No. 08-964

IN THE

Supreme Court of the United States

BERNARD L. BILSKI AND RAND A. WARSAW,
Petitioners,
v.

JOHN J. DOLL, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Respondent.

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

BRIEF OF AMICUS CURIAE
THE UNIVERSITY OF SOUTH FLORIDA
IN SUPPORT OF PETITIONERS

Jeff Lloyd
Counsel of Record
Saliwanchik, Lloyd & Saliwanchik
A Professional Association
P.O. Box 142950
Gainesville, FL 32614-2950
(352) 375-8100

Attorney for Amicus Curiae
The University of South Florida

TABLE OF CONTENTS

Table of Contents i

Table of Cited Authorities ii

Interest of Amicus Curiae..... 1

Summary of the Argument 3

Argument..... 4

I. The Federal Circuit's new test is overly restrictive. ..4

II. The Framers of the Constitution intended to promote advances in medical diagnosis and treatment. 6

III. Congress intended advances in medical diagnosis and treatment to be patentable subject matter.....12

Conclusion 16

TABLE OF CITED AUTHORITIES

CASES

Classen Immunotherapies, Inc. v. Biogen IDEC, 304 F.App'x 866 (Fed. Cir. 2008) 2, 4-5
Classen Immunotherapies, Inc. v. Biogen IDEC, Civil No. WDQ-04-2607, 2006 WL 6161856 (D. Md. Aug. 16, 2006)..... 5
Diamond v. Chakrabarty, 447 U.S. 303 (1980).. 12-14
Diamond v. Diehr, 450 U.S. 175 (1981)..... 15
Gottschalk v. Benson, 409 U.S. 63 (1972)..... 4
Graham v. John Deere, 383 U.S. 1 (1966)..... 6-7
In re Bilski, 545 F.3d 943 (Fed. Cir. 2008).....*passim*
Parker v. Flook, 437 U.S. 584 (1978)..... 4
United States v. Dubilier Condenser Corp., 289 U.S. 178 (1933)..... 14-15

STATUTES

35 U.S.C. § 101 (2006)..... 13
35 U.S.C. § 287 (2006)..... 14
Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, 110 Stat. 3009-67 14
U.S. CONST. art. I, § 8, cl. 8..... 6

OTHER AUTHORITIES

1 WILLIAM CULLEN, FIRST LINES OF THE PRACTICE OF PHYSIC (New York, L. Nichols 1801)..... 11
3 A SOC'Y OF GENTLEMEN IN SCOT., ENCYCLOPÆDIA BRITANNICA (1st ed. 1771) 7, 10-11
HIPPOCRATES, THE OATH AND LAW OF HIPPOCRATES, reprinted in 38 HARVARD CLASSICS, pt. 1 (Charles W. Eliot ed., P.F. Collier & Son 1910) (1909) 6
THOMAS JEFFERSON, WRITINGS (Merrill D. Peterson ed., Library of America 1984)..... 8-10

INTEREST OF AMICUS CURIAE[1]

The University of South Florida (hereinafter, "USF") is the nation's ninth largest public university and a leading research institution. Founded in 1956, USF has over 46,000 students and more than 13,000 faculty and staff members, with an annual operating budget in excess of $1.8 billion dollars. USF's mission includes research and scientific discovery for the generation, dissemination, and translation of new knowledge across disciplines; to strengthen the economy; to promote civic culture and the arts; and to design and build sustainable, healthy communities. Fueled by its research efforts, USF has a substantial economic impact on its region estimated at over $3.2 billion dollars annually.

USF medical researchers strive to expand the frontiers of medicine, searching for improved methods of diagnosing, prognosing, and treating diseases such as cancer, HIV, diabetes, and neurological disorders such as Alzheimer's and Parkinson's diseases. USF is one of the top 50

---

[1] In accordance with Supreme Court Rule 37, *amicus curiae* states that this brief was not authored in whole or in part by counsel for any party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than *amicus curiae* or its counsel. Counsel of record for all parties were timely notified 10 days prior to the filing of this brief. Petitioners have consented to the filing of all *amicus curiae* briefs in support of either or neither party, and respondent has consented to the filing of this brief via a separate letter of consent dated July 14, 2009. A copy of this letter has been filed with the Clerk of the Court.

medical schools receiving funding from the National Institutes of Health, and USF's Pediatric Epidemiology Center has received over $300 million dollars in NIH funding to direct global efforts in juvenile diabetes research. For the 2007/2008 fiscal year alone, USF was awarded more than $360 million dollars in research contracts and grants. USF's hospital partners, Tampa General Hospital and the H. Lee Moffitt Cancer Center and Research Institute, have been ranked among the nation's top 50 hospitals by U.S. News & World Report; and USF is classified by the Carnegie Foundation as a top tier research university.

