No. 08-964

In The Supreme Court of the United States

BERNARD L. BILSKI and RAND A. WARSAW,

Petitioners,

v.

DAVID J. KAPPOS, Under Secretary of Commerce for Intellectual Property and Director, Patent and Trademark Office,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

AMICUS CURIAE BRIEF IN SUPPORT OF THE RESPONDENT, SUBMITTED ON BEHALF OF ADAMAS PHARMACEUTICALS, INC. AND TETHYS BIOSCIENCE, INC.

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INTEREST OF THE *AMICI CURIAE*[1]

Tethys Bioscience and Adamas Pharmaceuticals have joined in this *amicus* brief to encourage the Court to correct a serious mistake in the law.

Tethys Bioscience is a predictive personalized medicine company developing novel tests to identify those at risk of diabetes, by discovering, developing, and commercializing novel biomarkers. Adamas Pharmaceuticals, Inc. is a pharmaceutical company focused on development treatments of infectious diseases, including H1N1 "Swine" flu.

Tethys and Adamas have no interest in any party to this litigation or stake in the outcome of this case, other than their joint desire for a correct interpretation and application of the United States Patent Laws.

[1] In accordance with Supreme Court Rule 37, Tethys Bioscience and Adamas Pharmaceuticals state that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amici curiae* or their counsel. In accordance with Supreme Court Rule 37, counsel for the *amici curiae* provided timely notice to and obtained written consent to the filing of this brief from counsel of record for the parties. The letters of consent have been filed with the Clerk of the Court.

SUMMARY OF THE ARGUMENT

This case provides an opportunity to eliminate problematic business method patents and establish a § 101 subject matter test that is objective and predictable, not duplicative of other patentability requirements, consistent with Congress's legislative scheme, and in compliance with United States treaty obligations. The "Machine or Transformation" test ("MoT" test) achieves none of these objectives, and instead invalidates a much broader swath of method patents, destroying investment incentives in key U.S. industries and subjecting the United States to trade sanctions. Conversely, a correct interpretation of § 101 allows this Court to affirm the USPTO's rejection of the claims at issue because they are to a non-technological process, the only exclusion from patentability permitted by treaty obligations and consistent with Congress's intent.

The MoT test, which denies patents for technological processes not involving a specialized machine or transformation of an article, violates at least two treaties to which the United States is a party. The 1994 TRIPS Agreement contains a provision – spearheaded by the United States and key American industries – requiring signatory countries to extend patent protection to all technologies without discrimination, with limited exceptions. The earlier NAFTA treaty contains an essentially identical provision. Since the MoT test discriminates against newer technologies, particularly cutting edge technologies of key industries in the developed world, ratification of the

MoT test by this Court will subject the United States to trade disputes that will be independently adjudicated by the World Trade Organization ("WTO"). Furthermore, this retrenchment from broad patentability at home will seriously undermine bilateral efforts to gain intellectual property protection in the export markets of domestic industries.

The MoT test also thwarts Congress's statutory scheme for providing investment incentives through the patent system. Congress provided a broad subject matter provision because it is impossible to predict the future course of technology and the risk was too great that investments in unforeseen yet beneficial technology would not occur. Indeed, Congress previously considered concerns that patent protection had gone too far with respect to diagnostic, surgical and therapeutic methods. It specifically rejected an attempt to eliminate such subject matter from patent protection. Instead, Congress fashioned a targeted solution to the problem that exempted physicians from suit for patent infringement: 35 U.S.C. § 287(c). The MoT test, however, directly overrules Congress's choice to maintain broad subject matter coverage for healthcare-related technology.

This Court must not make the same mistake the Federal Circuit has made by confusing the roles of the legislature and the judiciary, thereby obstructing industrial policy set through the political process and subjecting the United States to disputes over its treaty obligations. Appellate courts, with limited records and briefs, are ill-equipped to explore the

complex economic and technical facets of issues raised by many of the *amicus curiae*. Congress, however, is equipped to investigate these issues beyond page-limited briefs. For example, Congress could consider whether other limitations on patentability (*e.g.*, novelty, nonobviousness, enablement, written description and definiteness) are better vehicles for targeted solutions. The range and nuance of the remedies at Congress's disposal, like creating § 287(c), go far beyond the limited options available to this Court.

Amici Tethys and Adamas are prime examples of the soundness of Congress's policy to encourage investment in new technologies resulting in advances of incalculable value to this country. *Amicus* Tethys has invented a way to identify persons who will become diabetic years in advance with sufficient precision to allow targeted drug and lifestyle interventions that will prevent the disease before it arises. Beyond the importance to the patient, this is a momentous advance in healthcare economics. It is substantially cheaper to prevent diabetes than to treat it. Currently, one in five healthcare dollars is diabetes related. Thus, controlling these costs is a major initiative for federal deficit reform.

Amicus Adamas has made inventions not only important to national health, but to national security as well. There have been few reliable tools and treatments available to meet the swine flu pandemic expected this winter. Only limited amounts of vaccine will be available. Resistance to the drugs in the national stockpile has appeared and could become

widespread. Public officials are bracing for what could be the greatest health crisis since the Spanish Flu of 1918-20. Pandemic flu is recognized as a top national security threat. Fortunately, Adamas has invented methods of using and deploying existing flu drugs that provide more rapid recovery, prevent the development of drug resistance, and may even restore sensitivity to drugs in resistant viruses. Adamas has initiated clinical trials, and the U.S. Navy is collaborating because pandemic flu is a major force readiness concern.

The *amici* are representative of the numerous research-based startups working at the frontiers of medical science. The ability to obtain patent protection, and thus attract investment for their high-risk research, is in serious jeopardy from the MoT test. Ending the Congressionally created patent system's incentive to invest in technologies like those *amici* have developed would not only be improper for the judiciary, it would also be tragically misguided.

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ARGUMENT

I. When § 101 Is Properly Construed as Embracing Only Technological Processes, Bilski's Claims Are Not Patentable, But the Machine or Transformation Test ("MoT" test) Will Place the U.S. in Violation of International Treaty Obligations, Undermine U.S. Foreign Policy, and Is Contrary to Congressional Intent.

