# United States Court of Appeals for the Federal Circuit

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**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.*

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2010-1406

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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.

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MOORE, *Circuit Judge*, concurring in part.

I join the majority opinion with respect to standing and the patentability of the method claims at issue. I join the majority with respect to claims to isolated cDNA sequences, and concur in the judgment with respect to isolated DNA sequences. I write separately to explain my reasoning.

I.

The Patent Act, 35 U.S.C. § 101, allows "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" to obtain a patent. The plain language of this statute only requires that an invention be "new and useful," and fall into one of four categories: a "process, machine, manufacture, or composition of matter." "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting the statutory history).

While the plain language used by Congress did not limit the scope of patentable subject matter in the statute,

the "Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Bilski v. Kappos*, 130 S. Ct. 3218, 3226 (2010) (quoting *Chakrabarty*, 447 U.S. at 309). These exceptions "rest[], not on the notion that natural phenomena are not processes [or other articulated statutory categories], but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect." *Parker v. Flook*, 437 U.S. 584, 593 (1978).

Applying the judicially created exception to the otherwise broad demarcation of statutory subject matter in section 101 can be difficult. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 134-45 (1948) (Frankfurter, J., concurring) ("[S]uch terms as 'the work of nature' and the 'laws of nature' . . . are vague and malleable . . . . Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."). The analysis is relatively simple if the invention previously existed in nature exactly as claimed. For example, naturally existing minerals, a plant found in the wild, and physical laws such as gravity or $E=mc^2$ are not patentable subject matter, even if they were "discovered" by an enterprising inventor. *Chakrabarty*, 447 U.S. at 309.

Even when an invention does not exist in nature in the claimed state, it may still be directed to subject matter that is not patentable. For example, in *Funk Brothers*, the Supreme Court held a patent to a combination of multiple naturally occurring bacterial strains was not patentable. Although there was "an advantage in the combination," which was apparently "new and useful," none of the bacterial strains "acquire[ed] a different use" in combination. *Funk Bros.*, 333 U.S. at 131-32. The aggregation of the bacterial strains into a single product

produced "no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. . . . They serve the ends nature originally provided and act quite independently of any effort of the patentee." *Id.*

In contrast, the Supreme Court held bacteria that included extra genetic material introduced by the inventor were "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use'" and therefore patentable. *Chakrabarty*, 447 U.S. at 309-310 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). *Chakrabarty* explained that there is no distinction between inventions based on living and inanimate objects for the purpose of the patent statute; instead, the "relevant distinction" for the section 101 analysis is "between products of nature . . . and human-made inventions." *Id.* at 312-13. Even if the invention was based on nature, and resulted in a living organism, it may fall within the scope of section 101. For example, "the work of the plant breeder 'in aid of nature' was patentable invention" because "'a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man.'" *Id.* (quoting S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930)). In *Chakrabarty*, the intervention of man resulted in bacteria with "markedly different characteristics" from nature and "the potential for significant utility," resulting in patentable subject matter. *Id.* at 310.

*Funk Brothers* and *Chakrabarty* do not stake out the exact bounds of patentable subject matter. Instead, each applies a flexible test to the specific question presented in order to determine whether the claimed invention falls within one of the judicial exceptions to patentability.

*Funk Brothers* indicates that an invention which "serve[s] the ends nature originally provided" is likely unpatentable subject matter, but an invention that is an "enlargement of the range of . . . utility" as compared to nature may be patentable. 333 U.S. at 131. Likewise, *Chakrabarty* illustrates that an invention with a distinctive name, character, and use, e.g., markedly different characteristics with the potential for significant utility, is patentable subject matter. 447 U.S. at 309-10. Although the two cases result in different outcomes, the inquiry itself is similar.