USF has a diverse portfolio of patents and pending patent applications across a wide range of medical technologies, which through USF's licensing efforts generate additional funding to support further research. The new patent eligibility standards adopted by the Court of Appeals for the Federal Circuit in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), and as applied by the Federal Circuit in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 F.App'x 866 (Fed. Cir. 2008), if allowed to stand and proceed unchecked may have an adverse affect on USF's research programs.

Amicus curiae therefore submits this brief to present argument in support of an affirmative response to the first question presented. Amicus curiae presents no argument here on the second question presented.

SUMMARY OF THE ARGUMENT

The Federal Circuit's "machine-or-transformation" test is more restrictive than any Supreme Court precedent, excluding from patent eligibility certain processes that Congress intended to be patent eligible. The test has been applied to invalidate issued claims directed to certain medical methods. There is no legislative basis for such a restriction. Methods that promote the progress of medicine, diagnosis and treatment in particular, were clearly contemplated by the Framers of the Constitution as well as members of Congress to be patent eligible. Courts should not read into the patent laws limitations and conditions which Congress has not expressed. Despite this, the Federal Circuit adopted the "machine-or-transformation" test as the sole test for patent eligibility of a process, thereby excluding from patent eligibility subject matter that Congress clearly considered patent eligible. This was error. The first question presented should be answered in the affirmative, and the Federal Circuit's error should be reversed.

ARGUMENT

I. The Federal Circuit's new test is overly restrictive.

The Federal Circuit's holding that a process claim that "neither recites a particular machine or apparatus, nor transforms any article into a different state or thing, is not drawn to patent-eligible subject matter" unnecessarily, unwisely, and improperly excludes from patent protection technologies that Congress clearly intended to be patentable. *In re Bilski*, 545 F.3d 943, 961 (Fed. Cir. 2008). This "machine-or-transformation" test is useful as a **starting point** for determining whether process claims are directed to patent eligible subject matter. This Court has held that the "machine-or-transformation" test is sufficient to qualify a process claim as patent eligible, but the Court has declined to state that passing this test is a necessary requirement for the patent eligibility of a process claim. *See Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972). Excluding from patent eligibility certain processes involving medical diagnosis and treatment merely because they do not recite a particular machine or apparatus or transform an article into a different state or thing is improper, as such processes are unquestionably within the realm of patent eligible subject matter. Yet this is exactly what the Federal Circuit's "machine-or-transformation" test has done.

The Federal Circuit first applied its new "machine-or-transformation" test in a single-paragraph, nonprecedential opinion in *Classen*

Immunotherapies, Inc. v. Biogen IDEC, affirming a district court judgment invalidating claims to methods of immunizing a mammalian subject.[2] 304 F.App'x 866 (Fed. Cir. Dec. 19, 2008), *reh'g denied en banc reh'g denied* (Feb. 9, 2009). While the claims at issue might well have been found invalid on other grounds (for example, as obvious or anticipated), as discussed below, they are certainly within the realm of subject matter contemplated as patent eligible by the Framers of the Constitution and Congress. Thus, applying the "machine-or-transformation" test as the