A. In Signing and Ratifying TRIPS, the Executive and Congress Committed the U.S. to Broad Patent Protection for All Types of Technology. The MoT Test Limits Patent Protection for Some Areas of Technology in Violation of TRIPS Article 27(1) and Undermines Decades of U.S. Foreign Policy.

The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")[2] was the culmination of years of U.S.-led negotiations to strengthen intellectual property protection around the world for the benefit of, among others, the U.S. healthcare industry, which faced exclusion from patentability for its key technologies in many developing countries. *See generally*, 1 Devereaux *et al*., *Case Studies in U.S. Trade Negotiation* 42-76 (2006). The

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1197 (1994).

negotiations leading to the TRIPS agreement have been characterized "as having been initiated and driven by U.S. knowledge-based industries," such as U.S. healthcare companies. *Id.* at 43. The resulting TRIPS Article 27(1) prohibits member states from discriminating in their patent systems against *any* field of technology:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application. (Emphasis added).

The Federal Circuit's MoT test, by disqualifying patent protection for technological processes that do not involve a transformation of an article or are not tied to a particular machine, places the United States in breach of its treaty obligations and undermines decades of foreign policy related to intellectual property. Numerous examples of such technological discrimination by the MoT test have been discussed in other *amici* briefs (such as software and data processing inventions), and need not be repeated here.[3]

TRIPS came into force in the United States through implementing legislation that conformed

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[3] *See, e.g.,* International Business Machines Corporation Amicus Br.

U.S. law to it. Uruguay Round Agreements Act (URAA), Pub. L. No. 103-465, 108 Stat. 4809 (1994). Congress amended Title 35 of the U.S. Code to bring it into conformity with the patent provisions of TRIPS. URAA §§ 531-534. Among the significant changes to U.S. law was the term of patents. *Id.* at § 532. Pointedly, Congress did not amend § 101 in order to bring it into compliance with Article 27(1). Indeed, not even a suggestion contemporaneous with the URAA that § 101 might be out of compliance with TRIPS has come to *amici's* attention. The compelling presumption is that Congress did not believe § 101 contained any such discrimination, particularly since the United States had for years complained that other countries discriminated against some technologies *in contrast to the U.S.* and this provision of TRIPS was an attempt to address that problem. *See* Devereaux, *supra*.[4] Furthermore, while TRIPS

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[4] In contrast to a lack of concern regarding § 101 compliance with TRIPS when the URAA was under consideration, compare Congressional and administration concerns regarding a later house bill (discussed in Section I.B., *infra*) that proposed merely limiting USPTO funds for some medical process patents:

> The House-passed Ganske amendment to limit the authority to expend funds to issue medical procedure patents undercuts the hard fought gains of the GATT Treaty TRIPS provisions (Trade-Related Intellectual Property Rights). The House language invites, however unintentionally, our trading partners to adopt intellectual property protections that comply with TRIPS but, at the same time, functionally nullifies these apparent gains by simply not appropriating administrative funds. If this technique were used by our

(Continued on following page)

permitted countries to specifically exclude from patent protection certain healthcare technologies,[5] Congress did not choose to enact any such limitations.[6] The Federal Circuit's MoT test, in addition to violating TRIPS, ignores Congress's specific decisions in its implementation.

If this Court adopts the Federal Circuit's MoT test, or another test that discriminates against any area of technology, the United States will be subject to trade disputes for violations of Article 27(1). Such disputes will be decided by the WTO, not this Court. TRIPS art. 64. This Court must consider carefully whether it should subject this country to international disputes that will be independently adjudicated. Interpretation of Article 27(1) will be "in

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foreign trading partners not to enforce American-owned patents on, for example, pharmaceuticals or automobile parts, Congress and the public would demand action. 142 Cong. Rec. S11,844 (daily ed. Sept. 30, 1996).

[5] Article 27(2)-(3) permits member states to "exclude from patentability" certain inventions, including "diagnostics, therapeutic and surgical methods for the treatment of humans or animals." Importantly, Congress has never availed itself of these exceptions and in fact has rejected such approaches. *See* Section I.B., *infra*; fn. 6, *infra*.

[6] In connection with the Ganske bill debates, discussed below, Senator Hatch placed into the Congressional Record a letter from the United States Trade Representative (USTR) voicing concern over the trade implications of the pending bill, premised on the basis that the United States had not exercised its right to exclude from patentability the inventions listed in Article 27(2)-(3). 142 Cong. Rec. S11,844 (daily ed. Sept. 30, 1996).

accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. . . ." Vienna Convention on the Law of Treaties art. 31(1), May 23, 1969, 1155 U.N.T.S. 331.[7] It does not seem reasonable to expect the "context" of Article 27(1)'s meaning to include this Court's precedent or other U.S. patent practices from the 19th to mid-20th centuries.

Clearly the "context" of Article 27(1) includes its genesis in the U.S. agenda to broadly expand patent protection around the world for U.S. industries like software and healthcare. Devereaux *et al*., *supra*. Prior to TRIPS, the U.S. had negotiated the North American Free Trade Agreement,[8] with a patent provision essentially identical to TRIPS' Article 27(1). NAFTA, art. 1709. Well before the TRIPS agreement, Congress pursued a bilateral policy of trade sanctions when countries did not provide patent protection for subject matter key to the U.S. healthcare industry. The Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-148, 102 Stat. 1107 (1988), contained the "Special 301" program of retaliation against countries that deny

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[7] *See generally* Naigen Zhang, *Treaty Interpretation of the WTO Dispute Settlement*, 4 U.S.-China L. Rev. 22, 23 (2007) (noting that, since 1996, WTO has adopted Art. 31 of Vienna Convention as the customary rule of interpretation "without exception").

