable subject matter . . . ." Kevin E. Collins, *Propertizing Thought,* 60 SMU L. REV. 317, 350 (2007). The Supreme Court in *Diehr* confirms this view: "

> We recognize, of course, that when a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract . . . . On the other hand, when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101."

Diehr, 450 U.S. at 191-192.

III. Patent history supports the understanding of "abstract" as meaning overly broad.

Patent history supports this understanding of "abstract" as being the equivalent of overly "broad" and the opposite of "specific." The English case of *Boulton and Watt v. Bull*, 126 Eng. Rep. 651 (1795) summarizes the state of patent law at the moment of the drafting of the first U.S. patent statutes. The case involved a claim to Watt's steam engine that was worded as a method consisting of certain principles relating to steam and the application of those principles to an engine. While the court split on whether Watt's claim read over a principle or an application of the principle, all four judges agreed that principles cannot be the subject of a patent right. As Chief Justice Eyre held:

> Undoubtedly there can be no patent for a mere principle, but for a principle so far embodied and connected with corporeal substances as to be in a condition to act, and to produce effects in any art, trade, mystery, or manual occupation, I think there may be a patent . . . . It is not that the patentee has conceived an abstract notion that the consumption of steam in fire-engines may be lessened but he has discovered a practical manner of doing it; and for that practical manner of doing it he has taken this patent. Surely this is a very different thing from taking a patent for a principle.

Boulton, 126 Eng. Rep. at 667.

The English understanding of "abstract" as being the opposite of "practical manner of doing it" carried over to early American patent law and practice. Edward C. Walterscheid, *Charting a Novel Course: The Creation of the Patent Act of 1790,* 25 AIPLA Q. J. 445, 497 (1997).

Thomas Jefferson recognized that patent law aimed at finding an equilibrium between the principle that "ingenuity should receive a liberal encouragement" and the need for inventors to limit themselves to what they had specifically contributed to the art. *Chakrabarty*, 447 U.S. at 308-309 (1980), quoting 5 *Writings of Thomas Jefferson* 75-76 (H. Washington ed. 1871). He stated that: "Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent and those which are not." Thomas Jefferson, Letter to Isaac McPherson, August 13, 1813, reprinted in 6 *Writings of Thomas Jefferson*, 181 (H.A. Washington, ed. 1854).

Jefferson's writings confirm his understanding that "abstract" means the opposite of "specific." Mirroring the distinction in *Boulton* and setting the standard adopted in later Supreme Court decisions, he distinguished that which is patentable from that which is not at the boundary between the practical application of principle and principle itself: "I can conceive how a machine may improve the manufacture of flour; but not how a principle abstracted from any machine can do it. It must then be the machine, and the principle of that machine, which is secured to you by your patent." Thomas Jefferson, Letter to Oliver Evans, January 16, 1814, reprinted in 6 *Writings of Thomas Jefferson*, 298 (H.A. Washington, ed. 1854).

Born out of long history and experience, this distinction between the abstract and the specific became a touchstone for determining the outer boundaries of patentable subject-matter. Thus, in *LeRoy v. Tatham*, 55 U.S. 156, 174-175 (1852), the Supreme Court held that "[i]t is admitted that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." On the other hand, the Court continued that "[a] new property discovered in matter, when practically applied in the construction of a useful article of commerce or manufacture, is patentable . . . ." *LeRoy*, 55 U.S. at 175. Later, the Supreme Court in *Rubber Tip Pencil Company v. Howard*, 87 U.S. 498, 507 (1874) pithily concluded that "[a]n idea of itself is not patentable, but a new device by which it may be made practically useful is."

Some 150 years later, the distinction between abstract and specific remains one of the fundamental, unalterable features of patent law: "In searching for a limiting principle, this Court's precedents on the unpatentability of abstract ideas provide useful tools." *Bilski v. Kappos*, 130 S. Ct. at 3229. Despite the change from an industrial to an informational economy, this limit against the abstract continues to apply.

