NO. 08-964

IN THE

Supreme Court of the United States

BERNARD L. BILSKI AND RAND A. WARSAW,

Petitioners,

v.

JOHN DOLL, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING DIRECTOR, PATENT AND TRADEMARK OFFICE,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF DR. ANANDA CHAKRABARTY AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTEREST OF *AMICUS CURIAE* 1

STATEMENT OF CASE 1

SUMMARY OF ARGUMENT 8

ARGUMENT 12

I. The Federal Circuit's Approach Conflicts with the Statute 12

II. The Federal Circuit's Approach Conflicts with this Court's Precedent 14

III. The Federal Circuit's Approach Conflicts with Sound Policy 15

A. Sound Patent Law Need Not Tie a Patentable Invention to Some Physical Mode of Its Expression 15

B. Strong Patent Protection Opens Technology Markets to Multiple Players and Facilitates Cooperation Among Them 17

C. Localized Solutions Offer the Best Means for Dealing with Particular Defects of the Patent System..... 19

IV. The Federal Circuit's Approach Will Have a Profound Adverse Effect on the Public's Ability to Benefit from Dr. Chakrabarty's Own Research 23

CONCLUSION 26

TABLE OF AUTHORITIES

CASES Page

In re Alappat,
33 F.3d 1526 (Fed. Cir. 1994).....6, 22

In re Bilski,
545 F.3d 943 (Fed. Cir. 2008).....2, 6, 12-15

Diamond v. Chakrabarty,
447 U.S. 303 (1980) .....*passim*

Diamond v. Diehr,
450 U.S. 175 (1981) 6, 9, 13-15, 26

Funk Brothers Seed Co. v. Kalo Inoculant Co,
333 U.S. 127 (1948) 14, 15

Gottschalk v. Benson,
409 U.S. 63 (1972) 5, 6, 14, 15

Graham v. John Deere,
383 U.S. 1 (1966) 16-17

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.,
534 U.S. 124 (2001) 9, 14, 26

In re Johnston,
502 F.2d 765 (CCPA 1974).....6

Parker v. Flook,
437 U.S. 584 (1978) 14, 15

Picard v. United Aircraft Corp.,
128 F.2d 632 (2d Cir. 1942).....17

State Street Bank & Trust Co. v. Signature Fin. Group Inc.,
149 F.3d 1368 (Fed. Cir. 1998).....6, 22

Page

STATUTES

35 U.S.C. § 100(b) 13

35 U.S.C. § 101..... 9, 12, 13, 14

35 U.S.C. § 102..... 13, 20

35 U.S.C. § 103..... 13, 20

35 U.S.C. § 112..... 13, 20

35 U.S.C. § 122..... 20

OTHER AUTHORITIES

Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 Nature Biotechnology 1091 (2006) 8

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Richard A. Epstein & Bruce Kuhlik, *Is There a Biomedical Anticommons*, Regulation, Summer 2004, at 54 7-8

Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 700 (1998) 7

OTHER AUTHORITIES (continued) Page

F. Scott Kieff, *On Coordinating Transactions in Information: A Response to Smith's Delineating Entitlements in Information*, 117 Yale L.J. Pocket Part 101 (2007) 8, 19

NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 108th Cong. (2003), *available at* http://energycommerce.house.gov/108/action/108-38.pdf (statement of Phyllis Gardner, Senior Associate Dean for Education and Student Affairs, Stanford University) 4

Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 Yale L.J. 1742 (2007) 19

John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 Science 2002 (2005) 8

INTEREST OF *AMICUS* CURIAE

Dr. Ananda Chakrabarty is Distinguished University Professor in the College of Medicine's Department of Microbiology and Immunology at the University of Illinois at Chicago. He was the inventor of the bacterium at issue in this Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which supported a broad definition of patent eligibility. Since that time, he has been a leading voice in the field of patent policy. He has no direct stake in the outcome of this case and is primarily interested in ensuring that patent law develops in a way that best promotes innovation and competition.[1]

