No. 11–725

IN THE

Supreme Court of the United States

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, MS, ELSA REICH, MS, BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Petitioners,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE
and
MYRIAD GENETICS, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICI CURIAE* CANCER COUNCIL AUSTRALIA, THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA, HUMAN GENETIC SOCIETY OF AUSTRALASIA, NATIONAL BREAST CANCER FOUNDATION, MYLES JACKSON PHD, PETER CASHMAN PHD, DAVID KOEPSELL JD, PHD and LUIGI PALOMBI PHD IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

Pages

TABLE OF AUTHORITIES

Cases **Pages**

TABLE OF AUTHORITIES (continued)

Constitution, Statutes, and Regulations

Other Authorities

TABLE OF AUTHORITIES (continued)

Other Authorities (continued) **Pages**

TABLE OF AUTHORITIES (continued)

Other Authorities (continued) **Pages**

STATEMENT OF INTEREST*

Cancer Council Australia is Australia's peak national non-government cancer control organization. It advises the Australian government and other Australian non-government bodies on practices and policies to help prevent, detect and treat cancer. It also advocates for the rights of cancer patients for best treatment and supportive care. It works with its members, the eight Australian state and territory cancer organizations, to undertake and fund cancer research, prevent and control cancer and provide information and support for people affected by cancer.

The Royal College of Pathologists of Australasia, established in 1956, is the leading organization representing pathologists in Australasia. In 1970 Her Majesty, Elizabeth II, assented to the inclusion of "Royal" in the title. Its mission is to train and support pathologists and to improve the use of pathology testing to achieve better healthcare and is responsible for the promotion of the science and practice of pathology in the Australasian region. Pathology is about the study of the causes of disease, and pathologists are the specialist medical doctors involved in the diagnosis and monitoring almost of all acute and chronic ill-

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*No party or counsel for a party authored or contributed monetarily to the preparation or submission of any portion of this brief. Counsel of record for all parties received notice of Amici's intention to file this brief more than 10 days before it was due. Petitioner has filed with the Clerk of the Court a letter granting blanket consent to the filing of *amicus* briefs, and a letter reflecting the consent of respondent to the filing of this brief has been filed with the Clerk.

nesses. It publishes the quarterly scientific journal *Pathology*. Members come from across Australasia including Australia, New Zealand, Hong Kong, Singapore, Malaysia and Saudi Arabia.

The Human Genetics Society of Australasia was formed in 1977 to provide a forum for the various disciplines collected under the title of Human Genetics in the Australasian region. Membership consists of ordinary members who are defined as those who hold a recognized qualification in a discipline relevant to Human Genetics and are employed in a position appropriate to this discipline, whether it be as a teacher, clinician, laboratory scientist, counselor or in pure research. Membership includes those who reside outside Australia, students, organizations and associate memberships. Emeritus membership is achieved by invitation only, in recognition of eminence in the field.

The National Breast Cancer Foundation, established in 1994, is Australia's leading community-funded national organization dedicated to the support, promotion and funding of research into the prevention and cure of breast cancer. It has, to date, been responsible for awarding nearly 300 research projects valued at over $74 million. It is widely recognized by the Australian people, Australian corporations, Australian State and Federal governments and Australian researchers for the charitable services it provides in supporting those affected by breast cancer including their families.

Myles Jackson, PhD is Joint Dibner Family Professor of the History and Philosophy of Science and Technology and the Director of Science, Technology, and Society at the Polytechnic Institute, New York University and also Professor of the History of Science and Technology, The Gallatin

School of Individualized Study of New York University. He was deposed as an expert witness in the U.S. District Court in *Association for Molecular Pathology v. USPTO and Myriad Genetics, Inc.*

Peter Cashman, PhD is the Kim Santow Professor in Law and Social Justice at the University of Sydney. He is Counsel to Cancer Voices Australia in its challenge to the validity of Australian BRCA 1 patent granted to Myriad Genetics, Inc.

