Appeal No. 2010-1406

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,

(For Continuation of Caption See Inside Cover)

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 FOR NOVARTIS CORPORATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT MYRIAD GENETICS, INC.

AARON STIEFEL
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
(212) 836-8000

SYLVIA M. BECKER
KAYE SCHOLER LLP
901 Fifteenth Street, NW
Washington, DC 20005
(202) 682-3500

Attorneys for Amicus Curiae

October 29, 2010

– 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.

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Novartis Corporation certifies the following:

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

   Novartis Corporation.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   None.

3. All parent corporations and any publicly held companies that own 10% or more the stock of the *amicus* that I represent is:

   Novartis Corporation is a wholly owned subsidiary of Novartis Holding AG, which is wholly owned by Novartis AG.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* represented by me in the trial court or agency or are expected to appear in this court are:

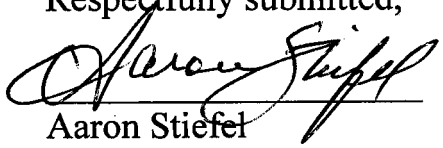
   Novartis Corporation did not appear in the trial court. Before this Court, Novartis Corporation is represented by:

Of Counsel
Sylvia M. Becker
KAYE SCHOLER LLP
901 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 682-3500

Aaron Stiefel
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Counsel for *Amicus Curiae*
Novartis Corporation
(212) 836-8000

Dated: October 29, 2010

Respectfully submitted,



Aaron Stiefel
Counsel for Novartis Corporation as Amicus Curiae

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

Novartis Corporation ("Novartis") is an indirect wholly owned subsidiary of Novartis AG, a Swiss holding company, whose affiliates around the world provide healthcare solutions that address the evolving needs of patients and societies. Novartis is a U.S. holding company which owns, directly or indirectly, several of Novartis AG's subsidiaries and affiliates. Focused solely on healthcare, the Novartis companies offer a diversified portfolio to best meet patient and societal needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products.

The Novartis companies rely on the patent system to protect their many innovations in patient care. Without the promise of exclusionary rights in validly patented subject matter, the investment incentive for the research and development required to discover innovative pharmaceutical and diagnostic products is substantially diminished.

Novartis has great interest in this case because the district court's decision threatens to remove from patent eligibility, under 35 U.S.C. § 101, the fruits of the enormous investment made by the Novartis companies in research, development and manufacturing which provide much-needed healthcare solutions to patients and societies. The patentability of DNA molecules and other purified biological materials is the bedrock of the biotechnology industry which has and

will, if afforded the necessary intellectual property protections, continue to produce extraordinary breakthroughs in the diagnosis and treatment of disease. Affirming the district court's decision would have an immediate, negative impact on the public by undermining the basis on which Novartis's subsidiaries and affiliates as well as other life sciences companies have invested and plan to continue to invest vast research and development resources.

Novartis submits this brief in support of reversal of the district court's decision in order to preserve the future of biotechnology research and avoid the inevitable negative consequences which the district court disregarded.

Novartis has no stake in any of the parties to this litigation or the specific disposition of this case, nor has any of the parties contributed to preparing this brief.[1]

INTRODUCTION

At the heart of the biotechnology research conducted by life sciences companies, such as Novartis's subsidiaries and affiliates, is the identification, production, amplification and use of isolated DNA sequences. Inside the body, DNA is hidden in chromosomes -- strands of millions of base pairs of DNA that contain many genes -- where the DNA is bound to proteins that are integral to the

[1] As required by Federal Rule of Appellate Procedure 29(a), Novartis states that all parties to this appeal have consented to the filing of this brief.

structure of the chromosome. Although the DNA "codes for" the multitude of proteins that the body manufactures, native DNA contains inoperative non-coding sequences as well. Thus, *in situ*, DNA is unknown, unavailable and unusable. Biotechnology research is directed to identifying operative DNA sequences and recreating them in a purified form in the laboratory where they can be put to a host of diagnostic and therapeutic uses. Such isolated DNA molecules are not found as such in nature and thus were not previously available to mankind. The patent eligibility that has for decades been afforded to isolated DNA molecules which prove to have utility when recreated outside of the body is what allows researchers to devote significant resources to discovering such DNA. That research in turn yields monumental advances in the treatment and prevention of disease.

The decision of the court below threatens the underpinnings of biotechnology research by removing the incentives for conducting the costly and time consuming research needed to identify and isolate previously unknown DNA sequences. As shown below and in the briefs of the Appellants and other *amici curiae*, the decision of the district court is not only contrary to the public interest, but also at loggerheads with longstanding precedent. The decision below should, therefore, be reversed.