STATEMENT OF CASE

Any patent application must go through two stages before actual patent rights are awarded by the Patent Office. The first of these inquiries deals with "patent eligibility." That question determines what types of inventions can be considered for patent protection. Patent eligibility thus performs a gatekeeper function. If an invention is not patent eligible, no other provision of the patent law can secure patent rights for that invention. Patent eligible inventions are not, however, automatically

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[1] *Amicus* has no financial interest in the outcome of this case. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. The Hoover Project on Commercializing Innovation at Stanford University's Hoover Institution paid the actual printing and filing costs. Counsel for *amicus curiae* prepared this brief on a *pro bono* basis as part of their academic work in the field.

entitled to protection. Each such invention must thereafter be examined under a second, well-known set of requirements: novelty, non-obviousness, and disclosure. These are more specific inquiries that ask whether or not the claimed invention merits the protection of the state by being a sufficient advance over the existing body of patented materials and by being supported by a sufficient disclosure to provide the public with notice and scientific teaching.

In the decision below, the Federal Circuit held that the Patent Office properly rejected the applicants' claimed process for managing legal and business risk. The court's sole ground was that the claimed process failed to meet the court's newly announced and seriously restrictive test for patent eligibility. Under the court's "machine or transformation test," a claimed process must be "tied to a particular machine or apparatus, or … transform[ ] a particular article into a different state or thing." *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (*en banc*).

This test threatens to transform patent law for the worse. The key to modern technology lies in the assembly, organization and use of information of all sorts, kinds and descriptions. The physical substrate in which it is contained is at best a mere technical detail that is under the Federal Circuit's rule elevated to an end in itself, which only frustrates the great ends for which the patent law is designed. Dr. Chakrabarty's own research on advanced techniques for personalized medicine is placed at risk by the narrow definition of patent eligibility used in the Federal Circuit.

In light of all the relevant information, the Federal Circuit's approach must be rejected because it is in conflict with the statute, with the precedents of this Court, and with sound public policy. Of particular concern to Professor Chakrabarty is that affirming the decision below will place a dark cloud over the status of his own future research. A broad reading of patent eligibility has played a central role in fostering both output from and competition within a range of technology industries.

The course charted in the Federal Circuit marks an abrupt and unwarranted about-face from the bold decision in this Court's 1980 *Chakrabarty* case. Over strong objections that living things were *per se* patent ineligible, this Court rejected the argument of the Patent Office that subject matter relating to living things was excluded from patent eligibility. That case involved Dr. Chakrabarty's patent application for a genetically engineered bacterium.

The *Chakrabarty* decision's strong affirmation of the broad scope for the patent system has been the fundamental pillar supporting the dramatic success of the United States' biotechnology industry. At the same time, the *Chakrabarty* decision is situated squarely in the middle of a host of this Court's decisions relating to the patent eligibility of various business- and computer-related inventions, which have spurred huge technical advances in related fields.

Before the 1980 *Chakrabarty* decision, the United States, Europe, and Japan each had large

biotechnology companies, often collectively called "Big Pharma," which competed with rough parity with each other. Each region has continued to be home to Big Pharma companies to this day. All three regions have enjoyed access to comparable technological and capital resources. But neither Europe nor Japan took the decisive step that the United States made through this Court's *Chakrabarty* decision, which ignited the boom in basic biotechnology that continues to this day. The rest of the world lags behind because the narrow vision of patent law that was adopted elsewhere led to the erection of various artificial roadblocks to effective patents, and resulting industrial development.

This distinctive United States stance has paid huge dividends to this country in the 29 years after *Chakrabarty*. Since 1980, the United States biotechnology industry has expanded so that Big Pharma companies are no longer the only significant players. Their skills have been augmented by an expanding pool of small- and medium-sized companies that regularly numbers around 1,400 in its ranks.[2] The pool is constantly turning over as some of these companies fail while others succeed spectacularly and fuel the appetite for more start-

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[2] *NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 108th Cong. 47 (2003), *available at* http://energycommerce.house.gov/108/action/108-38.pdf (statement of Phyllis Gardner, Senior Associate Dean for Education and Student Affairs, Stanford University) (detailing the differences between the smaller biotechnology companies and those in Big Pharma).

ups, whose livelihood depends on their ability to develop some patentable technology.