David Koepsell, JD, PhD, is a lawyer and philosopher specializing in issues of ethics, technology, and justice. In 2006-7 he was the Donaghue Visiting Scholar in Bioethics at the Yale Center for Bioethics. He currently teaches ethics and engineering at the Delft University of Technology in the Netherlands, and is a senior fellow of the 3TU Ethics Centre. (*See*: *Who Owns You? The Corporate Gold Rush to Patent Your Genes,* (UK: Wiley-Blackwell) (2009)).

Luigi Palombi, PhD, is a lawyer and Visiting Fellow at the Australian National University. He has, since 1993, specialized in the field of biotechnology and gene patents. (*See*: *The Patenting of Biological Materials in the Context of TRIPS*, PhD thesis, The University of New South Wales (2004); *Gene Cartels Biotech Patents in the Age of Free Trade* (Cheltenham U.K. and Northhampton U.S.A.: Edward Elgar (2009)).

SUMMARY OF ARGUMENT

The most fundamental principle of patent law is the social contract between an inventor and the State. At the heart of a patent is an invention. For the purposes of Anglo-American patent law this principle was codified in England in the Statute of

Monopolies of 1623.[1] Revoking "all monopolies" as being "utterly void and of none effect", one of the few exceptions made to this prohibition was for letters patent not exceeding 14 years granted to the "true and first inventor" of "any manner of new manufacture".[2]

This principle was adopted in the U.S. Patents Act, 1790 and continues to be part of U.S. patent law. *Bilski v. Kappos*, 130 S. Ct 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)). As a result, "laws of nature, natural phenomenon, and abstract ideas" are not patentable subject matter.

The application of this principle in a line of U.S. Supreme Court authority starting with *O'Reilly v. Morse* 56 U.S. (How.) 62 (1853) has not, however, resolved the current controversy which has raged for 30 years. Nowhere is this more apparent than on the facts of this case. As to what is a "composition of matter" within 35 U.S.C. § 101 (and therefore patentable subject matter) as distinct from a "natural phenomenon" (and therefore not patentable subject matter), the definitive ruling in *Diamond v. Chakrabarty* ("a new bacterium with *markedly different characteristics from any found in nature* and one having the potential for significant utility" is patentable subject matter). (Id., at 310) has been misapplied by USPTO.

In summary, the first of three issues, which has arisen since *Diamond v. Chakrabarty* and which is raised for the first time in U.S. jurispru-

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[1] The common law first applies this policy in *Darcy v Allein (The Case of Monopolies)* (1602) 77 ER 1260.

[2] Section 6, Statute of Monopolies, 1623.

dence by this case, is whether a biological material, such as a DNA molecule, that has been isolated, in other words, removed from its natural environment but which is otherwise identical, is a "composition of matter" within 35 U.S.C. § 101. That this issue was not reached in *Diamond v. Chakrabarty* is long acknowledged. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177, 189 (1987), BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY, 6 (*Association for Molecular Pathology v. United States Patent & Trademark Office and Myriad Genetics, Inc.* (Fed. Cir.)) and *Intervet, Inc v. Merial Ltd.*, 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J., concurring in part) (observing that "thus far the question as evaded judicial review").

The second issue to arise is the extent to which an artificial construct of a biological material, such as a complementary DNA molecule (cDNA) capable of performing the identical function of the natural DNA molecule, that is, encoding a protein that is identical or substantially identical to the protein encoded by the natural DNA molecule, is a "composition of matter" within 35 U.S.C. § 101. The patent claims in issue are directed to cDNA molecules containing the same, or effectively the same, genetic information encoding naturally occurring human proteins BRCA 1 and BRCA 2, specifically to characteristics, which have been linked to breast and ovarian cancers. The issue, therefore, is the degree of artificiality required to be transformative. Is it enough that the cDNA molecule is man-made?

Finally, the Court in *Diamond v. Chakrabarty* referred to the "gruesome parade of horribles", a

list of negative consequences put up by the U.S. government and other amici, that would befall society should the patenting of genetically modified life forms be allowed (Id., at 316), but ruled it was "without competence to entertain [them] – either to brush them aside as fantasies generated by fear of the unknown, or act on them". (Id, at 317). It, instead, relegated the task of balancing the "competing values and interests" exclusively to the "elected representatives" (Id., at 317) for the reason that its task was "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). That said, there is 150 years of U.S. Supreme Court authority ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable.") which falls fairly and squarely within U.S. Const., Art I, §8, cl. 8.