Courts applied an analogous patentability inquiry long before *Funk Brothers* or *Chakrabarty*. In one notable case, Judge Learned Hand held that purified adrenaline, a natural product, was patentable subject matter. Judge Hand explained that even if the claimed purified adrenaline were "merely an extracted product without change, there is no rule that such products are not patentable." *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911). This is because "while it is of course possible logically to call this a purification of the principle" the resulting purified adrenaline was "for every practical purpose a new thing commercially and therapeutically." *Id.* Similarly, in a case applying the Patent Act of 1952,[1] purified vitamin B-12, another natural product, was also held patentable subject matter within the meaning of section 101. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958). The Fourth Circuit explained that purified vitamin B-12 was "far from the premise of the [naturally occurring] princi-

[1] The Patent Act of 1952 was the first time patentable subject matter (the current section 101) was separated out from novelty (the current section 102). Previously, these two concepts were combined into a single section.

ple. . . . The new product, not just the method, had such advantageous characteristics as to replace the [naturally occurring] liver products. What was produced was, in no sense, an old product." *Id.* at 162-63. These purified pharmaceutical cases are both consistent with Supreme Court precedent: the purified substance was "a new thing . . . therapeutically," *Parke-Davis*, 189 F. at 103, and had such "advantageous characteristics" that what was produced by purification "was, in no sense, an old product." *Merck*, 253 F.2d at 162-63. In other words, the purified natural products were held to have "markedly different characteristics," as compared to the impure products, which resulted in "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310.

In contrast, mere purification of a naturally occurring element is typically insufficient to make it patentable subject matter. For example, our predecessor court held that claims to purified vanadium and purified uranium were not patentable subject matter since these were naturally occurring elements with inherent physical properties unchanged upon purification. *See In re Marden*, 47 F.2d 958, 959 (CCPA 1931) ("[P]ure vanadium is not new in the inventive sense, and, it being a product of nature, no one is entitled to a monopoly of the same."); *In re Marden*, 47 F.2d 957 (CCPA 1931) ("ductile uranium" not patentable because uranium is inherently ductile). Likewise, claims to purified ductile tungsten were not patentable subject matter since pure tungsten existed in nature and was inherently ductile. *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928). In each of these cases, purification did not result in an element with new properties. Instead, the court held the naturally occurring element inherently had the same characteristics and utility (e.g. ductility) as the claimed invention. Consistent with *Funk Brothers* and

*Chakrabarty*, the claims all fell within the laws of nature exception.

As illustrated by these examples, courts have long applied the principles articulated in *Funk Brothers* and *Chakrabarty* to different factual scenarios in order to determine whether an invention, as claimed, falls into the laws of nature exception. I see no reason to deviate from this longstanding flexible approach in this case.

II.

We reconsider whether the claims at issue in this case are directed to patentable subject matter following the remand from the Supreme Court in light of its opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (*Prometheus*). While the *Prometheus* decision does not control the outcome in this case, it is nonetheless instructive regarding the scope of the law of nature exception. As an initial matter, the *Prometheus* discussion of laws of nature (process claims) clearly ought to apply equally to manifestations of nature (composition claims). Myriad's argument that *Prometheus* is constrained to methods is an untenable position.

As the *Prometheus* court explained: "If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Id.* at 1297. *Prometheus* did not, however, overturn *Funk Brothers* or *Chakrabarty*; cases clearly more analogous to the one before us. Using the framework of *Funk Brothers* and *Chakrabarty* in conjunction with the direction of *Prometheus*, the applicable principles are: (1) laws of nature/manifestations of nature are not patentable; (2) a composition of matter with "markedly different characteristics" from that found in nature with

the potential for significant utility is directed to patentable subject matter.

Does the isolation process change the DNA from an unpatentable manifestation of nature into a patentable composition of matter? *Id.* at 1299. Does the claimed isolated DNA have markedly different characteristics with the potential for significant utility, e.g., an "enlargement of the range of . . . utility" as compared to nature? *Chakrabarty*, 447 U.S. at 309-310; *Funk Bros.*, 333 U.S. at 131.

The isolated DNA claims of the patents in suit fall into two categories. The first category of claims is directed to isolated sequences that are identical to naturally occurring gene sequences. These include claims encompassing both the isolated full length gene sequence (e.g. claim 1 of '282 patent), which are thousands of nucleotides, and claims to shorter isolated DNA strands, with as few as fifteen nucleotides, whose nucleotide sequence is found on the chromosome (e.g. claim 5 of '282 patent). The second category of claims is directed to isolated DNA sequences that are different from the naturally occurring gene sequences. These include claims to isolated cDNA molecules (e.g. claim 2 of the '282 patent), which differ from the natural gene sequence in that the introns are removed, and are the opposite (complementary) sequence of the naturally occurring RNA.