IV. Ideas, concepts and information are "abstract" and only constitute patentable subject-matter when linked with a specific function.

An idea or concept cannot, itself, be patented, not because it is intangible, but because it is too abstract. *Bilski,* 130 S. Ct. at 3231 ("The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea . . . ."). As all ideas and concepts have a physical embodiment (in the sense recognized in *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007))—they must be recorded in some form (book, mechanical device, digital storage medium or in human neurons)—tangibility cannot be the key to understanding abstraction.

Information—" . . . something (as a message, experimental data, or a picture) which justifies change in a construct (as a plan or theory) that represents physical or mental experience or another construct . . . " (*Information Definition*, *Merriam-Webster* (2003)—is the building block of ideas and concepts. As such, information is understood not to constitute patentable subject-matter:

> Patent rights are not well adapted to protecting information, particularly information about the natural world. Given that independent discovery of such information is quite likely to happen without the efforts of any particular patent holder, excessive protection of such information as intellectual property may slow down subsequent research more than it promotes the original data collection.

Rebecca S. Eisenberg, *Patenting Genome Research Tools And The Law*, 326 COMPTES RENDUS BIOLOGIES 1115, 1118 (2003); *see also In re Comiskey*, 554 F.3d 967, 978-980 (Fed. Cir. 2009).

An applicant cannot transform an abstract claim to information into patentable subject-matter by restricting the claim to a particular technological environment. *See, e.g., Diamond v. Diehr*, 450 U.S. at 191 ("A mathematical formula as such is not accorded the protection of our patent laws . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.") (citations omitted).

Similarly, an applicant cannot turn an unpatentable claim to information into a patentable claim by limiting the invention to a particular medium without also indicating the additional function that embodying this information on that medium accomplishes. *See In re Bradley*, 600 F.2d 807, 812 (C.C.P.A. 1979) ("If appellants were claiming the information embodied in the firmware or the firmware itself, per se, a different case would be presented."). This conclusion is illustrated through a consideration of this Court's treatment of the "printed matter" doctrine in *King Pharmaceuticals, Inc. v. Eon Labs., Inc.*, 616 F.3d 1267 (Fed. Cir. 2010).

"Roughly stated, [the 'printed matter' doctrine] dictates that 'information recorded in [a] substrate or medium' is not eligible for patent protection—regardless of how nonobvious and useful it is—if the advance over the prior art resides in the 'content of the information.'" Kevin E. Collins, *Semiotics 101:*

Taking the Printed Matter Doctrine Seriously, 85 IND. L.J. 1379, 1380 (2010) ("*Semiotics 101*").

One of the claims at issue in *King Pharmaceuticals* involved a claim to dispensing a known medicine while informing patients to take the medicine with food and another claim to dispensing of that medicine in conjunction with a printed label that informed the patient to take the medicine with food. The Court rejected both claims, noting that:

> In an analogous context, we have held that "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." . . . In such cases, we have recognized that the printed matter is not independently patentable.

King Pharmaceuticals, 616 F.3d at 1278-79 (citations omitted). The Court held that there was no functional relationship between the information provided—to take the medicine with food—and the medicine itself. *Id.* at 1279.

While the information of taking medicine with food does not constitute patentable subject-matter in itself, that information could result in a patentable invention if limited to an embodiment in a specific medium or to a context in which doing so has a functional advantage. This was the case in *In re Gulack,* 703 F.2d 1381 (Fed Cir. 1983), in which this Court held as patentable an invention consisting of a series of numbers that, when printed on a circular band, served the function of educating about number theory. While the information itself was too

abstract to be patented, that information when recorded on the particular medium served a specific function that neither the numbers themselves nor their being printed on another medium—*e.g.*, a sheet of paper—accomplished. *See, e.g.*, *id.* at 1386-87.

