CORALLO
MEDIA STRATEGIES

EXCERPTS FROM 15 AMICI BRIEFS

SUPPORTING RESPONDENT PROMETHEUS:

Mayo Collaborative Services v. Prometheus Laboratories, Inc.

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OVERVIEW OF KEY QUOTATIONS:

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA:

"Patents for medical processes, including those involving pharmaceuticals, have been issued and upheld for more than a hundred years. At present, tremendous and life-saving advances are being made with respect to various kinds of medical processes, including new uses for existing pharmaceuticals and processes for 'personalized' medicine. These advances, which entail extraordinary risk and expense on the part of the pharmaceutical and biotechnology industries, likely would not take place without the certainty and stability provided by the promise of patent protection."

BRIEF OF THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION:

"One of the greatest challenges facing the personalized medicine industry is obtaining funding for the necessary clinical research…. The availability of patent protection is essential to obtaining that funding. A ruling that novel and nonobvious diagnostic methods are ineligible for patent protection would cripple the nascent personalized medicine industry, to the detriment of the public."

BRIEF OF THE INTELLECTUAL PROPERTY OWNERS ASSOCIATION:

"[T]he promise of patent protection has led to the development of high-profile innovations like a prognosis for colon cancer…, a test for HIV/AIDS…, and a test for breast and ovarian cancer…. These medical advances depend heavily on the strong protection of intellectual property rights."

"Patent protection for medical innovations has jump-started growth in the biotechnology industry, especially in small-to-mid size companies that rely heavily on patented technologies…."

BRIEF OF HEALTH LAW, POLICY, AND ETHICS SCHOLARS:

"*Amici* write to advocate caution… and offer Hippocrates' own counsel: First, do no harm. Patent protection for medical process inventions has resulted in long-term benefits to public health, benefits that result from both private investment, and increased public knowledge. This Court should not limit the arsenal of incentives available to combat future health threats."

BRIEF OF NOVARTIS CORPORATION:

"The identification of biomarkers that help predict the efficacy of particular therapies permits physicians to tailor a treatment regimen for a particular patient. Such tailoring, in turn, lowers healthcare costs…. Personalized medicine achieves significant efficiencies—and dramatic improvements in results and quality of life—by identifying which therapeutics will work for a particular patient, and which might be less effective. Crucially, this is done without physicians having to engage, as they have traditionally, in the expensive, time-consuming, often empirical, and sometimes painful or tragic process of racing against the clock to determine whether a patient will respond favorably to a therapy."

BRIEF OF GENOMIC HEALTH, INC., VERACYTE, INC., XDX, INC., BIODESIX, INC., TARGET DISCOVERY, INC., THE COALITION FOR 21ST MEDICINE, AND BAYBIO:

"[T]housands of patents for innovations in the area of genetics and personalized medicine were sought and obtained over the last two decades. Reliant on the ability to patent their discoveries, private enterprise invested heavily in personalized medicine and freely disclosed invention-related data to the public. The resulting patent-protected investments have created a nascent industry that, if allowed to continue to thrive, promises to dramatically reduce ballooning health care costs while improving lives."

BRIEF OF THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS:

"Without the availability of patent protection to fuel the engine of tech transfer, medical research in academic laboratories would more often sit on the shelf, and the number and diversity of innovative discoveries entering the product development pipeline would decline."

"The very reason Mayo Labs could develop a purportedly improved product and potentially offer it at a lower price point was that Mayo Labs was able to take advantage of the work disclosed by the inventors of Prometheus's patented methods, without incurring the initial investment Prometheus itself had made when it licensed the technology from the inventors."

BRIEF OF THE NATIONAL VENTURE CAPITAL ASSOCIATION:

"With all the other uncertainties that exist in the personalized medicine industry, patents are needed to counterbalance the extremely high risk faced by startup companies. The lack of patent protection discourages venture investment, and will leave the promise of personalized medicine unrealized."

BRIEF OF THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO:

"The profound truth underlying Congress' broad statement of eligibility is that it fosters more innovation. Indeed, the foundation of our patent system is the notion that the lure of a United States patent encourages creativity. Filing an application provides the applicant's quid pro quo—disclosure and ultimate publication—to the benefit of the public. Even if those applications do not issue as patents, the public benefits because of their dedication. A cramped reading of section 101 would discourage filings, and we would never know what the public lost without them."