The cDNA claims present the easiest analysis. Although the plaintiffs (now plaintiff) in the suit argue, and the district court held, that cDNA falls within the "laws of nature" exception to section 101 patentability, the claimed cDNA sequences do *not* exist in nature. Moreover, since cDNA has all of the introns removed, and only contains the coding nucleotides, it can be used to express a protein in a cell which does *not* normally produce it. Of course,

the claimed isolated cDNA is inspired by nature—after all naturally occurring RNA is the template upon which cDNA is constructed. Because it is used as a template, however, cDNA has a complementary sequence of nucleotides, and therefore has a *completely different* nucleotide sequence than the RNA. Moreover, DNA has a different chemical structure than RNA, including a different base (T instead of U, respectively) and sugar units (deoxyribose instead of ribose, respectively). This results in, among other things, greater stability for the DNA sequence as compared to the RNA sequence.

cDNA sequences thus have a distinctive character and use, with markedly different chemical characteristics from either the naturally occurring RNA or any continuous DNA sequence found on the chromosome. The claimed isolated cDNA sequences are the creation of man, made using biological tools and the naturally occurring mRNA as a template. cDNA is therefore not one of the "'manifestations of . . . nature, free to all men and reserved exclusively to none'" that falls outside of the patent system. *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros.*, 333 U.S. at 130). I decline to extend the laws of nature exception to reach entirely manmade sequences of isolated cDNA, even if those sequences are inspired by a natural template. I therefore join the majority opinion with respect to the claims to cDNA sequences.[2]

DNA sequences that have the same pattern of DNA bases as a natural gene, in whole or in part, present a more difficult issue. Unlike the isolated cDNA molecules, whose sequence is not present in nature, the isolated

[2] To the extent the claims to shorter portions of cDNA include only naturally occurring sequences found in the chromosome, for example claim 6 of the '282 patent, my reasoning is the same as for the isolated sequences of claim 5, discussed below.

DNA claims include nucleotide sequences which are found in the human body, albeit as part of a much larger molecule, the chromosome. To the extent the majority rests its conclusion on the chemical differences between genomic and isolated DNA (breaking the covalent bonds), I cannot agree that this is sufficient to hold that the claims to human genes are directed to patentable subject matter. I agree that isolated genes are a different molecule and are therefore not squarely analogous to unpatentable minerals, created by nature without the assistance of man. The claimed isolated DNA molecules, which are truncations (with different ends) of the naturally occurring DNA found as part of the chromosome in nature, are not naturally produced without the intervention of man.

I begin with the short isolated sequences such as those covered by claim 5 which is directed to "an isolated DNA having at least 15 nucleotides of the DNA of claim 1." This claim covers a sequence as short as 15 nucleotides and arguably as long as the entire gene. For this claim to be patent eligible, all of the sequences ranging from the 15 nucleotide sequence to the full gene must be patentable subject matter. The shorter isolated DNA sequences have a variety of applications and uses in isolation that are new and distinct as compared to the sequence as it occurs in nature. For example, these sequences can be used as primers in a diagnostic screening process to detect gene mutations. These smaller isolated DNA sequences—including isolated radiolabeled sequences mirroring those on the chromosome—can also be used as the basis for probes. Naturally occurring DNA cannot do this. Unlike the isolated DNA, naturally occurring DNA simply does not have the requisite chemical and physical properties needed to perform these functions.

The ability to use isolated DNA molecules as the basis for diagnostic genetic testing is clearly an "enlargement of

the range of . . . utility" as compared to nature. *Funk Bros.*, 333 U.S. at 131. In *Prometheus*, the Supreme Court held that the claims at issue were not directed to patentable subject matter because they merely "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 132 S. Ct. at 1296-97. The claimed relationship was "a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." *Id.* at 1297.