Despite the fact that the *King Pharmaceuticals* Court applied the "printed matter" doctrine under 35 U.S.C. § 103, the same analysis can be applied often more persuasively under 35 U.S.C. § 101. *See, e.g.*, *In re Nuijten*, 500 F.3d at 1365 (Linn, J., concurring-in-part and dissenting-in-part); *Semiotics 101* at 1380 n. 1 ("The Federal Circuit grounds the printed matter doctrine alternately in 35 U.S.C. §§ 101 & 103, but there is no principled basis for the statutory distinction.").

One of the critical holdings in *King Pharmaceuticals* is that the Court extended the application of the "printed matter" doctrine to a large range of media:

> Although these "printed matter" cases involved the addition of printed matter, such as written instructions, to a known product, we see no principled reason for limiting their reasoning to that specific factual context.

King Pharmaceuticals, 616 F.3d at 1279.

While information cannot be claimed *as* information, even when embodied on a medium, this Court's precedents make it clear that when the restriction of the information to a particular medium serves some purpose beyond imposing some physical limit on the claim, then the claim is not too abstract:

> More than mere abstraction, the data structures are specific electrical or magnetic structural elements in a memory. According to Lowry, the data structures provide tangible benefits: data stored in accordance with the claimed data structures are more easily accessed, stored, and erased.... In short, Lowry's data structures are physical entities that provide increased efficiency in computer operation.

In re Lowry, 32 F.3d 1579, 1583-1584 (Fed. Cir. 1994).

When the invention involves information that is necessarily tied to the medium on which information is stored, as were the data structures in *Lowry*, then the invention constitutes patentable subject-matter under § 101. On the other hand, where the embodiment of information on a particular medium implies no particular function beyond holding the information it contains, then that limitation cannot save the claim from a § 101 rejection.

V. Using "abstract" as a test for patentable subject-matter enhances the patent office's ability to conduct analyses of utility, non-obviousness and written description.

Once it is recognized that the reason for rejecting the patentability of information *qua* information is the abstract nature of that information rather than a *per se* prohibition of subject-matter, and that information can indeed be the subject of a patent when embodied in a particular medium where that embodiment has a clear function distinct from the information in the abstract, several conclusions become clear.

First, discussions of the tangibility or intangibility of an invention are not relevant to determining the patentability of inventions. The data-structures in

Lowry are patentable despite being intangible (although recorded in a tangible medium) while the printed labels in *King Pharmaceuticals* did not render the claimed invention patentable.

Second, what is critical to a § 101 analysis is not the form—composition of matter, method, system, etc.—of the invention but its abstractness. A claim to information is abstract if the applicant does not specify a function, or use, for the information in the form claimed. Abstract claims derive their value from the use of the information itself rather than a specified function related to that information.

Third, the problem of abstractness under § 101 is different from that of definiteness under 35 U.S.C. § 112. Abstraction relates to the breadth of subject-matter falling within the claim while the requirement of definiteness "requires an analysis of 'whether one skilled in the art would understand the bounds of the claim when read in light of the specification . . . If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.'" *Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1320-21 (Fed. Cir. 2003) (quoting *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993)). A claim may be abstract but definite (*e.g.*, the law of gravity) or specific and indefinite (*see, e.g., Novo Industries, L.P. v. Micro Molds Corp.*, 350 F.3d 1348 (Fed. Cir. 2003)). Despite the independence of the concepts of abstraction and definiteness, it should be observed that it is

easier to hide an indefinite claim if it is stated abstractly. This is because a more general principle hides a multitude of ambiguities within its general language whereas a specific claim lays out its assumptions more transparently.