---

[2] The district court had summarized the *Classen* claims as requiring "1) comparing the incidence of immune mediated disorders in treatment groups with different vaccination schedules; and 2) immunizing patients on a schedule identified as low risk." *Classen Immunotherapies, Inc. v. Biogen IDEC*, Civil No. WDQ-04-2607, 2006 WL 6161856, at *5 (D. Md. Aug. 16, 2006). Rather than properly construing the claims as "a method for reducing the incidence of chronic immune mediated disorders" and recognizing that an improved process of vaccination is a human invention, the district court held that the claims describe a natural correlation. *Id.* Characterizing the correlation between vaccination schedules and incidents of immune mediated disorders as a natural phenomenon, the court held the claims invalid as an attempt to patent a natural phenomenon. *Id.* The district court's reasoning was faulty: the existence of an immune response in mammals is a natural phenomenon. Human experimentation, manipulation, and optimization of the immune response to achieve beneficial results is **not** a natural phenomenon. On appeal, the Federal Circuit did not discuss whether the claims describe a natural phenomenon. Instead, the panel applied the new test without analysis, declaring "Dr. Classen's claims are neither 'tied to a particular machine or apparatus' nor do they 'transform[ ] a particular article into a different state or thing.' Therefore we affirm." *Classen*, 304 F.App'x at 867 (quoting *In re Bilski*, 545 F.3d. at 954) (alteration in original).

only test for patent eligibility is clearly improper.

II. The Framers of the Constitution intended to promote advances in medical diagnosis and treatment.

The Constitution grants Congress broad power to legislate to "promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. CONST. art. I, § 8, cl. 8. At the time the Constitution was drafted, medicine had for more than two thousand years been known as one of the "useful Arts." *The Oath of Hippocrates* refers to medicine as "the art," "this art," or "my art" on five occasions. HIPPOCRATES, THE OATH AND LAW OF HIPPOCRATES, reprinted in 38 HARVARD CLASSICS, pt. 1 (Charles W. Eliot ed., P.F. Collier & Son 1910) (1909). The first sentence of *The Law of Hippocrates* states "Medicine is of all the Arts the most noble; but owing to the ignorance of the ones who practice it, . . . it is at present far behind all the other arts." *Id.* In the late 18th century, those who were educated in classical learning included Thomas Jefferson, and they were well aware that medicine was one of the "useful Arts."

In *Graham v. John Deere*, this Court discussed the legislative history of patent law at length, including analysis of the influence of Thomas Jefferson on the development of our patent system, noting "[b]ecause of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution, as well as

his conclusions as to conditions for patentability under the statutory scheme, are worthy of note." 383 U.S. 1, 7 (1966). As illustrated below, Jefferson's writings and other writings of his time indicate that medicine, including methods of treatment and diagnosis, would have been included in the Framers' definition of "useful Arts."

In Jefferson's time and in Jefferson's mind, medicine was clearly understood to be one of the "useful Arts." The first edition of the *Encyclopædia Britannica* states:

> Medicine is generally defined to be, **The art** of preserving health when present and of restoring it when lost . . . . Most **arts** require the experience of ages before they can arrive at a high degree of perfection. Medicine is unquestionably one of the most ancient; and consequently, the improvement of it might be expected to bear some proportion to its antiquity but, whilst philosophy, in all its branches, has been cultivated and improved to a great extent; medicine, not withstanding the collateral advantages it has of late derived from anatomy and other sciences still continues to be buried in rubbish and obscurity.

3 A SOC'Y OF GENTLEMEN IN SCOT., ENCYCLOPÆDIA BRITANNICA 58 (1st ed. 1771) [hereinafter ENCYCLOPÆDIA BRITANNICA] (emphasis added).

Jefferson's letters make clear that he considered medicine to be one of the "useful Arts" in need of

advancement through both observation and innovation. For example, in his letter on "Freedom of Mind" to William Green Munford dated June 18, 1799, Jefferson states:

> Surgery is well advanced; but prodigiously short of what may be. The state of medecine [sic] is worse than that of total ignorance . . . . We have a few medecines, as the bark, opium, mercury, which in a few well defined diseases are of unquestionable virtue: but the residuary list of the materia medica, long as it is, contains but the charlataneries of **the art**; and of the diseases of doubtful form, physicians have ever had a false knowledge, worse than ignorance. Yet surely the list of unequivocal diseases & remedies is capable of enlargement; and it is still more certain that in the other branches of science, great fields are yet to be explored to which our faculties are equal, & that to an extent of which we cannot fix the limits. I join you therefore in branding as cowardly the idea that the human mind is incapable of further advances.