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION:

"[I]nventions in the field of personalized medicine often exploit known elements and discoveries. They do so, however, in the service of new and useful ways of diagnosing and treating patients. The inventive spark—a spark that is lit by extensive funding and research—occurs when a scientist connects the dots between these known and unknown elements, such as by using biomarkers to devise a new way of selecting patients, identifying symptoms that can be associated with a disease or using a drug to treat

those patients, or selecting a drug that does not trigger adverse reactions in the patient. The result of these insights—a novel and useful method or treatment—is and should remain patent-eligible."

*"*An inclusive standard for patent eligibility has proven essential to the successful development and commercialization of over 200 biotechnology therapies and vaccines, hundreds of diagnostic tests, and pest- and herbicide-resistant crops."

BRIEF FOR MYRIAD GENETICS, INC.:

"In reliance on the prospect of continuing patent protection for its advances, Myriad is making substantial investment in research and development and working diligently to deliver the next generation of personalized medicine products. Myriad scientists analyze thousands of specimens, searching the human body's biochemicals (DNA, RNA, microRNA, proteins, and metabolites) to identify molecular markers that correlate with disease characters and drug response…. The massive investment in researching and developing these new products and methods would not be feasible for Myriad, or for any company, without the promise of patent protection for the resulting inventions."

"European patents have been routinely granted on medical diagnosis method claims like those at issue in this case. Failure to protect medical diagnosis claims similarly in the United States threatens to put the U.S. at a competitive disadvantage."

BRIEF OF CONNECT AND SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION:

"[I]t is vitally important that the legal framework for obtaining and enforcing patents not ossify, but instead retain the maximum flexibility reasonably provided it by Congress to adapt to ever changing technology. A primary aim of the patent system should always be to foster, not hinder the development of new and unforeseen technologies."

BRIEF OF SAP AMERICA, INC:

"The software and computer industries are a vital part of today's Information Age economy and these industries depend on patent protection for growth and innovation. A decision regarding the scope of 35 U.S.C. § 101 as applied to medical diagnostic processes could have far-reaching effects in all technology areas, including software and other computer-related technologies."

BRIEF OF THE JUHASZ LAW FIRM, P.C.:

"[T]he issue in Prometheus is not simply about an 'observed correlation,' as the question presented strongly suggests. Rather, it is also about a methodology including chemical transformative steps for working up a chemistry inside of the body (to enable the observation of a correlation) not unlike transformative steps that work up a chemistry outside of the body which are not excluded by the Court as to subject matter patent eligibility in chemical process patents. The fact that the 'observed correlation' is occurring on body chemistry should be of no consequence."

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA):

PhRMA is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. In the past decade, PhRMA's members have invested more than $406 billion to discover and develop new medicines and new uses for existing medicines. The results of this research save lives. The Court's decision in this case will potentially have a significant impact on PhRMA's members. A ruling limiting the availability of patents for medical processes could dramatically diminish the incentives for investment in innovation. The average cost of bringing a pharmaceutical to market is over a billion dollars. In the absence of the incentives provided by patent protection, promising research for new methods of diagnosis and treatment likely will not occur.

> ***"Patents for medical processes, including those involving pharmaceuticals, have been issued and upheld for more than a hundred years. At present, tremendous and life-saving advances are being made with respect to various kinds of medical processes, including new uses for existing pharmaceuticals and processes for 'personalized' medicine. These advances, which entail extraordinary risk and expense on the part of the pharmaceutical and biotechnology industries, likely would not take place without the certainty and stability provided by the promise of patent protection." (p. 4)***

Under This Court's Precedents, Medical-Process Patents Involving Pharmaceuticals Are Patentable Under Section 101.

- "[M]edical-process patents involving pharmaceuticals – which are the products of human ingenuity, and cannot be found in nature – necessarily fall within the scope of § 101." (p. 3)

- "The wide scope of patentable subject matter, beginning with the 1793 Patent Act and extending through each subsequent re-codification, reflects Jefferson' s view that 'ingenuity should receive a liberal encouragement.'" (pp. 4-5) (quoting Writings of Thomas Jefferson)

- "Patents involving pharmaceuticals – whether they cover a chemical substance or a process in which that substance is measured or employed – necessarily involve such a transformation, and fall within the scope of § 101. Pharmaceuticals are not found materials like minerals or plants; they exist only as the result of human ingenuity. And the mixing of chemical substances, or a process for chemical transformation of a substance or object, is in the heartland of patent-eligible subject matter." (pp. 6-7)

- "In this case, for example, the patent covers the administration of a man-made drug, which creates metabolites in the body that would not exist in the absence of that drug, as well as the determination of the resulting effects on the patient…. Although there are natural laws at work that help explain why the drug creates a particular metabolite at particular levels, none of this is purely the 'handiwork of nature.'" (p. 7)

Congress Has Balanced Competing Policy Considerations And Clearly Expressed Its Intent To Provide Patent Protection for Medical Processes Involving Pharmaceuticals.