There is no suggestion that the human body naturally uses 15-mers as primers to synthesize DNA, or that the attendant process of "probing" a patient's DNA to detect a mutation is somehow a natural law. The ability to use a short strand of DNA as a primer or probe to determine whether a patient has a mutation is a new and important utility substantially different from the role of that DNA as it occurs in nature. Indeed, many of the plaintiffs in this case submitted declarations indicating that they wanted to either offer such testing or receive such testing. Unlike *Prometheus*, the claims to short isolated strands of DNA are not directed to the relationship between the mutation and cancer, but rather to a new tool that can be used to determine if that relationship exists. The short isolated DNA sequences have markedly different properties which are directly responsible for their new and significant utility. *Chakrabarty*, 447 U.S. at 309-10. It is not the chemical change alone, but that change combined with the different and beneficial utility that leads me to conclude that small isolated DNA fragments are patentable subject matter. *Id.* at 310.

In fact, much of the dissent's analysis with regard to the full gene would seem to support my conclusion that small isolated DNA molecules are directed to patent-

eligible subject matter. The dissent explains why the baseball bat is directed to patent eligible subject matter: "man has defined the parts that are to be retained and the parts that are to be discarded, and he has molded the retained portion into a product that bears little resemblance to that which occurs naturally." Dissent at 11-12. The exact same thing is true with regard to primer and probe claims. Man has whittled the chromosomal DNA molecule down to a 15 nucleotide sequence – defining the parts to be retained and discarded.[3] And the result is a product with a function (primer or probe) that is entirely different from the full gene from which it was obtained.[4] I conclude that the small, isolated DNA molecules are an alteration of the natural product "with markedly different characteristics from any found in nature and one having the potential for significant utility." 447 U.S. at 310.

Turning now to the longer strands of isolated DNA, isolated strands which include most or all of the gene present a more difficult case. Some of the claims at issue, for example '282 patent claim 5, are genus claims, drafted

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[3] If adding functionality to a naturally occurring molecule, for example adding a lipid chain, is a creation of man then removing functionality, for example truncating a natural DNA sequence or protein to yield smaller molecules with new properties should also be. In either case, it is the intervention of man that created a new molecule. After all, the hand of man is just as apparent in the David, created by removing stone from a block of marble, as the ceiling of the Sistine Chapel, created by adding layers of paint to an existing structure.

[4] The dissent analogizes the full BRCA gene to a slab of marble found in the earth as distinct from the sculpture carved into it – which the dissent indicates would be worthy of intellectual property protection. If the multi-thousand nucleotide BRCA gene is the slab, isn't the 15 nucleotide primer the sculpture?

broadly enough to include both short fragments as well as the entire isolated gene sequence. While I ultimately conclude that these longer isolated sequences, including the isolated gene sequence as a whole, are also patentable subject matter, I do so for a reason different than for the shorter sequences.

All of the same structural arguments apply to any length of isolated DNA so, like the shorter strands, an isolated DNA coding for a gene does have a literal chemical difference from the gene as it appears on the chromosome. Unlike the shorter strands of isolated DNA, the chemical and structural differences in the isolated gene do not clearly lead to an "enlargement of the range of . . . utility" as compared to nature. *Funk Bros.*, 333 U.S. at 131. For example, the full length gene is too large to be used as a probe. *See* J.A. 4322 (a probe is a DNA molecule usually 100-1,000 bases long). Likewise, an entire isolated gene appears unsuitable for use as a primer in genetic screening for mutations in that same gene. *See* J.A. 4323 (Primers "are complementary to an exact location of a much larger target DNA molecule."). The isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence.

If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter. The scope of the law of nature/manifestation of nature exception was certainly enlarged in *Prometheus*. But we do not decide this case on a blank canvas. Congress has, for centuries, authorized an expansive scope of patentable subject matter. Likewise, the United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified

natural products for centuries. There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof.[5] As I explain below, I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved.[6]

III.

For more than a decade the Patent Office's policy has been that "[a]n isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because . . . that DNA molecule does

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[5] *See, e.g.*, U.S. Patent 3,067,099 (claiming vancomycin, an antibiotic produced by bacteria found in soil) and U.S. Patent 4,552,701 (claiming a vancomycin fragment produced by removing a sugar unit). A natural product fragment, for example a naturally occurring antibiotic with a sugar moiety removed, is highly analogous to isolated DNA. In each case, the claimed molecule is a smaller fragment of a naturally occurring molecule, with some naturally occurring functionality removed. *See* U.S. Patent 4,552,701, col.3-4 (compare entry 2 with entries 10 and 13).