THOMAS JEFFERSON, WRITINGS 1065 (Merrill D. Peterson ed., Library of America 1984) (emphasis added). Similar evidence is found in Jefferson's letter entitled "Unlearned Views of Medicine" to Dr. Caspar, dated June 21, 1807. In this letter, Jefferson provides his opinions on the state of medicine and medical education:

> . . . [F]ulness of the stomach we can relieve

> by emetics; diseases of the bowels, by purgatives; inflammatory cases, by bleeding; intermittents [fevers], by the Peruvian bark; syphilis, by mercury; watchfulness, by opium; etc. So far, I bow to the **utility of medicine**. It goes to the well-defined forms of disease, & happily, to those the most frequent. But the disorders of the animal body . . . are as various as the elements of which the body is composed . . . . To an unknown disease, there cannot be a known remedy. Here then, the judicious, the moral, the humane physician should stop . . . . But the adventurous physician goes on, & substitutes presumption for knolege [sic] . . . . It is in this part of medicine that I wish to see a reform, an abandonment of hypothesis for sober facts, the first degree of value set on clinical observation, and the lowest on visionary theories . . . . I would wish the young practitioner . . . to have deeply impressed on his mind, the real limits of **his art**.

Id. at 1181-1185 (emphasis added). Yet another example can be found in Jefferson's letter "The Value of Classical Learning" to John Brazier dated August 24, 1819. Jefferson advocated studying the Classics in their original Greek and Latin and was thoroughly familiar with the writings of Hippocrates. In discussing the benefits of classical learning and in particular its utility to various members of society, Jefferson notes that the Greek and Roman texts have given to physicians:

> as good a code of **his art** as has been given us to this day. Theories and systems of medicine, indeed, have been in perpetual change from the days of the good Hippocrates to the days of the good Rush, but which of them is the true one? The present, to be sure, as long as it is the present, but to yield its place in turn to the next novelty, which is then to become the true system, and is to mark the vast advance of medicine since the days of Hippocrates. **Our situation is certainly benefited** by the discovery of some new and very valuable medicines; and substituting those for some of his with the treasure of facts, and of sound observations recorded by him (mixed to be sure with anilities of his day) and we shall have nearly the present sum of **the healing art**.

Id. at 1424 (emphasis added). Thus, substantial evidence exists that Jefferson and others of his time considered the term "useful Arts" to encompass medicine. Moreover, these letters indicate that Jefferson considered medicine, including medical diagnosis and treatment, to be a field in which great progress was both possible and needed for the benefit of society.

The 1771 edition of *Encyclopædia Britannica* again echoes Jefferson's sentiments regarding the need for progress in the "art" of medicine:

> In every art which is not founded on known facts and established principles, new projects

> are eagerly grasped at; and though they lead to error and false reasoning, it is long before the professors of that art can be induced to give over the pursuit. **This observation is particularly applicable to medicine.** The theories of diseases, as well as the mode of prescription, are as variable as the fashion of a lady's headdress. No other argument is necessary to shew the crude state of **the art** and the boundless field for improvement.

3 ENCYCLOPÆDIA BRITANNICA, *supra,* at 60 (emphasis added).

Finally, one of the foremost medical experts of the 18th Century, Dr. William Cullen wrote in the first lines of the introduction of his two-volume treatise *First Lines of the Practice of Physic*:

> 1.] In teaching the Practice of Physic, we endeavor to give instruction for *discerning*, *distinguishing*, *preventing*, and *curing* diseases, as they occur in particular persons.
>
> 2.] **The art** of DISCERNING and DISTINGUISHING diseases . . . .

1 WILLIAM CULLEN, FIRST LINES OF THE PRACTICE OF PHYSIC 25 (New York, L. Nichols 1801) (Introduction written in 1789) (second emphasis added). Thus, authorities in the field of medicine also viewed various aspects of the field as an "art."

From the foregoing it is clear that the field of medicine was considered by the Framers to be one of

the "useful Arts." It is also clear that procedures for diagnosis and treatment of diseases were considered arts within the more general art of medicine. Moreover, Jefferson and his contemporaries repeatedly voiced an acute need for progress in the art of medicine. The Constitution was thus drafted with an understanding of medicine as a "useful Art" in which "progress" was greatly desired.