- "Congress has also clearly expressed its intent to protect medical-process patents involving pharmaceuticals. It has, for example, provided for term extensions for patents covering a 'method of using' a drug product, 35 U.S.C. § 156(a), and has decided not to enact legislation that would have restricted the patentability of medical processes." (p. 3)

- "Congress has balanced the interests of physicians and inventors by immunizing physicians when they infringe certain method patents, but not when they infringe patents for new uses of pharmaceuticals." (p. 3)

- "Congress has also made clear that medical processes are patentable, especially if they involve the administration of a pharmaceutical or a new use for a pharmaceutical. Any interpretation of § 101 that excludes medical processes involving pharmaceuticals would effectively write a number of provisions out of the U.S. Code, and would contravene other strong evidence of congressional intent." (p. 8)

- "Congress has also more specifically addressed patents involving a method of using a pharmaceutical, in several different enactments." (p. 8)

- "It is plain that Congress – having thoroughly considered the issue – wanted to protect all medical-process patents involving pharmaceuticals, including those that cover the relationship between the levels of a pharmaceutical in the body and a patient's health." (p. 11)

- "All of this makes clear that Congress has weighed the various policy considerations that Petitioners identify… and has decided that medical-process patents involving methods of using pharmaceuticals are entitled to protection even if they could conceivably affect the practice of medicine in some narrow circumstances. Because Congress has already determined that the benefits of pharmaceutical-related medical-process patents in spurring life-saving innovation outweigh any burdens that may be associated with those patents during their limited terms, Petitioners' concerns are wholly misplaced." (p. 12)

- "Congress' s enactments also show that any interpretation of § 101 that disqualifies medical-process patents involving correlations between administration of a pharmaceutical and reactions in the human body – a category into which a number of such patents fall – would significantly alter the scope of §101 in a way that is inconsistent with the legislature's own policy choices." (p. 13)

- "When Congress wishes to remove a particular subject matter from the broad scope of patent protection, it knows how to do so…. Here, far from excluding medical-process patents involving methods of using pharmaceuticals, Congress has repeatedly and expressly included them." (p. 13)

Patent Protection for Medical Processes Has Spurred Innovation that Improves Patient Health.

- "Under the regime reflected in this Court's decisions and Congress's enactments, medical innovation has thrived. The resulting inventions comprise medicines, devices, and diagnostic and therapeutic methods that have enabled physicians throughout the world to diagnose and treat many diseases. Patent protection has been – and will continue to be – critical in spurring the progress of science in this vital area." (pp. 13-14)

- "Relying on § 101, innovators have developed and patented medical processes, such as the process of using a particular drug in a particular fashion, for more than a hundred years." (p. 14)

- "The availability of patents covering such medical processes has provided incentives for inventors to undertake highly expensive and risky research and development, and has therefore been critical to the advancement of medicine." (p. 16)

- "But progress as to these kinds of processes would likely grind to a halt without stable and predictable patent protection, which offers the promise of recouping the extraordinary investments that are poured into inventing the processes and obtaining the government approval necessary to use them." (p. 16)

- "Today, much of the innovation in medical care comes from intensive study of possible new uses for existing medicines…. Where the underlying compound is already known, the compound itself is not eligible for patent protection. The 'practice has therefore been to patent as a "useful process" the use of a known drug for a recently discovered purpose.'" (pp. 16-17)

- "Personalized medicine is also an area in which extraordinary innovation is taking place…. Personalized medicine identifies 'biomarkers' – genetic or other biological characteristics – that permit doctors to tailor a course of treatment to a particular individual. That allows doctors to guide 'medication selection and dosage regimens' to 'ensure maximal drug efficiency and minimal adverse drug reaction.'… Correlations are the basis for this kind of personalization. People with a certain set of genetic characteristics may respond to a particular pharmaceutical when others do not; or they may require a higher dosage for the pharmaceutical to be effective, or experience a drug as toxic to their systems at lower levels than others do. Development of personalized medicine requires clinical research that identifies these correlations and permits creation of diagnostic tests to identify the relevant biomarkers." (pp. 18-19)