This unique growth in the United States' biotechnology industry stems from the virtuous circle that the *Chakrabarty* decision helped create. The firms that have grown through their patented technologies in turn supply fresh resources to fund the basic biological research community. That community in turn improves the knowledge of general scientific laws, which aids the formation of new commercial firms. The general public benefits from the steady stream of new and better goods and services that have revolutionized vital industries such as healthcare.[3] The broad account of patent eligibility has lowered the gates so that more can play, and in so doing it has spurred our biotechnology industry to be the most vibrant and competitive in the world.

The key role played by a broad eligibility requirement is equally important within the field of business- and computer-related inventions, which encompasses the patent application filed by Petitioner in this case. In the early 1970s, the United States' software industry was devoid of meaningful patent protection because of the uncertainty created by this Court's decision in *Gottschalk v. Benson*, 409 U.S. 63 (1972).

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[3] Ian *Cockburn et al., Pharmaceuticals and Biotechnology, in* U.S. Industry in 2000 Studies in Competitive Performance 389-92 (David C. Mowery ed., 1999) (reviewing relative performance of the U.S. biotechnology industry).

While *Benson's* holding was narrow, its impact was to leave all patents for computer software vulnerable to serious challenges.[4] Unfortunately, the *Benson* approach controlled throughout the 1970s, until this Court's decisions in *Chakrabarty* and *Diamond v. Diehr*, 450 U.S. 175 (1981), holding that software patents were not subject to *per se* exclusion, started to revive the market. Indeed, it was only with *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (*en banc*) and *State Street Bank & Trust Co. v. Signature Fin. Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) that the increased confidence in software patents translated into major infusions of investment capital. Yet these are the very decisions that the Federal Circuit has unwisely called into question in the instant case. *Bilski*, 545 F.3d at 990-92 (Newman, J., dissenting) (noting the majority's break with these important precedents). That window of reliable eligibility for business method and software patents has been closed over the past several months by the recent Federal Circuit cases including the *en banc* decision now before this Court. That point raises real concern because the same patent system that creates the initial economic advantage to the first in the field also gives a strong encouragement for new firms to compete against its initial patent advantage by affording powerful patent protection to the next generation of new and useful inventions.

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[4] For a discussion of the lead-up to *Benson*, and its impact, see *In re Johnston*, 502 F.2d 765, 772–774 (CCPA 1974) (Rich, J., dissenting) (noting normative problems with such a rule against software patents but pointing out the appellate court's duty to follow this Court's case law on the issue).

It may seem at first blush that broad patent eligibility would lead to an unseemly deluge of patents. But the ultimate success or failure of any patent in any field of technology must still be tested through a gauntlet of challenges that are both legal and economic. On the legal side, an applicant will only receive a valid patent if it can carry the burden of preparing a sufficiently strong application containing claims that avoid the prior art. On the economic side, the patentee can recover its initial investment only if it can successfully navigate the complex world of commercial transactions in the face of ever shifting technological and market landscapes.

Restraints like these deter frivolous Patent Office and patent litigation filings whose sole purpose is to block other innovators from making their mark in the marketplace. The empirical findings on the ground do not bear out all the gloomy talk about patent blockades, for private owners of valid patents do not act like Soviet-style bureaucrats who only prosper by blocking the gainful activities of others. Patents are wasting assets that can produce revenue only to the extent that they lead to production or licensing or both.[5]

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[5] A popular trend in policy debates is to worry about a putative problem of a patent "anticommons" that might be created when there are too many valid patents in an area. See Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 700 (1998). But the worries about an anticommons in the U.S. patent system are misplaced for several reasons, including the nature of the holder of the underlying assets, the nature of the licensing over those assets, and the flexibility private parties enjoy to bundle or divide both the assets and the licenses. See Richard A. Epstein & Bruce Kuhlik, *Is There a Biomedical*

A restrictive approach to patent eligibility embodies a dangerous view of industrial policy, because it puts the Patent Office in the business of picking winners and losers at the outset – by foreclosing patent examination on the merits for inventions that could well run the gauntlet of the second level challenges that face all patent applications. Broader eligibility rules avoid truncating the process by ruling out of bounds entire classes of useful inventions that have been routinely evaluated successfully on a case-by-case basis like all other inventions.