To be sure, if this narrow approach be correct then it applies equally to both sides of the argument in this case. Accordingly, whatever "gruesome parade of horribles" the patentee and its supporters may predict, they are irrelevant. Nonetheless, there is reason to question the correctness of this approach.

The resolution, by this Court, of these three issues is of great importance to the development of patent law beyond the United States. The Australian patent system shares common roots with the U.S. patent system. It too upholds the fundamental principle of invention and excludes products of nature from patentability. Like the United States there is a need for jurisprudential input on the issues raised by this case. And while the Australian courts are at liberty to come to their own conclusions on Australian patent law, the Austral-

ian High Court is increasingly looking to the jurisprudence of U.S. courts for guidance on patent related issues. ("The reasoning in … United States authorities should be accepted in preference to the path apparently taken in the English decisions, ... The United States decisions reflect an approach to the subject closer to that adopted in *Minnesota Mining* and *Wellcome Foundation*." *Aktiebolaget Hässle v. Alphapharm*. (2002) 212 CLR 411). Presently, there is no Australian court decision on the issues raised in this case. Therefore, in the circumstances, the intersession of this august Court is vital, not only to resolving this longstanding controversy in the United States, but in providing input into the development of societal opinions and patent law in Australia.

ARGUMENT

A. The Social Contract is of Paramount Importance to the Legitimacy of the Patent System.

Whatever the rationale for the creation of statutory monopolies, the social contract is of utmost importance to the legitimacy of the U.S. patent system - indeed, for all patent systems. (*See* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 953 (2007)). It is the social contract between the inventor and the State that links the U.S. patent system to all other patent systems. And it is the most fundamental principle of patent law that without an 'invention' the grant of a patent is void *ab initio*. That a patent is today property, not a

privilege, makes no difference to the application of that principle. A patent can be revoked if the consideration for the social contract, the invention, is found wanting. (*SmithKline Beecham v. Apotex* 403 F 3d 1346 (Fed. Cir., 2006). (Gajarsa J., observing: "Both this court and the Supreme Court have recognized that there is a significant public policy interest in removing invalid patents from the public arena", Id., at 1354).

As to what can be the proper subject of a patent, 35 U.S.C. § 101 lays down the statutory requirements under U.S. patent law. As a result, "laws of nature, natural phenomenon, and abstract ideas" are not patentable subject matter. (*Bilski v. Kappos*, quoting *Diamond v. Chakrabarty*). Anything which falls within the boundaries of this principle is incapable of being the subject of the grant of a valid patent.

Thus the distinction between "composition of matter" and "natural phenomena" must be both comprehensible and strictly applied if the principle, most recently restated by this Court in *Bilski v. Kappos,* is to have any practical purpose in the 21st century. ("*[T]oo much* patent protection can impede rather than "promote the Progress of Science and useful Arts," the constitutional objective of patent and copyright protection. U.S. Const., Art I, §8, cl. 8". Justices Breyer, Souter and Stevens (in dissent on the dismissal of the grant of certiorari) *Labcorp v. Metabolite Laboratories, Inc*. 126 S. Ct 2921 (2006)).

This case highlights the importance of this distinction in the context of the social contract. The subject matter in issue are 'isolated' DNAs and cDNAs, which encode proteins linked to breast and ovarian cancers in humans. Neither the iso-

lated DNAs nor the proteins for which they code, except for the fact that the DNAs are isolated from their natural environments, are different in any material way to what they are and how they function in a human body. They are natural phenomena in every sense of the term. That cDNAs are little more than copies of their natural corresponding counterparts also makes them natural phenomena even though they are artificial. For the first time since USPTO first granted such patents this Court has the opportunity to consider and rule on this most important issue; an issue that unless resolved threatens to undermine the legitimacy of the U.S. patent system, indeed, the legitimacy of other patent systems which have misguidedly followed USPTO policy.