Fourth, the concept of abstractness is legally distinct from that of utility: "[W]e have treated the utility requirement of § 101 as a distinct concept from the question of whether an invention qualifies as patentable subject matter." *In re Nuijten*, 500 F.3d at 1365 (Linn, J., dissenting). Further, the utility analysis is directed at the clarity and substantive nature of the utility while an abstractness analysis focuses on whether the applicant has disclosed a function linked to the information. *See, e.g., In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (discussing *Brenner v. Manson,* 383 U.S. 519 (1966) (in which an applicant claimed a process of making a compound)): "Following *Brenner,* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101.") Once again, the requirement that an inventor frame his or her claim in a more specific manner facilitates the analysis of whether the utility claimed is "specific and substantial."

Fifth, the nature of the medium on which information is stored is not material to the determination of whether the claim is abstract; rather, it is the presence of a specific function that is the key to patentability. This applies to both

product and process claims. A product claim to information embodied in medium X is patentable if the applicant specifies an additional function of the information embodied in that medium. A process claim relating to information is patentable if the applicant shows a function attached to that process.

On the other hand, a patent claim limited to information embodied on a particular medium is not patentable where the applicant fails to specify an additional function for the information so stored in that medium. Citing *Parker v. Flook*, 437 U.S. 584, 588–90, 593 (1978), Jeffrey M. Kuhn, *Patentable Subject Matter Matters: New Uses for an Old Doctrine*, 22 BERKELEY TECH. L.J. 89, 98 (2007) notes:

> The danger in allowing such abstract patent claims, the Court [in *Flook*] noted, was that it would "make the determination of patentable subject matter depend simply on the draftsman's art." This latitude would allow patentees to skirt the prohibition against patenting ideas and phenomena of nature by claiming the application rather than the idea directly.

VI. DNA, as information embodied in a molecule, is patentable when that embodiment is linked to a specific function beyond its function as storage medium.

DNA is both a molecule and an information storage medium: "DNA sequences are not simply molecules; they are also information. Knowing the DNA sequence for the genome of an organism provides valuable scientific information that can open the door to future discoveries." Rebecca S. Eisenberg, *How Can You Patent Genes?,* 2 AM. J. BIOETHICS 3, 4 (2002). Because of this duality, the granting of patents over DNA has been controversial with scientists, physicians and policy-makers: "[T]he central problem with human DNA sequence patents today is that they not only provide their holders with control over the invention itself – the physical molecule – but also over access to the particular health information coded in individual genes." E. Richard Gold, *Gene Patents and Medical Access,* 49 INTELL. PROP. F. 20, 24 (2002).

While perhaps more socially and politically charged than most patent law issues (*See, e.g.*, E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm,* 12 (4) GENETICS MED. S39–S70 (2010) (April supplement)), legal controversies over the patenting of human DNA can be resolved through the application of existing precedents. *See* Peter Yun-Hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter*

Doctrine to Constrain Patents on Biotechnology Research Tools, 19 HARV. J.L. & TECH. 79, 82 (2005).

The analysis set out in this brief provides a roadmap for distinguishing between patentable and non-patentable claims reading over DNA and associated methods. The result of such an analysis is that most DNA-based claims will be found to state patentable subject-matter, not because they are tangible, but because they will disclose a function for DNA that goes beyond the function of the information stored on the DNA. Whether they also satisfy the § 101 utility requirement or §§ 102, 103 and 112, we leave aside.

Concretely, this means that composition of matter claims relating to DNA would satisfy the patentable subject-matter test when the patent discloses a biochemical function attached to the form of DNA molecule claimed (*e.g.*, genomic DNA or cDNA in isolated form) that goes beyond simple embodiment of information. This function may include, for example, the DNA within a construct for gene therapy, inserted into a bacterium or other organism to produce insulin or another protein, modified to have new characteristics, as forming a replicon, or DNA injected into the body to encode proteins that elicit a vaccine response. We note that the same analysis would apply to other purified and isolated molecules, such as proteins, the function of which could be, for example, as a target in drug discovery or as a therapy.

Similarly, a method claim relating to DNA would satisfy the patentable subject-matter requirement when the patent discloses a function that relates to either the biochemical properties of DNA or that goes beyond the bare use of the unaltered information stored on the DNA. Such methods could include the use of DNA as a storage device for a computer, to treat a disease, to introduce a genetic modification or to produce a protein.