ARGUMENT

Novartis urges this Court to reverse the decision below based on the briefs submitted by *amicus curiae* Pharmaceutical Research and Manufacturers of America and Biotechnology Industry Organization. Novartis adds the following additional argument.

A. The District Court Erred In Treating DNA As Uniquely Unpatentable

In the startling words of the district court, its conclusions "concerning the subject matter patentability of isolated DNA . . . are based on the unique properties of DNA that distinguish it from all other chemicals and biological molecules found in nature." (A.216 n.51.)[2] The court stated that the "informational quality" of DNA "is unique among the chemical compounds in our bodies, and it would be erroneous to view DNA as 'no different[]' than other chemicals previously subject of patents." (A.216.)

In choosing to focus on the informational aspect of DNA to the exclusion of its material composition, the district court dismissed the fact that DNA is indisputably a chemical molecule comprised of atoms. DNA is thus fundamentally no different from other chemicals. *See Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) ("A gene is a chemical

[2] Materials in the Joint Appendix, which was filed with Appellants' Brief, are cited as "A.___."

compound, albeit a complex one . . . ."). Simply put, isolated DNA is without question a "composition of matter" that is patentable subject matter under 35 U.S.C. § 101.

The district court cites no basis for treating DNA differently from any other composition of matter under the patent laws. As Appellants and the *amici* point out, over the course of decades this Court and its predecessor have, at least implicitly, repeatedly confirmed the patentability of isolated DNA molecules. *See e.g.*, *In re Kubin*, 561 F.3d 1351, 1352 (Fed. Cir. 2009) (characterizing "the isolation and sequencing of a human gene that encodes a particular domain of a protein" as "a classic biotechnology invention"); *Amgen, Inc.*, 927 F.2d at 1207-09 (holding claim to "a purified and isolated DNA sequence" nonobvious); *see also* cases cited at Appellants' Br. at 38-39.

The United States Patent and Trademark Office ("PTO") too has consistently allowed claims to isolated DNA sequences, recognizing that they differ from DNA found in the body: "A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature." *USPTO Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1093 (2001).

Thus, affirmance of the district court's decision will upset the settled and well founded expectations in the biotechnology field that isolated DNA

molecules are patentable and that the invention of such useful molecules is protectable.

B. The District Court Erred In Invoking A Broad Exclusion From § 101 For "Products of Nature"

The district court also erred in applying a broad exception to the scope of patentable subject matter under 35 U.S.C. § 101 for "products of nature." The United States Supreme Court has pointed to the use of the term "any" -- which appears twice in § 101 -- as reflecting that "Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). As the district court observed, the Supreme Court has articulated just three exceptions from what is patentable subject matter under § 101: "laws of nature, physical phenomena, and abstract ideas." (A.190.) Clearly, however, isolated DNA molecules do not fall within any of these narrow exceptions. Nonetheless, the district court insists that an isolated DNA molecule is excluded from the broad scope of § 101 as a "product of nature." (A.225-28.) Again, however, the district court's position is at odds with longstanding precedent which recognizes the patentability of pure forms of naturally-occurring products which do not exist in pure form in nature. (*See* Appellants' Br. at 36.) The patentability of such purified products -- not limited to DNA molecules -- is a cornerstone of the biotechnology industry.

Moreover, the district court confuses the concepts of patentable subject matter and novelty. As a "composition of matter," DNA is patentable subject matter in accordance with the plain language of § 101. The district court deems isolated DNA not patentable subject matter because it is not "markedly different" from a product of nature. (A.214-28.) But that is a matter of novelty, not subject matter patentability. Nevertheless, even if DNA is viewed as information, the information contained in isolated DNA is markedly different from that in DNA found in nature because, until DNA is isolated and purified, the genetic code contained in the DNA and its utility and use for the advancement of science and benefit of patients would remain unknown. The patent eligibility of isolated DNA is essential to affording society access to a wealth of research and understanding about diseases.