B. The Isolation Contrivance and the Isolation of DNAs and cDNAs.

Naturally occurring biological materials in an isolated or purified form are the same in terms of what they are and what they do except for one thing; they are no longer in their natural environments. This fact is acknowledged in the patents in issue. Taking U.S. Patent 5,747,282 as an example, the definition of 'isolated' or 'substantially pure' is:

> An "isolated" or "substantially pure" nucleic acid (e.g. an RNA. DNA or a mixed polymer) is one which is substantially separated from other cellular components which naturally accompany a native human sequence or protein. e.g., ribosomes, polymerases,

> many other human genome sequences and proteins. The term embraces a nucleic acid sequence or protein which has been removed from its naturally occurring environment. And includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems.

The interchangeability of the word 'isolated' by the term 'substantially pure' in this definition is significant. According to the patent there is no *material point* of physical distinction between something that is 'isolated' from something that is 'substantially pure'. Consequently, an 'isolated' DNA molecule or a 'substantially pure' protein is, by definition, either identical or substantially identical in structure and function to the respective DNA molecule or protein in its natural environment. In other words, the isolation/purification of the relevant DNAs and the proteins for which they code is a form of legal semantics that cannot legitimately differentiate, as a 'fact', one biological material from another. Thus explained the distinction, which the word 'isolation' or the term' substantially pure' imply, is but a contrivance - "the isolation contrivance". The change in physicality is *in situ* not *in substance*. (See Luigi Palombi, *Gene Cartels*, supra, 205-225).

Also notable is the inclusiveness in the definition of "native human sequences" on the one hand and "proteins" on the other. Triplets of DNA, known as "codons" (e.g., GTG, AAG, etc. etc.,) code for a single amino acid (there are 20 naturally occurring amino acids which are the chemical build-

ing blocks of proteins). Though related, they are very different in structure and function. DNA is informational (genetic sequence), whereas the protein (amino acids) encoded by that DNA is the physical manifestation of that information. DNA and the encoded protein are inextricably linked much like the digital information recorded on a DVD is linked to the sound and picture ultimately produced when the DVD is played.

Critically, a change in the DNA sequence produces a change in the three dimensional shape, or structure, of a protein and it is for this reason, particularly true when a diagnostic or therapeutic application of a naturally occurring protein in a human is envisioned, that both the DNA sequence of the DNA molecule and the amino acid sequence of the protein must correspond identically or substantially so, regardless of whether they are isolated or purified or not, to these materials as they exist in nature.

Returning to the '282 patent, the definition of "BRCA1 Locus", "BRCA1 Gene" and "BRCA1 Nucleic Acids" or "BRCA1 Polynucleotide" links them to:

> a sequence which is either derived from or substantially similar to a natural BRCA1-encoding gene or one having substantial homology with a natural BRCA1-encoding gene or a portion thereof. The coding sequence for a BRCA1 polypeptide is shown in SEQ ID NO:1. with the amino acid sequence shown in SEQ ID N0:2.

Turning specifically to claim 1 of the '282 pa-

tent, the invention is defined as follows:

> 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID N0:2.

In simple terms, the subject matter of the patent as defined in claim 1 is a biological material in an isolated form, but, which is in every other way identical to what exists in nature. Indeed, the accuracy and reliability of a diagnostic test using this material to produce a clinically significant result is dependent upon that *exact* identity.

The logical law of identity is one of the three foundational laws of logic identified by Aristotle, and accepted as an axiom in the sciences even today. Simply put, the law states: A=A. (*See*: Irving M. Copi and Carl Cohen, *Introduction to Logic, 11th Edition* (USA: Prentice Hall) (2001)). The isolation contrivance, however, violates the law of identity. Logically, it suggests that Joseph Priestley would have been entitled to a patent on oxygen given his discovery of a new *process* for liberating and isolating oxygen from mercuric oxide. This 'isolation' of a naturally-occurring molecule, otherwise morphologically identical to oxygen in other forms, would arguably produce a patent-eligible *product* under Section 101. But it defies logic and is precisely analogous to the present dispute about the patented BRCA1 and 2 genes. It also illustrates the absurd implications of the isolation contrivance.