Composition of matter claims to a DNA molecule where no function beyond the storage of information is disclosed, however, are not patentable, nor are methods involving the manipulation of the information stored on DNA where the inventor contributes neither the method of carrying out that manipulation nor a consequence of that manipulation.

VII. The distinction between "specific" claims to DNA and associated methods, and "abstract" claims to DNA and associated methods promote the efficiency of the patent system, accord with scientific norms, and provide necessary incentives to invent.

The distinction drawn between abstract and specific claims to DNA and associated methods promote three policy goals that are supportive of the patent system and its goal of promoting innovation.

First, as noted earlier, requiring patent applicants to make their claims more specific facilitates the determination of whether the applicant has met the other criteria for patentability established under patent law. By requiring more precision in claim drafting, the patent process will be more transparent and consistent.

Further, the rule against the patenting of "abstract" inventions requires applicants to advance their invention to the point of practical application. "[A patent] is not a reward for the search, but compensation for its successful conclusion." *Brenner*, 383 U.S. at 536.

Second, the distinction between "abstract" and "specific" parallels important norms within the scientific and clinical communities in which being specific is of paramount importance. Being specific permits reproducibility in the laboratory and ensures high and consistent patient care. It also better enables researchers and clinicians to more confidently navigate the proprietary versus non-proprietary genetic landscape in carrying out their activities.

Third, the test proposed in this brief would leave intact incentives for drug discovery, protein and hormone replacement therapies, gene therapy and other interventions that will assist millions to live better lives. The test proposed accords with past decisions of this Court that emphasize the critical importance of patents to attracting investment, carrying out development—including clinical trials—and marketing products that address significant health needs.

On the other hand, the test also limits the ability of patent claimants who, while having conducted significant scientific discovery, have not sufficiently developed their inventions to the point of being able to specify a particular function of their efforts beyond the broad use of information they have uncovered.

Nowhere is this more important than in the field of human diagnostic genetic testing. In a recent study of U.S. and European patents affecting such testing, the researchers found that, out of the 22 inherited diseases studied, 15 diseases are subject to at least one blocking patent. Isabelle Huys, *et al.*, *Legal Uncertainty in the Area of Genetic Diagnostic Testing,* 27 Nature Biotechnology 903, 904 (2009).

In this field, patent incentives play a much reduced role: "[P]atents have not caused irreparable harm in genetic diagnostics, but neither have they proven greatly advantageous . . . . One justification for gene patents is that they speed up the development of tests. But the patent incentive is usually not necessary." Robert Cook-Deegan, *et al.*, *The Dangers of Diagnostic Monopolies,* 458 Nature 405, 405 (2009). Out of 10 clinical conditions studied, researchers found that "in no case was the exclusive licensee the first to market." Julia Carbone, *et al.*, *DNA Patents and Diagnostis: Not a Pretty Picture,* 28 Nature Biotechnology 784, 788 (2010).

VIII. The impugned claims encompass a wide variety of DNA molecules, classes of which have no link to a function and are therefore abstract.

The impugned claims fall into three classes: 1) those in which the inventors claim a broad class of DNA possessing a particular sequence (and, in some cases, other molecules), 2) those involving the comparison of one sample sequence with another, reference, sequence, and 3) one claim to a method of screening therapeutics. The above analysis provides insights into the first two classes of

claim. We offer no analysis of the third class of claim, represented by Claim 20 of the '282 patent.

In respect of both the composition of matter and method claims reading over DNA and the comparisons of sequence data, respectively, the inventors' patent claiming practices were overly abstract. All of these claims could have been saved if the inventors had either claimed more narrowly or had specified a function to the compositions of matter beyond their information storage function and methods with a specific outcome. As they did not, the impugned claims are invalid. This leaves, nevertheless, many of the claims in the patents intact since, in respect of those claims, the inventors were specific.