[8] U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) (hereinafter "NAFTA").

adequate intellectual property protection for U.S. industries. *Id.* at § 1303. This legislation was credited with advancing the United States agenda for strengthened patent protection, for example, by extracting a commitment from Brazil to provide patent protection for U.S. healthcare technology. Devereaux, *supra* at 62. Special 301 is still an important aspect of U.S. foreign policy, and countries which fail to provide adequate patent protection for U.S. healthcare companies are being investigated.[9]

Thus, if a trade dispute is brought to the WTO based upon the MoT test, there is substantial basis or "context" for that body to find the test violates Article 27(1). Furthermore, the MoT test will seriously undermine U.S. trade policy. The U.S. will no longer be able to credibly argue in Special 301 trade disputes that failure to protect healthcare inventions made by cutting-edge U.S. companies constitutes inadequate protection of intellectual property rights.

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[9] The USTR's most recent report demonstrates the role Special 301 investigations play in U.S. trade relations. *See, e.g.,* Office of the U.S. Trade Representative, *2009 Special 301 Report* 2 (2009), *available at* http://www.ustr.gov/about-us/press-office/reports-and-publications/2009/2009-special-301-report.

B. The History of the Ganske Bill and 35 U.S.C. § 287(c) Shows That Congress Intends § 101 to Be Broadly Construed and Favors Targeted, Non-§ 101 Solutions for Problematic Patents.

In 1995, Congressman Ganske, a physician, and Congressman Wyden introduced H.R. 1127 entitled the *Medical Procedures Innovation and Affordability Act*, H.R. 1127, 104th Cong. (1st Sess. 1995), *available at* http://bulk.resource.org/gpo.gov/bills/104/h1127ih.txt.pdf, to eliminate certain healthcare technology from patentable subject matter. The bill provided:

> LIMITATION ON ISSUANCE OF PATENTS. On or after the date of the enactment of this Act, a patent may not be issued for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacturer, or composition of matter may claim such technique, method or process.

The genesis of this bill was a patent granted to a physician for a method of cataract surgery, which the physician then attempted to enforce (unsuccessfully) against another physician. *See generally* Gerald J. Mossinghoff, *Remedies Under Patents on Medical and*

Surgical Procedures, 78 J. Pat. Tm. Office Soc'y 789 (1996).

Substantial opposition to the bill was raised by the pharmaceutical and biotechnology industries, *id.* at n.11, as well as members of Congress. *Id.* at n.20. An important principle raised by the opponents was that the broad sweep of patentable subject matter embraced by § 101 was a key feature in the success of the U.S. patent system, particularly in healthcare. 142 Cong. Rec. S11,844 (daily ed. Sept. 30, 1996). After lengthy negotiations involving members of Congress, the American Medical Association, the Pharmaceutical Manufacturers Association, and the Biotechnology Industry Organization, the approach of limiting patentable subject matter was rejected and a compromise was reached to eliminate remedies against physicians for infringement of patents. Mossinghoff, *supra*, at nn.16-18. The resulting compromise was enacted as 35 U.S.C. § 287(c).

The history of the Ganske bill demonstrates that Congress intends § 101 to broadly encompass medical innovations. In particular, subject matter limitations on claims to a "surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis" were rejected. Significantly, even though the original Ganske bill did not place limitations on such inventions when the process was "performed by or as a necessary component of a machine, manufacture, or composition of matter," even this more limited restriction on patentable subject matter was rejected by Congress. The rejected

Ganske bill's proposed limitation on patentability is remarkably similar in approach to the Federal Circuit's MoT test.

Congress wisely noted that the risk of limiting patentable subject matter in the fields of medical technology was fraught with danger because its impact would be unforeseeable and place at risk industries vital to the health of Americans and to the country's competitiveness. 142 Cong. Rec. S11,844 (daily ed. Sept. 30, 1996). This case illustrates well Congress's fears. In an effort to fashion industrial policy and eliminate business method patents, the Federal Circuit has caused unintended consequences – certainly consequences unintended by Congress. It does not matter that the MoT test is set forth in a technology-neutral manner. It clearly restricts patentable subject matter in fields of medical technology, impermissibly overruling Congress's statutory scheme, as illustrated by the history of § 287(c). This Court must not make the same mistake.

C. The Complex Interplay of U.S. Treaty Obligations, Congressional Pro-Patent Policy, and the Underlying Issue of What Constitutes Sound Industrial Policy Illustrates Why the Courts Should Not Intervene in a Problem That Can Only Be Effectively Addressed by the Political Branches of Government.

This Court is being asked by some to make a fundamental decision about industrial policy. Based

on the record of an *ex parte* patent prosecution (where the USPTO elected not to examine the claims on the other requirements of patentability[10]) and page-limited briefs, it is being asked to decide whether some technological method patents constitute good policy and fashion a solution that eliminates those patents it judges to be detrimental. At the same time, this Court should adequately protect valuable U.S. industries whose livelihoods depend on patent protection. Furthermore, any solution this Court crafts must avoid running afoul of U.S. treaty obligations and decades of U.S. foreign policy. Even if this were the proper role of the courts, the prospects of an optimal solution on the available record are not high.

The difficulty of making an informed decision in this area is illustrated by the dissenting opinion in the *Lab. Corp.* case. Relying on what it thought was a full record, *Laboratory Corp. of Am. Holdings v. Metabolite Labs., Inc.,* 548 U.S. 124 (2006) (Breyer, J., joined by Stevens and Souter, JJ., dissenting from dismissal of writ of certiorari), the dissent expressed a concern that appeared to underlie its position on limiting § 101 for a diagnostic method:

> [S]pecial public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions

[10] There is substantial reason to doubt the patentability of Bilski's claims under 35 U.S.C. §§ 102, 103 & 112. *See* fn. 21, *infra.*

> imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of healthcare to the legal task of searching patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery. *Id.* at 138.

In the relatively unconstrained fact gathering of the legislative process, it would have been called out that this exact concern was addressed by Congress when the Ganske bill was introduced, as discussed above. Congress rejected a subject matter solution in favor of a different solution. Congress provided 35 U.S.C. § 287(c) to exempt a physician from any suit whatsoever for patent infringement in the situation highlighted by the *Lab. Corp.* dissent.[11] Thus the dissent's concerns were unfounded.