[6] My analysis of the claims at issue assumes that they do not include an isolated, full length chromosome. I do not believe that a claim to an entire chromosome, for example chromosome 17, is patentable subject matter. First, there is no indication that the chromosome in isolation has markedly different characteristics compared to the chromosome in nature. Second, unlike claims to isolated genes, there is no indication of either settled expectations or extensive property rights for claims to isolated chromosomes. This is undoubtedly due to the small number of chromosomes as compared to the number of genes.

not occur in that isolated form in nature . . . ." 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). I do not agree with the dissent's characterization of the PTO position as perfunctory. The PTO concluded that isolated DNA is patentable because it is different from what is found in nature – the process of synthesizing it or isolating it changes it. While the PTO lacks substantive rule making authority, it is not without expertise in this area. The explicit statement of the Patent Office's position on isolated DNA, however, is simply a continuation of a longstanding and consistent policy of allowing patents for isolated natural products. *See id.* (noting U.S. Patent 141,072, claiming "[y]east, free from organic germs of disease," issued to Louis Pasteur in 1873); *cf. In re Bergstrom*, 427 F.2d 1394 (CCPA 1970) (isolated prostaglandins patentable). According to the Patent Office, isolated DNA is no different from the isolated natural products of *Parke-Davis*. *See* 66 Fed. Reg. at 1093 (quoting *Parke-Davis*).

Even before the current guidelines formalized the Patent Office's position, it granted patents to human genes in the early 1980s, and subsequently issued thousands of patents on "isolated DNA." Majority at 54. In fact, claims similar to the ones at issue in this case have been the focal point of important litigation. For example, *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991) involved a claim to "'[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.'" *Id.* at 1203-04 (quoting U.S. Patent No. 4,703,008, claim 2). We affirmed that this claim was valid and infringed. *Id.* at 1219. Erythropoietin, also known as EPO, went on to become the biggest-selling biotechnology drug developed to that point, resulted in billions of dollars in sales, and accounted for over 50% of Amgen's revenue in 1997. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 77

(D. Mass. 2001). Isolated DNA claims, at least in the case of Amgen, represent crucial and exceedingly valuable property rights.

The settled expectations of the biotechnology industry – not to mention the thousands of issued patents – cannot be taken lightly and deserve deference. This outpouring of scientific creativity, spurred by the patent system, reflects a substantial investment of time and money by the biotechnology industry to obtain property rights related to DNA sequences. The type of fundamental alteration in the scope of patentable subject matter argued in this case "risk[s] destroying the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). I believe leaving intact the settled expectations of property owners is particularly important in light of the large number of property rights involved, both to isolated DNA and to purified natural products generally.

The Supreme Court has warned that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Id.* at 739. The settled expectations of the inventing community with respect to isolated DNA claims are built upon the broad language of the statute, judicial precedent, such as *Parke-Davis* and *Merck*, and the Patent Office's longstanding policy and practice. Neither *Funk Brothers* nor *Chakrabarty* purported to overrule either the early cases or the Patent Office's practice; indeed, as discussed *supra*, these cases weigh the same considerations as *Parke-Davis* and *Merck*. "'To change so substantially the rules of the game now,'" after more than a century of practice, "'could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.'"

*Festo*, 535 U.S. at 739 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997)).

Although the Patent Office has consistently followed the same policy for a decade (and arguably a century or more), the United States, as an amicus, now argues that the Patent Office's published guidelines are incorrect and a misstatement of the law. In place of these guidelines, the government suggested that a "magic microscope" would provide a useful metaphor for guiding our section 101 analysis. The magic microscope, however, would not see the claimed DNA molecules at issue in this case. An isolated DNA molecule has different chemical bonds as compared to the "unisolated" sequence in the chromosome (the ends are different). In short, the claimed molecules cannot be seen in nature through the magic microscope. While you may be able to see the order of DNA nucleotides in the chromosome, the isolated fragment of DNA is a different molecule. Creating the claimed isolated DNA sequences therefore results in a distinctly unnatural molecule.[7] Even the dissent agrees that the isolated DNA molecules at issue require cleaving chemical bonds, though it disputes the importance of the resulting distinct