The only question before this Court is what types of inventions should be eligible for utility patent protection -- not whether the DNA claimed by defendant Myriad was new, nonobvious, properly disclosed and supported by the specification. The district court acknowledged defendant Myriad's showing as to the "structural and functional differences" between native DNA and isolated DNA. (A.217-18.) The court concluded, though, that those differences should be disregarded, under § 101, owing to "DNA's unique qualities as a physical embodiment of information." (*Id.*) That notion has no basis in law. The

patentability of a DNA molecule should turn -- as does the patentability of all molecules -- on whether the particular DNA in question is novel, obvious and enabled by the patent specification. DNA should not be unpatentable as ineligible subject matter under § 101.[3]

C. Affirming The District Court's Decision Would Greatly Reduce The Incentive For Novartis To Invest In Biotechnology Research

Novartis's subsidiaries and affiliates as well as others in the biotechnology field would be directly and severely affected by an affirmance of the decision below and its research plans would necessarily have to change dramatically. The public interest in the fruits of such research would necessarily suffer as well. The Novartis companies alone would face losses totaling hundreds of millions of dollars in lost sales of products which could be copied by others with impunity and lost royalties under licenses to their patents.

For example, Novartis Vaccines & Diagnostics, Inc. ("NVD") (previously Chiron Corporation) has long been at the forefront of biotechnology

[3] The method claims at issue in this case are also directed to patentable subject matter because the claimed methods -- which involve "analyzing" a gene sequence "from a human sample" -- require the transformation of materials, *e.g.*, isolating a test sample and then sequencing the DNA. *See Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1347 (Fed. Cir. 2009), *vacated*, 130 S. Ct. 3543 (2010) ("Some form of manipulation . . . or other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. . . . That is clearly a transformation.").

research. The company currently markets products used to screen the blood supply for various pathogens, markets life-saving vaccines and is developing products to quickly identify life-threatening hospital-acquired diseases. NVD devoted nearly a decade to identifying, isolating, characterizing and cloning the genome of the Hepatitis C Virus ("HCV"). Using the patented DNA, NVD was able to develop screening techniques that allow testing the blood supply for Hepatitis C. Today, the world's blood supply is virtually free of HCV. Similar work by NVD has yielded products employing DNA sequences derived from genomes of pathogens to test the blood supply for HIV, Hepatitis B and West Nile Viruses. Absent the ability to protect its work product by patenting isolated DNA sequences, these costly projects would never have been attempted and the world's blood supply would be far less safe.

Today, NVD is developing, among other things, genetic testing products that use DNA derived from the human genome to safely identify hereditary diseases in early stage fetuses and to develop and screen a nationwide bone marrow bank. These projects and similar future projects depend on Novartis being able to protect its investments in intellectual property and the research, development and manufacturing of these products.

The protections provided by patent eligibility have fueled and continue to fuel not only investments by the Novartis companies in research but

also the local economies in which Novartis maintains research and development facilities. Despite the present economic crisis in the United States, Novartis AG recently announced that one of its research sites is doubling the size of a planned office and lab complex in Cambridge, Massachusetts, spending $600 million to bolster its research operations and strengthen partnerships with local universities and biotechnology start-ups. An additional 200 to 300 employees are to be hired over the next five years, which would bring the total Novartis workforce in Cambridge alone to about 2,300.

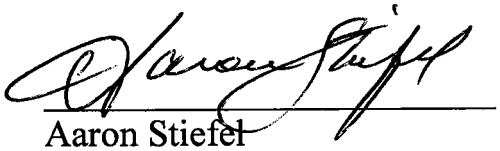
In sum, there is no disputing the fact that biotechnology research can be extraordinarily time-consuming and costly. As a practical matter, life-sciences companies simply cannot afford to put at risk the resources necessary to identify the DNA in elusive disease causing pathogens or the DNA necessary to express therapeutic biological agents if they will be unable to recoup their costs in those instances in which their efforts yield useful products. Patent protection of DNA discovered and isolated in the course of such research projects is necessary to incentivize the innovator to make the necessary investments and to prevent copiers from depriving innovators of the benefits of their hard-earned inventions. Affirmance of the decision below would upset settled expectations and, much to the detriment of society, drastically alter the way in which biotechnology research is conducted.

CONCLUSION

For the foregoing reasons, and those set forth in the briefs submitted by Appellant and *amicus curiae* Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization, the district court's grant of summary judgment on the ground of § 101 invalidity should be reversed.

Dated: October 29, 2010

Respectfully submitted,



Aaron Stiefel
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000

Sylvia M. Becker
KAYE SCHOLER LLP
901 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 682-3500

Counsel for Amicus Curiae
Novartis Corporation

CERTIFICATE OF COMPLIANCE

I, Aaron Stiefel, hereby certify under Federal Rule of Appellate Procedure 32(a)(7) that this brief is proportionately spaced, has a typeface of 14 points, in Times New Roman font, and contains 2312 words as counted by Microsoft Word 2007, the word processing program used to prepare the brief.

Dated: October 29, 2010

Aaron Stiefel