SUMMARY OF ARGUMENT

The Court should reject the Federal Circuit's new, restrictive approach to patent eligibility because it is in conflict with the statute, the precedents of this Court, and sound public policy. The approach of the Federal Circuit decision now on review finds no support in the statute. The statute speaks in broad,

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Anticommons, Regulation, Summer 2004, at 54 (discussing the incentives of private holders of wasting assets to negotiate towards productive use); F. Scott Kieff, *On Coordinating Transactions in Information: A Response to Smith's Delineating Entitlements in Information*, 117 Yale L.J. Pocket Part 101, 106 (2007) (discussing mechanisms by which holders of the assets and those seeking licenses can and do transact with each other). For empirical evidence against the Heller-Eisenberg hypothesis, *see* Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 Nature Biotechnology 1091 (2006) (reviewing data); John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 Science 2002 (2005) (reporting empirical results that demonstrate that "access to patents on knowledge inputs rarely imposes a significant burden on academic biomedical research").

expansive terms when it holds that patent protection should extend to "*any* new or useful process, machine, manufacturer, or composition of matter, or *any* new and useful improvement thereof." 35 U.S.C. §101 (2006) (emphasis added). There are no sound policy reasons that should lead this Court to unduly limit the ordinary meaning of these terms, whose sole proper office is to exclude the coverage of ideas, natural laws and natural phenomena.

The Federal Circuit's narrow interpretation of patent eligibility disrupts this sensible scheme. It strikes first at excluding patents in the area of business methods and software, in direct conflict with this Court's decision in *Diehr*. Worse still, the Federal Circuit's approach could easily cast a pall over all method claims in other areas of technology. Given the long established links between the eligibility rules for software and biotech, it is likely to spread its tentacles to biotech in particular, thereby undermining the huge boost that this Court's decision in *Chakrabarty* gave to bioscience, which this Court blessed in its subsequent decision of *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001).

The Federal Circuit's sharp break from established law is also bad policy. It would cloister off large segments of the economy from the vibrant beneficial impact that patents have had in the United States in improving innovation and competition for both domestic and international markets. That sudden and unexplained reversal of policy would by judicial fiat seriously frustrate the many investment-backed expectations in existing patents, which could

now be subject to challenge under far higher standards for patent eligibility than those under which the patents were granted. In particular, it would place the research efforts of Professor Chakrabarty under a cloud by reducing the prospects for its successful commercialization.

If left standing, the approach the Federal Circuit has taken in this case would likely engender other unfortunate consequences in the administration of patent law. There is little doubt that many of the modern advances in areas of technology and finance are wrapped up in the creation, organization, and interpretation of information. That information could be embodied in a wide number of different physical substrates, none of which is critical to its social utility or commercial success. There is a major risk, should the decision below be affirmed, that inventors will now seek to recast their patent claims in ways that seize onto some inessential detail of the invention's implementation in order to satisfy a "machine or transformation test" that is better suited to the nineteenth century than the twenty-first. But those strategic maneuvers will only produce deadweight losses, as these physical elements will unduly limit the scope of claims and put greater pressure on the doctrine of equivalents than is now the case.

Keeping the patent eligibility gates open is vital for information-intensive industries like healthcare and finance. The spate of new inventions will have positive ripple effects on key actors in adjacent and complementary fields. Patents on business and science methods require disclosure of valuable information about risky undertakings,

enabling patients, doctors, investors, and investment advisors to make more informed decisions. For example, investors would generally prefer for a hedge fund to disclose a risky derivatives scheme in a patent application than to keep it a trade secret. Patent transparency will also outperform mandatory disclosure regulation in getting valuable information into the public domain. Direct regulation does not offer any benefit to the regulated firm remotely comparable to that of patent protection.

No one doubts that there are a host of problems in the administration of patents, which should be addressed. But these are often localized to specific areas or involve the administration of the patent system. Patent eligibility is too blunt and too crude an axe to deal with these problems, for which much more laser-like fixes are appropriate.