The cited authority for this alleged threat to doctors was not a brief submitted by a physician's organization, but a brief from a trade association for

[11] Diagnosing and treating a vitamin deficiency is the type of medical procedure performed on the body exempted from all infringement remedies under § 287(c)(1) & (2). If this exemption does not satisfy the concerns of the dissent, it still remains a matter for Congress.

test providers. 548 U.S. at 138.[12] This Court needs to remain cautious in taking at face value the representations of parties who want to reduce royalties paid to innovators. Congress is much better equipped to evaluate the merits of competing private and public concerns.

Before this Court endorses a § 101 test that threatens the viability of entire fields of critical medical research, it needs to pause and ask whether it is in a position to avoid throwing the baby out with the bath water. In *Diamond v. Chakrabarty*, this Court wisely stated:

> The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. 447 U.S. 303, 317 (1980).

This Court should follow its own wise counsel and resist any attempt to interpret the statute in a manner that invades Congress's role and long-held policy of broad patentable subject matter. Any subject matter limitation beyond that proposed below will be based upon incomplete information and likely have significant, adverse unintended consequences to vital

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[12] *See also In re Bilski*, 545 F.3d 943, 1013-14 (2008) (Rader, J., dissenting and pointing out the incorrect premise of the *Lab Corp.* dissent with respect to the actual patent claim at issue).

domestic industries. Only Congress is capable of competently addressing this issue.

D. Bilski's Claims Are Unpatentable Under § 101 Because the Only Subject Matter Restriction Open to This Court That Does Not Contravene U.S. Treaty Obligations, Foreign Policy, and Congressional Intent Is to Limit Process Claims Coverage to Technological Processes, and Bilski's Claims Are to a Non-Technological Business Method.

There is only one approach open to this Court to find Bilski's claim unpatentable under § 101 and not contravene Congress's historical policy of broad subject matter eligibility for patents, or U.S. treaty obligations. Since the U.S. cannot withhold patent protection for any technological process, the only test available is whether or not a process is "technological." Such a test would meet the Respondent's concerns by excluding methods solely directed to organizing human activity, yet still embrace technological methods outside the rigid MoT test.

It is clear from Congressional action in the implementation of the TRIPS agreement that Congress did not consider § 101 too narrow to comply with the technology non-discrimination provision of TRIPS. That does not preclude the scope of patentable subject matter under § 101 being broader than the minimum required by TRIPS. This Court could inquire, however, whether the Constitution

permits Congress to enact a patent statute that provides patent protection for non-technological inventions.

Article I, section 8, of the U.S. Constitution provides that Congress has the power "[t]o promote the Progress of Science and the useful Arts. . . ." This Court, as it did when it found that patents must meet a Constitutional threshold of invention,[13] has recognized that there are limits to Congressional authority to authorize patents. For essentially the same reasons that the Constitution prohibits patents on inventions that are merely novel and not "inventive," patents on non-technological processes arguably have no role in promoting the useful arts. For any practical purpose, the minimum patent protection required by TRIPS and the maximum allowed by the Constitution potentially coincide.

Bilski's claim is not related in any way to the useful arts or technology.[14] It is purely a financial

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[13] The history of the Constitutionally imposed requirement of "invention" for patentability found by this Court, and its subsequent codification in the Patent Act of 1952 at 35 U.S.C. § 103, can be found in *Graham v. John Deere Co.*, 383 U.S. 1, 5-19 (1966).

[14] It is widely accepted that "Science" in Article I, section 8, refers to knowledge generally and that this relates copyrights, while "useful Arts" refers to the right to grant patents. *See, e.g., In re Bergy*, 56 F.2d 952, 958 (C.C.P.A. 1979).

It is also believed that in 1787 the phrase "'useful arts' meant basically helpful or valuable trades." Edward C. Walterscheid, *Nature of the Intellectual Property Clause: A Study in Historical*

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method, independent of the application of any scientific or technological principle. Thus, Bilski's claim could be held to fall outside the permissible Constitutional scope of § 101 because it is drawn to a non-technological process. It is argued by some that economics is now a field of technology. *See, e.g.,* Regulatory DataCorp Amicus Br. 29-33. Perhaps that is true. A § 101 analysis should focus on the claimed subject matter, however, not an arbitrary labeling of its field. Bilski's method of negotiating a series of contracts with certain financial parameters is independent of any technology. It may be labeled a "business method," but the determinative fact is that the method does not apply any technological innovation.

II. The Federal Circuit's MoT Test Threatens the Public Health, National Security, and Federal Deficit Reform, While Proponents of the MoT Test Have Failed to Demonstrate That It Is Targeted to Documented Problems and Will Not Eliminate the Incentive to Invest in Critical Medical Technology.

Proponents of using § 101 as the vehicle for solving alleged problems of the patent system need to demonstrate that the limitation they propose does not

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Perspective 126 (2002), and that this would be equivalent to the term "technology" today. *Id.* at 1, n.1.

restrict patentable subject matter in areas where the patent system serves the national interest, such as the healthcare industry. Some of the most promising advances in medicine are made possible through investment in newly available data collection and analysis tools that permit the recognition of hidden, multivariate empirical relationships in otherwise overwhelmingly complex biological systems.[15] Developing these techniques is expensive and risky, and important resulting inventions may not involve a transformation of articles or specialized machines. Congress certainly intended § 101 to embrace such important innovations and promote investments that improve the health and security of the American people.

The Respondent has given the MoT test's threat to healthcare short shrift. It argues "[n]o *extant* field of technology *or industry* . . . is *wholly* excluded" by the MoT test. Resp. Br. 36 (emphasis added). First, TRIPS's prohibition of discrimination against any technology is not met merely because some technology in an industry is patentable. Second, the focus on "extant" technology is exactly the myopic view of § 101 wisely eschewed by Congress. Third, and perhaps most importantly, the market segmentation in healthcare (discussed below) may make it impossible for important healthcare technology to be protected if machine or transformation steps are required to be in

[15] Biotechnology Industry Organization Amicus Br. 14-27.

claims. Finally, the Respondent contradicts itself by arguing on the one hand that this case is an inappropriate vehicle for the concerns of the software or healthcare industries because it involves business method inventions, *id.* at 37-40, and on the other that this Court should adopt a broadly applicable § 101 test. *Id*. at 43-44.