As explained above, the patented *product* encompasses a product that is morphologically identical to the naturally-occurring BRCA1 and 2

genes, (*See*: David Koepsell, *Who Owns You? The Corporate Gold Rush to Patent Your Genes*, (UK: Blackwell-Wylie) (2009), p. 6) just as Dr. Priestley's oxygen is identical to the oxygen produced naturally by photosynthesis. In essence, under modern patent law, isolation contrivance says that A does not equal A, or oxygen does not equal oxygen, or BRCA1 and 2 do not equal BRCA1 and 2. The law ought to be consistent at the very least with the fundamental laws of thought, rules of logic that make argumentation both possible and useful, and axioms that underlie all the sciences. By perpetuating this notion, that somehow identical biological materials are not identical because one is isolated and the other is not, is not only strained, but illogical.

C. "Everything Under the Sun Made By Man".[3]

Historically the U.S. Supreme Court has invalidated patents on the grounds that they are "products of nature". (*American Wood Paper v. Fibre Disintegrating*, 90 U.S. 566 (1874); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

The eligibility of patenting products of nature arose in *General Electric Co. v. De Forest Radio*

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[3] ["Under] section 101 a person may have invented *a machine or a manufacture*, which may include anything under the sun that is made by man. ...". (Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951). (Emphasis added)

Co. 28 F.2d 641 (3rd Cir., 1928). ("[A] patent cannot be awarded for a discovery or for a product of nature, or for a chemical."). (Id., at 642). Dr. William D. 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 WO_3 (tungsten III oxide) into pure tungsten. First, WO_3 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. However, the court denied his patents on the so-called pure tungsten. ("[W]ho 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."). (Id., at 643). Similarly, genes have existed in nature for centuries and the fact that the patentee linked naturally occurring DNA to naturally occurring proteins that are causative of breast and ovarian cancers does not negate their origin.

The Court also questioned whether the properties of the tungsten produced by the Coolidge process (ductility and a high tensile strength) could be attributed to Dr. Coolidge. ("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."). (Id., at 643). Similarly, the sequence of the gene, the sequence of variants, and the signi-

ficance of the variants have always been there and their characteristics, to use the language of Court in *Diamond v. Chakrabarty,* cannot be attributed to their isolation or purification.

Mr. Pascquale J. Federico, referred to in a footnote in the *Diamond v Chakrabarty* decision, had been an employee of the USPTO for 5 years when *General Electric Co. v. De Forest Radio Co.* was handed down. Having risen through the ranks of the USPTO to Division Chief in 1940 and appointed to the Board of Patent Appeals in 1947, in 1950 he was assigned the task of drafting what became the Patents Bill in 1951. And it was during testimony to a Congressional review of the Patents Bill that he made one of the most often cited statements in modern patent law and one cited with approval by the Court in *Diamond v Chakrabarty*, namely: ["Under] section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. ...". (Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951), referred to in *Diamond v Chakrabarty*, footnote 6 at 309).

Even so the Court qualified Mr. Federico's words in the context of 35 U.S.C. § 101 by reinforcing the fundamental principle that "laws of nature, physical phenomena, and abstract ideas" remain outside of the "broad language" used to define "statutory subject matter". The genetically modified bacterium in issue in that case was ruled to be patentable subject matter *only* because it displayed "markedly different characteristics from any found in nature". And while the Court also found that "the respondent's micro-organism is the result of human ingenuity and research", it

was not decisive. Accordingly, artificiality per se is not sufficiently transformative of a natural biological material. Much more is required.

However, USPTO misapplied *Diamond v. Chakrabarty* by relying on Mr. Federico's words as if they are, by themselves, an accurate restatement of statutory subject matter. Compounding the problem and providing some, albeit erroneous, justification for its policy is *Parke-Davis & Co. v. H. K. Mulford Co.* (189 F. 95, 1911), which concerns a patent granted over purified adrenalin. It is often cited by proponents of the patenting of isolated DNAs and cDNAs, yet the Federal Circuit distinguishes it on its facts. (per Lourie J., "*Parke-Davis* and *Marden* address a situation in which claimed compound A is purified from a physical mixture that contains compound A. In this case, the claimed isolated DNA molecules do not exist as in nature within a physical mixture to be purified").