In the end, *Amicus* of course does not take a position on how this particular patent application should be examined under the long established substantive rules relating to the disclosure and the prior art. But the looming tragedy if the Federal Circuit's ruling is upheld is that nobody will ever find out, as a large swath of patent applications will be unceremoniously barred at the gates from even having a shot at competing in the commercial arena of patents.

ARGUMENT

The Federal Circuit is improperly swinging the very blunt axe of the patent eligibility doctrine to excise from the patent system a huge swath of applications, many of which could well satisfy all of the substantive requirements for obtaining a patent. The court confessed to this charge when it wrote: "[w]hether a claim is drawn to patent-eligible subject matter under § 101 is a threshold inquiry, and any claim of an application failing the requirements of § 101 must be rejected even if it meets all of the other legal requirements of patentability." *Bilski*, 545 F.3d at 950. But at no point does it offer reasons that support this radical surgery. This Court should reject such an approach because it is inconsistent with the statutory language, the precedents of this Court, and sound public policy.

I. The Federal Circuit's Approach Conflicts with the Statute

The Federal Circuit's "machine or transformation" test has no basis in the relevant statutory language, which is both clear and broad with respect to the question of patent eligibility:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. 35 U.S.C § 101.

The section provides an expansive list in ways that do not try to prejudge which inventions will make sense for science and commerce and which do not. In case there were any doubt of the breadth intended by the word "process" in particular, the statute also expressly provides its own definition: "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C § 100(b) (2006). The combination of these two provisions in the statute creates a legal test that leaves the real limits on patentability to come from the other "conditions and requirements of this title." 35 U.S.C § 101. The linguistic framework of the next two sections in the statute confirms Section 101's broad reach. Those sections are respectively titled "Conditions for patentability; novelty and loss of right to patent" and "Conditions for patentability; non-obvious subject matter." 35 U.S.C §§ 102-103 (2006). That is, the serious limits on patent claims are imposed by the sections of Title 35 that are outside of Section 101. These substantive limits include the prior art rules of Sections 102 and 103, which are known as "novelty," "statutory bar" ("loss of right"), and "nonobviousness," as well as the disclosure rules set forth in Section 112, which are known as "written description," "best mode," "enablement," and "definiteness." See, 35 U.S.C § 112, ¶¶1-2 (2006). This Court has expressly agreed with this reading. As Judge Newman pointed out below in dissent, in "*Diehr*, the Court explained that Section 101 is not an independent condition of patentability, but a general statement of subject matter eligibility." *Bilski*, 545 F.3d at 977 (Newman, J., dissenting) (citing *Diehr*, 450 U.S. at 189-90).

II. The Federal Circuit's Approach Conflicts with this Court's Precedent

The Federal Circuit's machine or transformation test directly conflicts with this Court's well-established precedent, as Judge Newman also explained in depth in her dissent below. Not only did this Court expressly reject the "machine or transformation" test in both *Benson* and *Parker v. Flook*, 437 U.S. 584 (1978), this Court in *Chakrabarty*, *Diehr*, and *J.E.M. Ag Supply* expressly embraced a very broad reading of Section 101 eligibility to reach "anything under the sun made by man." *Bilski*, 545 F.3d at 977, 978-83 (Newman, J., dissenting) (providing detailed analysis of each case) (quoting *Chakrabarty*, 477 U.S. at 309 (citing S. Rep. No. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.S.C.C.A.N. 2394, 2399; H.R. Rep. No. 82-1923, at 6 (1952))).

The choice of those words was intended to allow the patent law to sweep broadly so as to embrace new forms of knowledge and technology that were unknown when they were incorporated in the 1952 Act by Congress (largely drafted by Judge Giles Rich), which was intended to reverse some of the narrow decisions on patent eligibility that had grown up in the courts in the 1940s, such as *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). The patentee in that case had devised a method in which multiple strains of a particular bacterium where able to coexist in order to help a wide range of plants take nitrogen from the air.