[7] This also illustrates why the government's analogies to situations dealing with elements, for example lithium, are inapposite. Even assuming the government's contention that lithium does not currently exist in isolated form in nature, it is nevertheless clear that elemental lithium, a basic building block provided by nature, at some point must have reacted with, e.g., water to form the naturally occurring lithium salts. In contrast, an isolated DNA sequence did not necessarily exist before reacting further to produce the corresponding naturally occurring chromosomal DNA. Unlike a lithium salt, the chromosome does not imply that an isolated DNA molecule of 15 nucleotides – or even a gene – necessarily previously existed as an isolated molecule in nature.

"'molecular species.'" Dissent at 7 (quoting Linus Pauling, *The Nature of the Chemical Bond* 6 (3d ed. 1960)).

The dissent claims that the Patent Office's past views are "substantially undermined by the position the government has taken in this case." Dissent at 20. The Patent Office's prior practice, however, is particularly important since it resulted in a large number of property rights over the past decades. If the government decided to change course in the Patent Office, and decline to issue new patents to isolated genes, it would not impact these existing property rights. This, however, is not what the government argues in this case. Instead the government argues for an entirely different interpretation of the law that would destroy existing property rights. Although the dissent points out that *Chakrabarty* overturned the Patent Office's practice of denying patents to microorganisms, there is a clear difference between allowing additional patent protection where none previously existed, and denying patent protection decades (or centuries) after the fact, thereby eliminating a large number of property rights. *Chakrabarty*, consistent with the broad language of the statute, allowed additional patents where none previously existed. In contrast, the government proposes to destroy existing property rights based on a judge made exception to that same broad language. This is a dramatic step that I believe is best left to the Congress.

Nevertheless, the government claims that "this is a pure question of law" and that we can therefore feel free to ignore the years of Patent Office practice and the accompanying expectations that practice created within the industry. The government argues that we should not defer to the broad language (all but unchanged since 1793) provided by Congress in the patent statute, or allow Congress to decide whether it is necessary to correct the Patent Office's practice through legislation. It is tempting

to use our judicial power in this fashion, especially when the patents in question raise substantial moral and ethical issues related to awarding a property right to isolated portions of human DNA – the very thing that makes us humans, and not chimpanzees.

The invitation is tempting, but I decline the opportunity to act where Congress has chosen not to. Congress at least implicitly approved of the Patent Office's policy of awarding patents on genes and DNA sequences. For example, Congress included, as part of the Patent Office's appropriations, language affirming the Patent Office's interpretation of section 101 to prohibit patents on human organisms. Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101. Although Congress was aware "that there are many institutions . . . that have extensive patents on human genes," 149 Cong. Rec. H7248, H7274, it explicitly declined to implement legislation to "affect any of those current existing patents." 149 Cong. Rec. E2417-01. To the contrary, it made clear that the language related to "human organisms" was not intended to change the Patent Office's policy with respect to claims to genes, stem cells, or other similar inventions.[8] Far from oblivious to the patenting of genes, Congress introduced and declined to pass several bills

[8] "What I want to point out is that *the U.S. Patent Office has already issued patents on genes*, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. *My amendment would not affect the former*, but would simply affirm the latter." 149 Cong. Rec. E2417-01 (emphasis added); *see also* 157 Cong. Rec. E1177-04 (resubmitting this testimony in the context of the current patent reform legislation).

which would put a moratorium on gene patents,[9] authorize funding for the study of whether genes ought to be patentable,[10] and exempt from patent infringement anyone who uses patented genes for non-commercial research purposes or medical practitioners who use genetic diagnostic tests.[11] Congress is obviously aware of the issues presented in this case and I believe "[a]ny recalibration of the standard of [patentability] remains in its hands." *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2252 (2011).