III. Congress intended advances in medical diagnosis and treatment to be patent eligible subject matter.

From the first Patent Act, Congress has broadly described the class of inventions eligible to be considered for Patents. Later acts of Congress made clear that medicine, including methods of diagnosis and treatment, were meant to be included in that description. As further discussed below, reading the Patent Act in a manner which excludes methods of diagnosis and treatment from the class of patent eligible inventions is contrary to the legislative history as interpreted by this Court.

This Court has repeatedly recognized that the legislative history of the Patent Act supports a broad construction of patent eligible subject matter. In *Diamond v. Chakrabarty*, this Court noted that:

> The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, § 1, 1 Stat. 319. The

> Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10, 86 S.Ct. 684, 688-690, 15 L.Ed.2d 545 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952).

447 U.S. 303, 308-309 (1980). Though Congress replaced the word "art" with "process," in the 1952 act, the act also defined "process" as "a process, art, or method." 35 U.S.C. § 101(b) (2006). Thus, the term "process" was defined as including that which it replaced. Accordingly, "any new and useful art . . . or any new or useful improvement [thereof]" which was patent eligible before enactment of the 1952 Patent Act remained patent eligible subject matter under the 1952 act.

In *Chakrabarty*, this Court went on to discuss the reasons behind a broad construction of the patent eligible subject matter provisions of the Patent Act. The Court recognized that "[t]he subject

matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with all that means for the social and economic benefits envisioned by Jefferson." *Chakrabarty,* 447 U.S. at 315. As discussed above, advances in medicine, particularly methods of diagnosis and treatment, were social benefits that Jefferson hoped for and envisioned.

The current act provides further evidence that Congress intended processes of diagnosis and treatment to be patent eligible subject matter. In 1996, the act was amended to explicitly exclude medical practitioners from liability for infringing a patent by the performance of a medical or surgical procedure on a body (including a human body, organ, or cadaver, or a non-human animal). Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, 110 Stat. 3009-67 (codified as amended at 35 U.S.C. § 287(c) (2006)). Significantly, § 287 excludes from its application the practice of patented biotechnology processes and certain pharmacy and clinical laboratory services, for which medical practitioners remain liable for patent infringement. 35 U.S.C. § 287(c) (2006). The fact that Congress felt the need to create such exclusions makes clear that they intended new and useful medical processes such as methods of diagnosis or treatment to be patent eligible subject matter.

In *United States v. Dubilier Condenser Corp.*, this Court cautioned: "We should not read into the patent laws limitations and conditions which the

Legislature has not expressed." 289 U.S. 178, 199 (1933). The Federal Circuit's "machine-or-transformation" test as set forth in *In re Bilski* is more restrictive than required by this Court's precedent and finds no support in any legislation. In practice, it has already been applied to strike down patents directed to methods of immunizing patients with improved efficacy and safety thereby casting a cloud on the validity of a great many process patents in the medical and biotechnological fields.

The "machine-or-transformation" test is a useful starting point for analysis of patent eligibility of process claims. However, if a process claim is not tied to a particular machine or does not recite transformation of an article into a different state or thing, the inquiry should not stop there, as the process may still be patent eligible as long as it does not attempt to claim "laws of nature, natural phenomena, [or] abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). The inquiry should carefully analyze whether the claimed process is truly claiming a phenomenon of nature, ever mindful of the difference between phenomena that are entirely products of nature and inventions that are the result of how nature reacts to the purposeful activity of man. Where the activities of man cause a useful, tangible, concrete result that did not exist before, the process should be considered patent eligible.

CONCLUSION

The Federal Circuit's holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing, to be patent eligible is too restrictive. The holding excludes subject matter that Congress clearly intended to be patent eligible. Therefore, *amicus curiae* respectfully requests that the Court reverse the decision of the Federal Circuit and answer the first question presented in the affirmative.

Respectfully submitted,

Jeff Lloyd
Counsel of Record
Saliwanchik, Lloyd & Saliwanchik
A Professional Association
P.O. Box 142950
Gainesville, FL 32614-2950
(352) 375-8100

Attorney for Amicus Curiae
The University of South Florida