Claim 1 of the '282 patent is illustrative of the composition of matter claims over DNA. It provides as follows: "An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2."

To interpret this claim, recourse must be made to the specification, which defines the term DNA and describes the functions attached to DNA. *In re Suitco Surface, Inc.,* 603 F.3d 1255, 1260 (Fed. Cir. 2010) ("Rather, claims should always be read in light of the specification and teachings in the underlying patent.").

The specifications demonstrate that the use of the term "DNA" as used in Claim 1 refers to unaltered genomic DNA, cDNA and altered forms of both. '282

Patent, col. 19, ll. 51-56. ("The polynucleotide compositions of this invention include RNA, cDNA, genomic DNA, synthetic forms, and mixed polymers, both sense and antisense strands, and may be chemically or biochemically modified or may contain non-natural or derivatized nucleotide bases, as will be readily appreciated by those skilled in the art."). Claim 1 restricts the set of DNA to those that have been "isolated." Thus, the inventors made clear that Claim 1 of the '282 patent includes, among other forms of DNA, isolated but otherwise unaltered genomic DNA.

A careful reading of the specifications attaches functions to the isolated cDNA and isolated and altered forms of genomic DNA and cDNA but not to the isolated, unaltered genomic DNA itself outside of its role as information storage medium. One of the functions attributed to isolated cDNA coding for the SEQ ID NO.2 include its use in gene therapy (the genomic DNA being well known at the time to be too large for insertion within a vector. *See generally,* Joseph Sambrook & David W. Russell, *Laboratory Cloning; A Laboratory Manual* (3rd ed. 2001)). One function attributed to small portions of isolated genomic DNA or cDNA include their use as probes or primers for diagnostic or other purposes. No function, other than as storage medium for naturally occurring genetic information is attributed to isolated, unaltered genomic DNA coding for SEQ ID NO:2. In fact, the specification emphasizes the informational content of the genomic DNA rather

than the biochemical functions of the molecule. '282 Patent, col. 12, ll. 42-44 ("The finding of BRCA1 mutations thus provides both diagnostic and prognostic *information*") (emphasis added); *id.* at col. 28, ll. 26-28 ("Results of these tests and interpretive *information* are returned to the health care provider for communication to the tested individual") (emphasis added).

In the absence of a stated function, Claim 1 of the '282 patent, insofar as it reads over unaltered, genomic DNA, reads over genetic information embodied in a particular medium – here a polynucleotide – where embodiment in that medium is not described as having a function beyond storing the information itself. Indeed, the very purpose of doing a genetic test is not to create a DNA molecule, but to determine the *information* stored in a sample's DNA. Since a claim to information cannot be saved by limiting it to a particular storage medium, unless embodying the information in that medium has some function beyond the use of the information itself, the claim is too abstract and constitutes non-patentable subject-matter.

If the inventors had adopted a more conservative patent claiming strategy, this and the other impugned claims in the category could have been saved. In particular, the inventors could have adopted a less broad definition of DNA that excluded, in this case, unaltered genomic DNA corresponding to SEQ ID NO:2. Potentially valuable sub-sequences of genomic DNA, particularly those found in

the non-coding intron regions, could have given rise to valid claims under a number of circumstances. As an example, if a piece of genomic DNA is found to bind competitively to an enhancer or promoter region in one of these introns, it could have the workings of a therapeutic molecule rather than of a storage medium for information and would be patentable for its molecular properties. Additionally, therapeutic molecules that target the intron sequences would constitute patentable subject-matter as they have a biochemical function. Finally, the inventors could have claimed specific DNA molecules that they demonstrated to be associated with high risk of cancer (as they did in unchallenged claims in this and other patents).