If the hostile attitude toward patents expressed in *Funk Brothers* had carried over to modern times, it is likely that the genetic revolution would have been long retarded. It was just to avoid this cramped interpretation of the patent law that Congress enacted the current Section 101. That work should not be undone by adopting a new rule that is inconsistent with the *Chakrabarty* line of cases

III. The Federal Circuit's Approach Conflicts with Sound Policy

A. Sound Patent Law Need Not Tie a Patentable Invention to Some Physical Mode of Its Expression.

As Judge Rader pointed out in dissent, below, a fundamental policy issue that seems to be overlooked by the Federal Circuit majority is the basic theoretical question of "*why* would [it make sense for] the expansive language of section 101 [to] preclude protection of innovation simply because it is not transformational or properly linked to a machine (whatever that means)?" *Bilski*, 545 F.3d at 1012 (Rader, J., dissenting) (emphasis in original). To be sure, as this Court has consistently held, it does make good sense to exclude from patent protection ideas, natural phenomena, and natural laws. *Diehr*, 450 U.S. at 185) (citing *Flook*, 437 U.S. at 589, *Benson*, 409 U.S. at 67). Indeed, these categories are already excluded by a basic application of the more substantive and more well known of patent law's requirements: the novelty and non-obviousness rules would prevent patents on all three because they already exist, in nature; and the disclosure rules

would prevent patents on at least abstract ideas because they are not able to be put to use if they are merely abstract.

It might seem as though the patent system needs to be updated to deal with the new technologies of today and tomorrow. It would be easy to conjure up the image of our Founding Fathers, dressed in 18th century fashions, unable to anticipate that the patent system they provided for in the Constitution would be applied to modern marvels like molecular biology or the internet. But the charge that the law must be updated to deal with new technologies is absurd when it comes to patents. The entire patent system, with its core patentability requirements of novelty and nonobviousness, was designed to embrace unforeseen technologies. As this Court pointed out in the *Chakrabarty* decision: "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability." 477 U.S. 315.

Indeed, the rapid advance of technology is precisely a reason why fears about hyper proliferation of patenting in new fields are overblown. With new areas of technology come new reservoirs of prior art. As this Court took pains to elaborate forty years ago in *Graham*, the ever-advancing state of the art fixes many of the problems with patents:

> Technology, however, has advanced – and with remarkable rapidity in the last 50 years. Moreover, the ambit of applicable art in given fields of science has widened by disciplines unheard of a

> half century ago. It is but an evenhanded application to require that those persons granted the benefit of a patent monopoly be charged with an awareness of these changed conditions. The same is true of the less technical, but still useful arts. He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office. *Graham v. John Deere*, 383 U.S. 1, 19 (1966).

B. Strong Patent Protection Opens Technology Markets to Multiple Players and Facilitates Cooperation Among Them.

A broad reading of patent eligibility has played a central role in fostering both output from and competition within a broad range of technology industries. As Judge Jerome Frank once put it, predictable patents can be the vital slingshots smaller innovative 'Davids' use to compete against large established 'Goliaths.' See *Picard v. United Aircraft Corp.*, 128 F.2d 632, 643–644 (2d Cir. 1942) (Frank, J. dissenting).

Getting an invention made and bringing it to market requires coordination among its many complementary users, including developers, managers, laborers, other technologists, financiers, manufacturers, marketers, and distributors. Patents help achieve this socially constructive coordination by allowing those various actors to interconnect with each other like modules of a larger system. The

underlying mechanism depends in at least three fundamental ways on the expectation that patents will be available and enforced.

First, the credible threat of a published patent's right to exclude acts like a beacon in the dark, drawing to itself all those interested in the patented subject matter. This beacon effect motivates those diverse actors to interact with one another and with the patentee, starting conversations among the relevant parties.

Second, the widespread expectation that the patent will be enforced motivates each of these parties to reach agreements with one another over the use and deployment of the technology. That bargaining effect falls apart if the parties are unsure that the patent will be enforced; if the patent is seen as unlikely to be enforced, there is significantly less need to reach agreement *ex ante*. Thus the fear of uncertain enforcement creates a disincentive for the necessary parties to work together at the outset. This change in result is not a matter of indifference. The voluntary agreements entered into by the various firms are dense relationships that are tailored to the specific circumstances of each case. A complex cooperative agreement could easily run hundreds of pages, all of which are calculated to maximize the gains from trade among the parties. Remove the patent system, and the gains from cooperation over technology will shrink. And the increased reliance on trade secrets will deny the rest of the scientific and other communities the public disclosures in the patent that help direct competitors

into fruitful areas of research, and customers, advisors, and regulators into fruitful areas of inquiry.