A. *Amicus* Tethys Develops Technology That Can Dramatically Improve Millions of Lives Threatened by Diabetes and Make a Substantial Contribution to Reining in Healthcare Costs and the Federal Deficit. But Rather Than Promoting Such Advances, the Federal Circuit's MoT Test Threatens Its Ability to Fund Development of Its Technology.

Slowing growth of healthcare costs is necessary to prevent "disastrous increases in the Federal budget deficit." Council of Economic Advisers, *The Economic Case For Health Care Reform* 1 (2009), *available at* http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf. One out of every five healthcare dollars is spent caring for diabetes patients. American Diabetes Ass'n, *Direct and Indirect Costs of Diabetes in the United States* (2009), *available at* http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp. Approximately 24 million Americans have diabetes (about 5.7 million undiagnosed) and by 2050 it is estimated that the number of diabetics will double. Centers for Disease Control,

Preventing Chronic Diseases: Investing Wisely in Health – Preventing Diabetes and Its Complications (2008), *available at* http://www.cdc.gov/NCCDPHP/publications/factsheets/Prevention/pdf/diabetes.pdf. Diabetes is a leading cause of kidney failure, blindness, and leg and foot amputations, and a major cause of heart disease and stroke. *Id.* It is not surprising that healthcare leaders have stated that preventing diabetes is key to reducing patient suffering and the high cost of diabetes to society. Alan J. Garber *et al*., *Diagnosis and Management of Prediabetes in the Continuum of Hyperglycemia – When Do the Risks of Diabetes Begin?,* 14 Endocrine Practice 933, 940 (2008), *available at* http://www.aace.com/meetings/consensus/hyperglycemia/hyperglycemia.pdf. A highly accurate diagnostic test that can identify those patients who will, absent targeted intervention, develop diabetes, would be an extremely important advance. *Id.* at 942.

Clinical studies have shown that lifestyle modification and drug intervention can prevent diabetes. Diabetes Prevention Program Research Group, *Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin*, 346 New England J. Med. 393 (2002). There are 57 million Americans who are identified as having "pre-diabetes." American Diabetes Ass'n, *Pre-Diabetes* (2009), *available at* http://www.diabetes.org/pre-diabetes.jsp. The tests used to diagnose pre-diabetes have only limited predictive value, because as few as 1 in 10 diagnosed pre-diabetics develop diabetes within five years.

Gregory A. Nichols *et al*., *Progression From Newly Acquired Impaired Fasting Glucose to Type 2 Diabetes*, 30 Diabetes Care 228 (2007). If limited healthcare resources could be better focused on those pre-diabetics most likely to develop diabetes, there could be both a significant improvement in quality of life for millions of Americans, as well as a significant reduction in future healthcare expenditures.

Armed with over $70 million in venture capital, Tethys entered the highly competitive and risky field of diabetes research expecting that if it developed a valuable invention, its investors would have effective patent protection. Against the odds, Tethys developed a way to predict which pre-diabetics will develop diabetes within five years with a previously unknown level of accuracy. Among populations tested so far, patients identified with Tethys' technology as high risk are as much as 12 to 24 times more likely to develop diabetes over the next five years as those classified as low risk. Mickey Urdea *et al*., *Validation of a Multimarker Model for Assessing Risk of Type 2 Diabetes from a Five-Year Prospective Study of 6,784 Danish People* (*Inter99*), 3 J. Diabetes Sci. Technol. 748 (2009).

Tethys' invention has enabled for the first time, targeted, cost-effective intervention in those pre-diabetes cases most likely to actually become diabetic. Tethys' success should be a paradigm of the societal benefits of a properly functioning patent system. Instead, Tethys' future ability to receive a return on its high-risk investment and fund the improvement

and extension of this technology to other diseases (*e.g.*, heart disease and osteoporosis) is at risk if the Federal Circuit's MoT test is adopted by this Court. The root of the problem is that key aspects of Tethys' innovative technology rely on recognizing the complex interrelationships of multiple "markers" in the blood to future risk of disease. This technology in significant part is independent of any specialized machine or transformation of an article.

B. *Amicus* Adamas Is at the Forefront of Improved Treatments for Influenza and Is Developing a Response to the Swine Flu Pandemic That Could Prevent the Emergence of Drug-Resistant Flu Strains, but the Federal Circuit's MoT Test Threatens Its Ability to Fund Future Development.

Pandemic flu is a threat to our national security and could kill more Americans than any bioterrorist attack. Bob Graham and Jim Talent, Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, *Preparing for Pandemics, Natural and Manmade*, http://www.preventwmd.gov/6_11_09/ (June 11, 2009); Association of State and Territorial Health Officials, *Preparedness Planning for State Health Officials: Nature's Terrorist Attack – Pandemic Influenza* (2002). The swine flu virus threatening global health is a novel form of the H1N1 influenza A virus. U.S. Centers for Disease Control, *Novel H1N1 Flu* (*Swine Flu*) *and You* (2009),

http://www.cdc.gov/h1n1flu/qa.htm. The swine flu pandemic has now reached 160 countries and it is projected to infect two billion people over the next two years. *Swine flu 'reaches 160 countries,'* BBC News, July 24, 2009, http://news.bbc.co.uk/2/hi/in_depth/8167961.stm. There are nearly 45,000 confirmed cases in the United States and over 300 deaths so far. U.S. Centers for Disease Control, *Novel H1N1 Flu Situation Update,* http://www.cdc.gov/h1n1flu/updates/072409.htm (July 24, 2009). Estimates of unconfirmed infections bring the number to over 1 million U.S. cases. *See, e.g.,* Timeline Update H1N1 2009 Swine Flu, http://www.medicinenet.com/swine_flu/page9.htm (2009). It is predicted that there will only be enough vaccine for a fraction of the population. Associated Press, *U.S.: 160M doses of swine flu vaccine due in Oct.* (July 22, 2009), *available at* http://www.newsday.com/us-160m-doses-of-swine-flu-vaccine-due-in-oct-1.1321315.