Other of the impugned composition of matter claims, such as Claims 5 and 6 of the '282 patent, are less broad but, given the lack of indication of the function of arbitrary chains of 15 nucleotides, remain abstract. A reading of some of the non-impugned claims in the '282 patent reveal that they, however, constitute patentable subject-matter. These would include claims 8 to 13, all of which involve the use of the polynucleotide as a biochemical agent in addition to or instead of as an information storage medium. Whether these claims will survive a utility, novelty non-obviousness or written description analysis is a separate question.

Claim 1 of U.S. Patent No. 5,753,441 (the '441 patent) is representative of the second class of claims, those which read over a method of comparing data. Claim 1 reads as follows:

> A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.

This claim comprises a method of comparing two sets of information, one against the other, to determine whether both contain the same information in the same order. The first set of information consists of the genetic sequence located on Chromosome 17 corresponding to the BRCA1 locus derived from a particular individual who may, or may not, be symptomatic. The second is from the wild type of that same genetic sequence. The claim does not specify how to carry out the comparison, relying instead on conventional techniques. '441 Patent, col. 25, ll. 49-52 ("The practice of the present invention employs, unless otherwise indicated, conventional techniques of chemistry, molecular biology, microbiology, recombinant DNA, genetics, and immunology.").

Beyond this, Claim 1 of the '441 patent discloses no function for the comparison other than the provision of information:

> Individuals at higher than normal risk might modify their lifestyles appropriately. In the case of BRCA1, the most significant non-genetic risk factor is the protective effect of an early, full term pregnancy. Therefore, women at risk could consider early childbearing or a therapy designed to simulate the hormonal effects of an early full-term pregnancy. Women at high risk would also strive for early detection

> and would be more highly motivated to learn and practice breast self examination. Such women would also be highly motivated to have regular mammograms, perhaps starting at an earlier age than the general population. Ovarian screening could also be undertaken at greater frequency.

'441 Patent, col. 64, ll. 22-34.

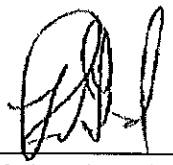
Neither the specifications nor the art at the time contain any indication of particular action that immediately ought to follow the information beyond that the information ought to be considered or taken into account in future encounters with the individual's physician. As the claim applies equally to symptomatic and non-symptomatic individuals and there is no indication of whether a particular mutation in a particular part of the gene will ever result in cancer, at what likely age and of what severity, the patent fails to disclose any concrete course of conduct beyond the advisement to "consider" the results. In sum, the method results in the comparison of two, abstract, pieces of information in order to create a new, abstract, piece of information. Given that there is a failure to link this information with any specific course of action, the claim is abstract and thus constitutes non-patentable subject-matter.

A reading of other of the '441 claims indicate, however, that they constitute patentable subject-matter. For example, Claims 6, 7, and 11 involve a particular biochemical process rather than a pure extraction of information.

CONCLUSION

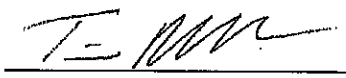
For these reasons, the Court should uphold the decision of the District Court with respect to all claims except that we offer no view on whether Claim 20 of the '282 patent constitutes patentable subject-matter.

Respectfully submitted,



E. Richard Gold

James Evans



Tania Bubela

APPENDIX A – LIST OF *AMICI CURIAE*

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United States Court of Appeals
for the Federal Circuit

ASSOCIATION FOR MOLECULAR V PTO, 2010-1406

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December 7, 2010

John Kruesi

United States Court of Appeals
for the Federal Circuit

ASSOCIATION FOR MOLECULAR V PTO, 2010-1406

CERTIFICATE OF SERVICE

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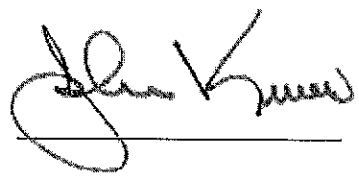

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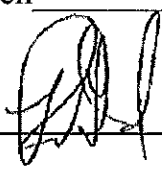
(s) 

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