Recognizing the problem with *Parke-Davis & Co.* the Federal Circuit attempts to apply the distinction between a "product of nature" and a "human-made invention" on the basis that the isolated DNAs in issue are, "chemically cleaved from their chemical combination with other genetic materials [and] … when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity." (per Lourie J.) Apart from the fact that neither the patentee in submission nor in evidence made this point, the patent itself makes no such distinction and defines the term "isolated" by reference to both DNAs and proteins having been "substantially separated from other cellular components which naturally accompany a native human sequence or

protein." It also expressly defines the term "isolated" to mean the same as "substantially pure". ("The term embraces a nucleic acid or protein which has been removed from its naturally occurring environment …"). ('828 at 19, lines 13-15). The patent's very language therefore undermines the Federal Circuit's reasoning, which brings *Parke-Davis & Co.* back into contention. (For a critique of the reasoning in *Parke-Davis & Co*: *See* Jon M. Harkness, *Dicta on Adrenalin(e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in Parke Davis v Mulford,* 93(4), J. PAT. OFF. SOC., (*forthcoming* 2011)). The same concerns arise with regard to cDNAs.

In other words, was the patented bacterium in *Diamond v. Chakrabarty* "new" merely because it was artificial? If it was, then how is it reconciled with *Cochrane v Badische Anilin & Soda Fabrik* 111 U.S. 293 (1884)? ("Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared artificially for the first time from anthracene, if it was set forth as alizarine, a well known substance."). (Id., at 311). The answer to this question is also of relevance in view of *Ex parte Latimer,* 1889 Dec. Com. Pat. 123 in which the Commissioner of Patents rejected a claim to a naturally occurring biological material, a fiber derived from the needle of a species of pine tree, even though it was in an 'isolated' form. ("[P]atents [to] be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible."). (Id., at 126). The patenting of new varieties and cultivars of plants is noteworthy since the relevant policy issues concerning their patenting were only re-

solved by specific legislation. (*See* Plant Patent Act, 1930 and the Plant Variety Protection Act, 1970). To be sure, in passing the Plant Patent Act, Congress "recognized the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions" (*Diamond v. Chakrabarty*, 447 U.S. 303, 313), but even so, how much "human ingenuity and research" (Id., at 313) is required before an artificial product derived from a naturally occurring biological material, such as the cDNA molecules at issue in this case, is patentable subject matter?

D. The U.S. Supreme Court's Role in Regard to Patent Policy.

The Court in *Diamond v. Chakrabarty* ruled that the task of balancing the "competing values and interests" over the patenting of life forms was a matter exclusively for the "elected representatives". (Id., at 317). It also narrowly construed the role of this Court: ([Its 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). That said, there is 150 years of U.S. Supreme Court authority ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable.") which falls fairly and squarely within U.S. Const., Art I, §8, cl. 8.

Nonetheless, there is reason to question this Court's narrow approach in *Diamond v. Chakrabarty* in the formulation of patent policy. Indeed, one need only look to the role the courts played in the 19th century, in transforming patents from a

privilege into a property right, to realize how they have shaped modern patent law. (*See* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 953 (2007)). At what point does this august Court abrogate its responsibility to society? ("*[T]oo much* patent protection can impede rather than "promote the Progress of Science and useful Arts," the constitutional objective of patent and copyright protection. U.S. Const., Art I, §8, cl. 8". (per Justices Breyer, Souter and Stevens in dissent in *Labcorp v. Metabolite Laboratories, Inc.* 126 S. Ct 2921 (2006)).

Respectfully, if statutory interpretation be this Court's only role then it must, for two reasons, reconsider the reliance placed by the Court in *Diamond v. Chakrabarty* on the Congressional testimony of Mr. P. J. Federico. ("[Under] section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. ..." Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951). (Id., at 309)).