The seriousness of the situation cannot be overstated. The President's Council of Advisors on Science and Technology (PCAST) has delivered a baseline scenario for the upcoming flu season concluding that (1) 30-50% of the U.S. population could be infected; (2) there could be 1.8 million hospital admissions; and (3) there could be 30,000-90,000 deaths concentrated among young adults and children (up to three times the normal fatalities, which are concentrated among people over 65). PCAST, *Report to the President on U.S. Preparations for 2009-H1N1 Influenza* (Aug. 7,

2009), *available at* http://www.whitehouse.gov/assets/documents/PCAST_H1N1_report.pdf.

Because of the expected vaccine shortfall, drug therapy will be a critical component in meeting the swine flu pandemic. The Centers for Disease Control has deployed 25 percent of the anti-influenza drug supplies in the Strategic National Stockpile (SNS). *Id.* at n.39. Unfortunately, drug resistance is a major concern. It arises when large populations are treated with drugs under conventional protocols. *Drug Resistance In An Influenza Pandemic*, ScienceDaily, January 23, 2007, http://www.sciencedaily.com/releases/2007/01/070123093523.htm. There are only four FDA-approved anti-influenza drugs: zanamivir, amantadine, rimantadine, and oseltamivir. Zanamivir, needs to be administered by inhalation which limits its usefulness to treat the seriously ill due to the respiratory complications of severe influenza. *See* Zanamivir Index, *available at* http://www.medicinenet.com/zanamivir/article.htm. All strains of the swine flu tested to date are resistant to amantadine and rimantadine. U.S. Ctrs. for Disease Control, *Update: Drug Susceptibility of Swine-Origin Influenza A* (*H1N1*) *Viruses*, (Apr., 2009), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58d0428a1.htm. Some strains of swine flu have been found recently that are resistant to oseltamivir, which is the primary drug in the SNS arsenal. *CDC Health Alert Network* (*HAN*) *Info Service Message: Three Reports of Oseltamivir Resistant Novel Influenza A* (*H1N1*) *Viruses*, http://www.cdc.gov/h1n1flu/HAN/070909.htm. This is particularly

alarming since over 99% of the most recent seasonal flu isolates (which are still in circulation) are also oseltamivir resistant. The amantadine/rimantadine-resistant Swine flu strain could recombine with the seasonal oseltamivir-resistant strain to produce a multi-drug resistant flu virus. Unfortunately, the widespread use of conventional drug therapy against the novel Swine flu strain could also rapidly lead to a multi-drug resistant virus. If that happens, the SNS would be completely ineffective. If there is no strategy for dealing with drug resistance, the swine flu pandemic could be devastating to the United States – and the world.

Adamas has made a technological breakthrough in treating severe influenza that not only clears infection faster, but prevents the generation of drug-resistant strains that normally arise when only a single (or even two) drugs are used to treat patients. Nguyen *et al*., *Triple combination therapy is highly synergistic and effective in in vitro and in vivo models of influenza A infection*, Presentation at Infectious Disease Society of America Conference on Seasonal and Pandemic Influenza (May 18-20, 2008), abstract *available at* http://www.idsaglobalhealth.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=11384. Unexpectedly, it appears that the Adamas therapeutic approach may also *restore* sensitivity to a drug-resistant influenza virus. Steve Sternberg, *H1N1 trials to use drug cocktail,* USA Today, Sept. 13, 2009, *available at* http://www.usatoday.com/news/health/2009-09-13-swineflu_N.htm (experts "surprised" by invention). Maximizing

Adamas' breakthrough, which involves a novel approach to the use of existing drugs, will depend on how drugs are deployed to the frontlines of a pandemic. To continue the development of this promising technology, Adamas has entered into a collaboration with the U.S. Navy, and is also rapidly conducting necessary, but expensive, clinical trials. It recently raised $40 million in private funding to pursue these urgent goals. Yet, like Tethys, important aspects of Adamas technology are not limited to particular machines or the transformation of an article.

While the United States faces the most serious public health threat since the Spanish Flu, it would be reckless to undermine the patent system's encouragement of the healthcare industry's highest priority effort. Yet the Federal Circuit's MoT test does exactly that. This Court should unambiguously rule that all technological methods, and in particular healthcare, are patentable subject matter and avoid the serious mistake of foreclosing investment in healthcare technology not yet imagined.

The Federal Circuit cast a pall over the most innovative segments of medical research. The Respondent is simply incorrect to suggest that claims with a "transformation of blood" step are generally sufficient to impart patentability. Resp. Br. 40. A method requiring transformations of blood was found unpatentable in the Federal Circuit's first post-*Bilski* application of the MoT test. In *Classen Immunotherapies Inc. v. Biogen IDEC*, No. 2006-1634, 2008 WL 5273107 (Fed. Cir. Dec. 19, 2008) (unpublished),

the Federal Circuit affirmed a summary judgment of invalidity under § 101. The claim at issue would, to any scientist, require a transformation of blood because an immunizing step requires the injection into a mammal of an "immunogen." Not only is the blood transformed by having a foreign body placed into it, the blood transforms further via an immune response, adding new B-cells, T-cells, and antibodies.[16] Yet the *Classen* opinion merely concluded: "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.'" *Classen*, 2008 WL 5273107 at *1. If the MoT test blocks inventions like the one in *Classen*, the ability to raise capital for valuable, high-risk, cutting edge biomedical research will be severely undercut.

The MoT test permits "insignificant postsolution activity" claim limitations to be ignored. *In re Bilski*, 545 F.3d 943, 957 & nn.14, 26-27 (Fed. Cir. 2008). This is an arbitrary and subjective standard provided without guidance. It allows a court to ignore the reasons a claim otherwise meets the MoT test. Of great concern is that the Federal Circuit cited with approval its decision in *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989), reasoning it could ignore the requirement to perform a clinical diagnostic test in a diagnostic claim because it was insignificant extra-solution

[16] For an explanation of the immune response to an immunogen, *see* http://www.globalhealth.org/bios/bio_3/#vaccines.

activity. *Id.* In the context of a diagnostic method, how could it ever be concluded that collecting and testing a sample is an insignificant step?