Third, patent protection allows patentees and all other complementary users of the invention engaged in the coordination process to appropriate the returns to inputs (many of which economists term "rival" because use by one person deprives use by another) to developing and commercializing innovation – labor, lab space, unique business relationships, and so forth – without the law having to trace their relative contributions through either complex administrative procedures or complex litigation. Instead patents form a platform on which coordination and development can take place.[6]

C. Localized Solutions Offer the Best Means for Dealing with Particular Defects of the Patent System.

While patents are important for increasing access to new technologies as well as competition, *Amicus* recognizes that a number of problems can be associated with patents. These should be taken seriously and they are. But using the tool of patent eligibility to solve them would make little sense because it would not help resolve problems that are far more localized.

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[6] Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 Yale L.J. 1742 (2007) (discussing modularity and information costs); F. Scott Kieff, *On Coordinating Transactions in Information: A Response to Smith's Delineating Entitlements in Information*, 117 Yale L.J. Pocket Part 101 (2007) (discussing beacon and bargaining effects for facilitating coordination).

Here are some examples of the basic proposition. The constant concerns about the delay in processing patents or in the reliability of patent determinations are well known. But patent eligibility is a vastly inferior device for dealing with these than a shift in budgetary allocations to the Patent Office or a change in the procedures whereby patents can be challenged either before the Patent Office or in court.

At a more doctrinal level, designing the prior art rules to prevent patents from issuing for technological advances that are already in the public domain or in patents acquired by third parties serves to protect the reliance interests of third parties against a late-comer into the field.[7]

Similarly, designing the publication rules of 35 U.S.C. § 122(b) and the disclosure rules of 35 U.S.C. § 112 to put the world on notice of patent claims soon after an application is filed mitigates similar opportunism concerns of third parties arising after a patent is filed.

The rules of laches, implied license, and estoppel can further act to prevent unfair surprise by a lurking patentee who sits on his rights when others actively seek to develop their own inventions.

Finally, good rules on licensing can increase the gains from trade by reducing the transaction costs needed to make voluntary agreements.

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[7] This is the role played by the novelty, statutory bar, and nonobviousness requirements. *See* 35 U.S.C. §§ 102-03.

Closer to home, claims of sloppy patent control for business patents do not require throwing out the baby with the bathwater, as the other patent levers could result in sensible standards for nonobviousness, novelty, and disclosure that are appropriate to each case.

We need not decide here which of these possible reforms is better handled by Congress and which by the Courts. It is enough to say that neither the legislature nor the judiciary should select patent eligibility as the tool of choice to deal with any of the problems mentioned above or others that may arise in the future. Targeted responses to specific problems dominate the blunderbuss approach of the Federal Circuit's "machine or transformation" test. Patent eligibility purports to pick winners and losers at the outset, before any of the more discriminating tests for patentability ever kick in.

Consider the specific rejection in this case of Petitioners' claim to a process for managing legal and business risk because the process failed to meet the Federal Circuit's unduly restrictive test for patent eligibility – the "machine or transformation test." That technology addressed one critical problem that contributed to the recent financial crash which was attributable at least in part to the inability of even the best financiers on Wall Street to appreciate a host of legal and business risks, which are difficult to model and thus difficult to guard against. The need for techniques to estimate the frequency and severity of so-called low probability events is critical to preventing a repetition of these massive dislocations.

Against that backdrop, it belies reality for the Federal Circuit majority to insist that the ability to develop new programs and protocols to deal with these issues is not of the highest order of importance. Yet that court's decision explicitly derogates from its own two earlier decisions, *State Street Bank & Trust v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), and *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994), which have afforded broader protection for business method and scientific patents. It shows deep inability to perceive the arc of modern technology to deny patent protection for the archaic reason that the proposed invention does not meet some nineteenth century test of physical transformation.