The judiciary cannot engage in an *ad hoc* innovation-based analysis, which is why the exceptions to patentability apply only to the clearest cases: a new mineral discovered in the earth, or a new plant found in the wild, or $E=mc^2$, or the law of gravity. It is Congress, with "the constitutional authority and the institutional ability to accommodate fully the varied permutations of competing interests that are inevitably implicated by such new technology," *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 431 (1984), who must decide whether it is necessary to change the scope of section 101

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[9] At least one bill was introduced in Congress to put a moratorium on patents to human genes or gene sequences. *See, e.g.*, The Animal and Gene Patent Moratorium Bill (S.387 1993).

[10] The Genomic Science and Technology Innovation Act of 2002 (H.R. 3966).

[11] The Genomic Research and Diagnostic Accessibility Act of 2002 (H.R. 3967). As the bill's sponsor explained: "It is important to note that this section would not overturn the commercial rights of patent holders. If a research [organization] utilizing the exemption makes a commercially viable finding, he or she would still have to negotiate any rights to market the new discovery with the patent holder." 148 Cong. Rec. E353-03.

to exclude the kind of isolated DNA claims at issue here. It is not clear to me that *Chakrabarty*, *Funk Brothers*, or *Prometheus* leads inexorably to the conclusion that isolated DNA molecules are not patentable subject matter. I decline the invitation to broaden the law of nature exception.

Given the complicated technology and conflicting incentives at issue here, any change must come from Congress. *See Gottschalk v. Benson*, 409 U.S. 63, 72-73 (1972) (A section 101 analysis raises "considerable problems . . . which only committees of Congress can manage, for broad powers of investigation are needed, including hearings which canvass the wide variety of views which those operating in this field entertain. The technological problems tendered [by the parties] . . . indicate to us that considered action by the Congress is needed.").

IV.

"The rule that the discovery of a law of nature cannot be patented rests . . . on the . . . fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect." *Flook*, 437 U.S. at 593. Is an isolated kidney patentable? Probably not, but as far as I can tell nobody ever thought isolating organs from someone's body was the kind of discovery "that the statute was enacted to protect." In contrast, purifying or isolating natural products has historically been exactly the kind of discovery protected by the patent statutes. There is a century-long history of affirming patent protection for isolated and purified biological products ranging from hormones to vitamins to proteins to antibiotics. These inventions must have seemed miraculous at the time, providing previously unknown therapeutic options to treat sickness. The fact that these molecules might have existed in nature did not foreclose patent protection in

view of the extraordinary benefits accessible to man after isolation.

The Patent Office has, for more than a decade, affirmatively stated its belief that isolated DNA is patentable for the same reasons as isolated vitamins or hormones. There is no indication from Congress that this view is wrong; to the contrary, it appears Congress also believes DNA is patentable. This long-term policy of protecting isolated DNA molecules has resulted in an explosion of innovation in the biotechnology industry, an industry which, unlike the financial services industry or even the software industry, depends on patents to survive. Holding isolated DNA not patentable would destroy long settled industry expectations for no reason other than a gut feeling that DNA is too close to nature to be patentable, an arbitrary decision based on a judge-made exception. I believe that isolated DNA fragments, which have both chemical changes from the naturally occurring genomic DNA as well as new utility, are "the kind of 'discoveries' that the statute was enacted to protect." I therefore decline to extend the "laws of nature" exception to include isolated DNA sequences.

This case typifies an observation by the late Chief Judge Markey, our first Chief Judge, that "[o]nly God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985) (quotation, citations omitted). Human DNA is, for better or worse, one of the old elements bequeathed to men to use in their work. The patents in this case revealed a new molecular understanding about ourselves; "the inventions most benefiting mankind are those that 'push back the frontiers of chemistry, physics, and the like.'" *Chakrabarty*, 447 U.S. at 316 (quoting *Great A.&P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 154 (1950)). We cannot, after decades of

patents and judicial precedent, now call human DNA fruit from the poisonous tree, and punish those inquisitive enough to investigate, isolate, and patent it. "Our task . . . is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted." *Id.* at 318. This inquiry does not have moral, ethical, or theological components. *Cf. id.* at 316-17 ("[W]e are without competence to entertain" arguments about "the grave risks" generated by genetic research.). "The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot." *Id.* at 317. The patents in this case might well deserve to be excluded from the patent system, but that is a debate for Congress to resolve. I will not strip an entire industry of the property rights it has invested in, earned, and owned for decades unchallenged under the facts of this case.