The Federal Circuit's most recent post-*Bilski* § 101 decision, *Prometheus Lab., Inc. v. Mayo Collaborative Services*, ___ F.3d ___, App. No. 2008-1403 (Fed. Cir., filed Sept. 17, 2009), found that a claim limitation for "determining" the levels of an analyte satisfied the MoT test because some form of manipulation was required. *Id.* at 16-17. The court further held that the determining step was "integral" to the claimed method and distinguished the clinical testing step in *Grams* because it "did not require the performing of clinical tests on individuals that were transformative . . . ," *id.* at 18-19, a fact not found in *Grams*. The invention at issue in *Prometheus* is close to that claimed in *Classen*, but the outcome was the opposite. While it is encouraging that *Prometheus* is a precedential decision and *Classen* is not, the unpredictability of the MoT test's application will discourage investment in valuable medical research.

Even if a predictable view of the MoT test is adopted by this Court, medical research companies will remain at risk. Typically process claims are drafted to contain the minimum steps needed to define the technological contribution. The MoT test, however, could force the inclusions of "integral" transformation steps that are not needed to define the technological advance. Because of market segmentation in healthcare, one commercial entity could perform the transformation step of a patented

method, while another commercial entity carries out the non-transformative steps.[17] In order for a claim to be infringed, one entity and/or its agents must practice all the steps of the claim. *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007) (allowing parties practicing different steps of process claim to avoid joint infringement liability by arms-length relationship). By requiring claims to include unnecessary transformation steps, there may not be any effective patent protection from competitors who cleverly structure their business. Thus, even though high-risk investment leads to an important advance in a field of technology that Congress intended to be covered by § 101, the MoT test can defeat the patent incentive.

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[17] An existing test exemplifies the risk from requiring "extra" claim limitations in a segmented market. Berkeley HeartLab, Inc. is an innovator in heart disease diagnostics. It offers a testing service that analyzes markers of potential heart disease from a blood sample and provides physicians with the tools needed to create personalized treatment plans for each patient. *See, e.g.,* Berkeley HeartLab Clinicians, http://www.bhlinc.com/clinicians.php. The blood sample collection could be done at essentially any independent reference laboratory and then sent to a competitor who performs the same marker analysis. If Berkeley HeartLab was required to have the sample collection step in their claims for § 101 purposes, the competitor would not have infringed the claims, yet it would have appropriated the technological advance underlying Berkeley HeartLab's invention.

III. The Court Should Use This Opportunity to Correct Decades of Ill-Conceived Dissection of § 101 and Let the Patent Statute as a Whole Operate to Limit Patentability.

A. This Court Has Held That Laws of Nature, Natural Phenomena, Abstract Ideas, and Algorithms Are Excluded From § 101, Which Is Consistent With Congressional Intent and U.S. Treaty Obligations, Because These Are Not Technological Processes.

This Court has held that a claim is not a patent-eligible "process" if it claims algorithms, laws of nature, natural phenomena, or abstract ideas. *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). Stated another way, and consistent with Congressional intent and U.S. treaty obligations, these scientific and mathematical principles are not, *if claimed as such*, processes and thus not a recognized category under § 101. Pursuant to TRIPS, patents cannot be withheld for any area of technology. A technological process is by definition a practical application of scientific principle and thus patentable. On the other hand, the principles themselves cannot be patented and others are free to invent new practical applications thereof.

Under this restated § 101 test, the holding in *Diehr* was correct because a method of curing rubber does not become patent ineligible merely because it employed a scientific principle (an empirical relationship between curing and temperature) to calculate

the curing time of rubber. The invention there was clearly a technological process, and as such must apply scientific principles.[18]

B. Attempts to Further Parse Process Claims Into Patent-Worthy and Unworthy Categories Has Led to a Confused and Contradictory Body of Law Making Some Process Claims Unpatentable by Ignoring Claim Limitations Arbitrarily Characterized as "Insignificant Post-Solution Activity," "Mere Field of Use" Limitations, or Insufficient to Avoid "Preemption" of a Fundamental Principle.

Statements from this Court that claim limitations restricting a patent to a technological process can be ignored and the invention deemed to be ineligible subject matter have painted the test for patentable subject matter into an arbitrary and unpredictable corner. Take for example the statement

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[18] The dissent in *Lab. Corp. of Am. Holding v. Metabolite Labs., Inc.* stated "After all, many a patentable invention rests upon its inventor's knowledge of natural phenomena; many 'process' patents seek to make abstract intellectual concepts workably concrete. . . ." 548 U.S. 124, 134 (2006). It should be beyond debate that *all* inventions, not just "many," must inherently be based on the laws of nature. *Cf. Diehr,* 450 U.S. at 198 n.12 ("To accept the analysis proffered by the petitioner would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature. . . .").

of the *Diehr* Court that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process." 450 U.S. at 191-92. Neither this Court nor the Federal Circuit has articulated an objective test as to what constitutes "insignificant" activity. This has permitted the USPTO and the Federal Circuit to arbitrarily throw out claim limitations and thwart an applicant's attempt to limit its invention to a technological process.

The above statement in *Diehr* relied upon a statement in *Parker v. Flook*, 437 U.S. 584 (1978): "The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance." *Id.* at 590. Without explanation, the statement premises the objection to patentability on a suggestion that obvious claim limitations can somehow impart patentability. Yet obvious claims are unpatentable under 35 U.S.C. § 103.

The Court in *Flook* offered additional problematic dictum:

> A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques. 437 U.S. at 590.

Rather than approach the hypothetical invention for what it is, a method of surveying (*i.e.*, a technological process), the Court arbitrarily characterized the invention as an attempt to patent the Pythagorean theorem. There is, however, no reasoned difference between *Diehr*'s patentable rubber curing process employing a mathematical relationship between temperature and curing, and a method of surveying using a mathematical theorem. Apparently there was a subjective determination that the Pythagorean theorem was a more "fundamental" principle than a rubber-curing algorithm. The vast grey area between these examples does not clarify § 101. Decisions like *Flook* have made it opaque and unpredictable. If for some reason the processes of curing rubber and surveying are deserving of different patent treatment, it should be for Congress to decide, not the courts.