First, Mr. Federico was greatly influenced by Judge Learned Hand's decision in *Parke-Davis & Co.* (*See* P. J. Federico, *Patents For New Chemical Compounds*, 21(7) J. PAT. OFF. SOC., 544, (1939), 549, fn 9). The problem, however, is that patentable subject matter was not in issue in that case. Accordingly, Judge Hand's comments were strictly *obiter dicta* ("... even if it were merely an extracted product without change, there is no rule that such products are not patentable subject matter."; Id., at 103). Understandably, Judge

Hand did not address *Ex parte Latimer* 1889 Dec. Com. Pat. 123. (*See* Jon M. Harkness, *Dicta on Adrenalin(e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in Parke Davis v Mulford,* 93(4), J. PAT. OFF. SOC., (2011), Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NAT. REVS: GENETICS, 803 (2002), and J. Doll, *The Patenting of DNA*, 280 SCIENCE, 689 (1998)).

Secondly, in 1939 Mr. Federico posed this question: "[i]f a substance, hitherto not known to exist, is discovered in some plant or animal material, extracted in concentrated or pure form, and demonstrated to be highly useful, can the product be patented?". (Id, at 549). To which he replied: "A categorical answer of 'No, because the substance is not really new,' cannot be made". (Id., at 549). This answer, given some 14 years before Drs. James Watson and Francis Crick discovered the molecular structure of DNA reveals, even with the benefit of hindsight, a rudimentary understanding of the biological sciences and an idiosyncratic approach to what is 'new'. (Id., at 549).

It is arguable, on the basis of this perspective, that in 1951 Mr. Federico's opinion that "anything under the sun made by man" was patentable subject matter was erroneous. Artificiality *per se* was neither then, nor has it since been, the sole indicium of patentable subject matter. In fact, apart from *Parke-Davis & Co.* there was no authority in 1951 for such a proposition in law. More to the point, the Court in *Diamond v. Chakrabarty* has since unequivocally stipulated that artificiality *per se* is not enough ("markedly different characteristics from any found in nature", Id., at 310). Whatever remaining argument, no matter how

flawed it might be, over how to draw the line between "composition of matter" and "natural phenomena" must be erased once and for all.[4]

E. Clarification is a Matter of Great Importance to Health Policy and National Security.

The need for clarification with respect to these issues is not only of "great importance to the national economy, to medical science, and to the public health". (*See* BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY, 6 (*Association for Molecular Pathology v. United States Patent & Trademark Office and Myriad Genetics, Inc.* (Fed. Cir., 2010)). It is also of great importance to the national security of the United States for the reason that should the threshold of patentability be set too low, the U.S. patent system may be used, much like it was used by German chemical companies prior to WWI, to suppress chemical research and industry within the United States, to suppress medical and scientific research and industry in the future. (*See* Floyd W. Vaughan, *Suppression and Non-Working of Patents, With Special Reference to the Dye and Chemical Industries*, 9 AMER. ECO. REV., 693

[4] Mr. Federico conceded that the patent claim granted to Louis Pasteur (U.S. Patent No. 135,245 granted January 28, 1873: "Yeast, free from organic germs, as an article of manufacture.") would have "probably been refused by [an] examiner" in light of *American Fruit Growers v. Brogdex* 283 U.S. 1 (1931). (See P.J. Federico, *Louis Pasteur's Patents*, 86 SCIENCE, 327 (1937).

(1919); Kathryn Steen, *Patents, Patriotism, and "Skilled in the Art"*, 92 ISIS, 91 (2001); Luigi Palombi, *Gene Cartels*, supra, 36-91).

Allowing the patenting of chemical substances in the United States, producing very negative impacts of American industrialization prior to and during WWI, should be a reminder of the adverse impact of too liberal a patent policy in regard to isolated DNAs and cDNAs. And the concerns expressed by the Commissioner of Patents in *Ex Parte Latimer* Dec. Com. Pat 123 (1889) in the context of plant materials, made using a hypothetical example, are equally applicable here:

> The result would be that an alleged inventor in Germany would acquire a patent which would give him the exclusive use of *Pinus sylvestris*, the applicant in this case would secure a patent for the fibre of the *Pinus australis*, and thus, successively, patents might be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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