Put differently, all modern understandings of risk take seriously that a true reduction (or increase) in risk leads to a significant change in overall social welfare. There is no doubt that even the Federal Circuit's cramped test treats as patent eligible a method of rescuing an innocent citizen who has been crushed by a freight train. No sound policy reason countenances turning our back categorically on patent protection for those novel technologies that enable us to better manage the risk of collision in the first instance.

In sum, many of the other areas of the patent system's rules have been under consideration for change in recent debates before Congress and this Court. And perhaps they should be changed. But any sensible reform should come through the front door of a reasoned and focused debate about the merits and demerits of specific changes as they relate

to each other and to the larger patent system. Back door reform by way of a new judge-made limit on patent eligibility is the worst way to go.

IV. The Federal Circuit's Approach Will Have a Profound Adverse Effect on the Public's Ability to Benefit from Dr. Chakrabarty's Own Research

Professor Chakrabarty's own research on infectious diseases and drug design and discovery gives ample testimony to the importance of the case that bears his name. It is now well known that the effectiveness of a drug varies with each patient, whose genes often dictate whether a particular compound will reach its target and how it will act when it arrives. One example involves the use of the drug Herceptin, a monoclonal antibody, in breast cancer patients. Only some breast cancer patients, about 10 to 15%, will have the cancers expressing a gene, called HER 2, that Herceptin targets. Thus HER 2-positive breast cancer patients in whom the gene is well expressed will be excellent recipients for Herceptin treatment. In contrast, others with low-level expression of the gene will derive little benefit from this drug. Expression of genes can also dictate if a person infected with the AIDS virus HIV-1 will develop AIDS or not, because of the expression of a gene or genes that are involved in the entry of the virus to the CD4+ T cells.

These general ideas are of course in the public domain. But much hard work remains to translate them into useful inventions that will reduce human disease and suffering. These innovative ideas in

human genotypes and drug effectiveness have given rise to the fast emerging medical field of personalized medicine, where the efficacy of a drug is determined based on the genetic constitution of the patient. The narrow definitions of patent eligibility adopted by the Federal Circuit could slow down the pace of progress. To determine the genetic constitution of each patient requires not only the knowledge of the sequence of the genomic DNA but also methodologies to determine which genetic variant may represent drug susceptibility or a lack of it. Such methods may not involve any machine, or transformation of an article to another state or thing. But it is virtually certain that they will require extensive literature searches, insightful analyses, logical deductions, and complex experimentation to determine if the target of a drug is properly expressed in the patient's genome to make the drug functional and effective.

Professor Chakrabarty's current research lies at the intersection of these new fields in bioscience. It concerns the development of multi-disease-targeting drugs, where a single candidate drug may be used in the treatment of a multitude of diverse diseases such as cancer, HIV/AIDS, malaria, and others. No such drug currently exists. Yet strong patent laws will speed their development. Seven U.S. patents have been issued between 2006 and 2009 relating to the fruits of Dr. Chakrabarty's work on the development of candidate drugs and several other patents are pending. Thus, there is no question of the patent eligibility of these drugs. Yet there is ample reason to support Professor Chakrabarty's worry that the highly restricted definition of patent eligibility by the Federal Circuit will prevent future

patents on many aspects of personalized medicine. The baleful consequences of such a decision would be to greatly reduce progress in this field and the consequent development of new, innovative processes to determine drug efficacy in individual patients.

This Court's 1980 *Chakrabarty* decision declared "anything under the sun that is made by man" is the proper test for patent eligibility. 447 U.S. 309. That broad interpretation, not any stylized "machine or transformation test," is the key to the full development of personalized medicine and other aspects of biomedical science. The Federal Circuit's decision to restrict patent eligibility of these important innovations will do much to prevent or delay such critical innovations from reaching the bedside or the market place.

CONCLUSION

Amicus respectfully urges this Court to reject the "machine or transformation" test articulated by the Federal Circuit and reaffirm the broad rules for patent eligibility elucidated by this Court in *Chakrabarty*, *Diehr*, and *J.E.M. Ag Supply*.

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August 6, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I have caused three true and correct copies of this BRIEF OF DR. ANANDA CHAKRABARTY AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS to be served on this 6th day of August, 2009, by Federal Express, as well as one electronic copy by email, to the following:

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