No analytical framework has been provided to objectively identify when a claim's limitations to a technological process can be ignored in the context of a § 101 analysis.[19] In reality, there is no sound reason

[19] Similarly problematic is the *Diehr* Court's statement that mere field-of-use limitations are insufficient to render an otherwise ineligible process claim patent-eligible. *See* 450 U.S. at 191-92 (noting ineligibility under § 101 "cannot be circumvented by attempting to limit the use of the formula to a particular technological environment"). Like the "insignificant post-solution activity" exception, this Court has not provided an objective framework to determine when a field of use limitation can be ignored.

to ignore *any* claim limitation and the need to do so merely confirms that the problem with the claimed invention, if there is one, is not related to subject matter. Changing what in fact is claimed for purposes of § 101 analysis is tantamount to an appellate court changing the facts of a case to justify its holding.

This Court's statements that claims are unpatentable if they preempt all practical applications of an algorithm or fundamental principle[20] are also highly problematic and incapable of consistent application. In chemical engineering, for example, substantial research can lead to the discovery of an empirical relationship between the shape of a pipe and the energy a pump needs to push liquid through it. The algorithm describing this relationship may have other applications, but it is unlikely that a team of researchers focused on solving a particular problem will have diverted resources to discovering applications in another field. Perhaps there is no practical application of the algorithm outside the focused patent claims. In either case, the inventors will be unable to rebut a "preemption" rejection. Thus, the preemption test penalizes those whose invention employs a new algorithm, even when the claims are limited to the practical application that was invented.

It is critically important that this Court recognize that § 101 is neither the only, nor the most appropriate

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[20] *See, e.g., Diamond v. Diehr* at 185; *Gottschalk v. Benson* at 72.

statutory basis for limiting patents containing overly broad claims. Congress provided three other sections of the Patent Act to limit overly broad claims: 35 U.S.C. §§ 102 and 103 to deal with claims so broad as to encompass the prior art; and § 112 for claims so broad they fail the enablement, written description, or definiteness requirements. Section 101 is ill-suited to police such issues.

Consider the Court's characterization of the patent application and broad claim at issue in *Flook*:

> The patent application does not purport to explain how to select the appropriate margin of safety, the weighting factor, or any of the other variables. Nor does it purport to contain any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system. All that it provides is a formula for computing an updated alarm limit. Although the computations can be made by pencil and paper calculations, the abstract of disclosure makes it clear that the formula is primarily useful for computerized calculations producing automatic adjustments in alarm settings.
>
> The patent claims cover any use of respondent's formula for updating the value of an alarm limit on any process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons. Since there are numerous processes of that kind in the petrochemical and oil-refining industries,

> the claims cover a broad range of potential uses of the method. 437 U.S. at 586 (footnotes omitted).

The *Flook* majority could not have stated a better unpatentability rejection for failing to comply with the enablement requirement of § 112. Both the *Flook* (unpatentable) and *Diehr* (patentable) claims were directed to technological processes (control of a chemical process), the only objective distinction being claim breadth. There is no reason that a correct application of § 112 would not have reached the same result and avoided the confusion that has arisen over § 101.

As discussed above, the Federal Circuit's application of the MoT test, both after *Bilski* and to its prior decisions retrospectively, demonstrates the legacy of unpredictability that has arisen from importing concepts of overbreadth into the analytical framework for subject matter. All the claims at issue in *Grams*, *Classen*, and *Prometheus* were drawn to medical or diagnostic methods, long generally recognized as statutory subject matter. They are technological processes. That is their subject matter. The only objection to some of the claims was in fact overbreadth, which should be dealt with under § 112. There is no sound policy reason to foreclose important areas of technological innovation from patentability when sections 102, 103, and 112 can police overly

broad claims.[21] Finding claims unpatentable under these provisions is clearly permissible under TRIPS Article 27(1)[22] and avoids the risk of subjecting the U.S. to trade disputes for discriminating against some technological processes.

The only consistent, predictable, and fair test for patentable subject matter is to look at each claim as a whole without excluding any limitation. If a claim is limited to a technological process having utility, such as a diagnostic process or a response to a pandemic, the § 101 inquiry can stop there. If a company has invested significant capital into research and invented a technological process that is novel (§ 102) and not obvious from the prior art (§ 103), and prepared a patent application that describes and enables the practice of the invention across the scope

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[21] Bilski's claims are also likely unpatentable under §§ 102, 103 and/or 112. With respect to novelty and obviousness, for example, the method appears to read upon a grain broker who enters into conventional futures contracts with farmers and supply contracts with its customers; all market-based prices have been "based" in some way upon "historical averages" once the market existed. Enablement across the scope of the claim is also highly suspect because it does not appear possible to enable the person of ordinary skill to negotiate the necessary agreements in all market conditions. Finally, the claim appears hopelessly indefinite since whether "transactions balance the risk position" is inherently subjective. The Bilski patent application is not an example of an invention that "but for" a limitation on § 101, an undesirable patent will result.

[22] Article 27(1) only requires patent protection for technological inventions "provided they are new, involve an inventive step and are capable of industrial application."

of the claim and the claim is sufficiently definite (§ 112), what policy end is served by barring the chance for a patent under § 101 and drastically reducing future investment in that field? This Court has the opportunity to close the chapter on unworkable, subjective distinctions among inventions that appear nowhere in § 101. *Amici* urge that prior decisions underlying these arbitrary and unworkable § 101 standards be distinguished or overruled.

CONCLUSION

This Court should hold that the only proper limitation on process claims under § 101 is the exclusion of non-technological processes. Bilski's claims are not valid under § 101 because they are drawn to a non-technological process. Most importantly, this Court should reject the MoT test fashioned by the Federal Circuit and preserve the patentability of cutting edge medical research. Nuanced industrial policy should be left to Congress.

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