- "Advances in personalized medicine lower costs from adverse medical events and save lives." (p. 19)

- "Petitioners suggest that patent protection is not necessary in order for advances in medicine like these to take place – and may even prevent such advances…. Petitioners are wrong. Without some assurance that breakthroughs in these areas will fall within the scope of patentable subject matter, the extraordinary progress described above will likely cease, and the public will suffer." (p. 21)

- "Development of processes involving new uses for existing compounds and processes for personalized medicine involves similar challenges, and patent protection is equally necessary to

ensure continued progress in these highly significant areas of innovation. Just like an initial indication, a new indication must clear regulatory hurdles, including clinical trials and approval by the FDA – and this process is costly, time consuming, and risky." (p. 22)

- "Research and development in personalized medicine – for which a dizzying amount of data must be gathered, tested, and analyzed – is arduous in these same ways…. Accordingly, medical-process patents are (like patents on the pharmaceuticals themselves) critical to spurring innovation that will save or improve countless lives. Without the promise of protection that will enable recoupment of the enormous investment that goes into development of these processes, the development will not be undertaken." (pp. 22-23)

- "[I]nnovations related to new uses for existing drugs frequently happen at the hands of companies that did not discover the compound in the first place…. Such companies can protect their investment in innovation only by patenting the process." (p. 24)

- "Petitioners try to counter these weighty concerns by contending that academic research is inhibited by patent protection for medical processes…. Academic research does not generally put life- saving tests and treatments in the hands of patients; the tremendous investments described above are necessary to do that…. Petitioners' suggestion is without any basis – and, indeed, empirical research suggests that patent protection is no bar to academic advances. According to one study, only 1% of academic respondents reported a project delay of more than a month due to patents on inputs necessary for their research; none reported abandoning a research project due to the existence of patents." (pp. 24-25)

- "In fact, just the opposite is true. Patent disclosures educate the research community on important advances and spark additional progress. Patents make the exchange or acquisition of knowledge more efficient and less costly, allowing the scientific community to learn from the successes and failures of others." (p. 26)

- "[I]t is clear that disrupting expectations of patent protection in medical processes will severely restrict important medical gains." (p. 26)

Petitioners' Approach Destabilizes This Regime and Undercuts Incentives for Innovation.

- "While purporting to rest on this Court's existing precedents, Petitioners call into question the long- established regime that has given rise to these important medical advances." (p. 27)

- "Petitioners seek to change the law so as to destabilize this regime, and undercut the incentives for innovation, in at least three ways – all of which should be rejected." (p. 4)

- "[T]he kinds of medical-process patents described above regarding new indications and personalized medicine, which are adding immeasurably to the quality of patient care, involve such laws to the extent that they depend on chemical reactions and other basic scientific principles. Were it permissible to search for the law of nature hidden somewhere within a patent claim, then virtually every patent could conceivably be drawn into question under § 101." (pp. 31-32)

- "Petitioners' approach of breaking a claim into its building blocks, and then insisting that the claim is invalid if any one of those blocks can be characterized as a law of nature (or as falling within one of the other exceptions associated with §101), is irreconcilable with these well-established doctrines." (pp. 32-33)

- "In Prometheus's patent, it is the administration of the pharmaceutical that creates the metabolites in the first place, and the determining step that allows those new metabolites to be quantified – and both of these are necessary in order for a physician to be advised that metabolite levels are too low or too high to treat the family of diseases at which the patented method is directed." (p. 33)

- "Were this Court to adopt the approach that Petitioners urge, lower courts would be forced to engage in what is essentially a policy-based analysis in order to decide questions of patentability under § 101, asking in the most general terms whether the patent at hand sweeps too broadly and covers things that society would prefer to remain unencumbered. It is hard to imagine anything more likely to engender uncertainty and confusion among would-be inventors, and thus to discourage inventions that require significant up-front risk and investment of time and money – as do societally beneficial medical- process inventions." (p. 36)

BRIEF OF THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION:

The American Intellectual Property Law Association ("AIPLA") is a national bar association whose approximately 16,000 members have interests and practice primarily in the areas of intellectual property. AIPLA's members include attorneys in private practice, corporate practice, and government or academic positions involved directly or indirectly in the practice of patent, trademark, copyright, unfair competition, and other fields of law affecting intellectual property. AIPLA members include both owners and users of intellectual property, representing the interests of both plaintiffs and defendants. The issue of patent eligible subject matter is vital to most, if not all, members. Many members practice in the biotechnology, pharmaceutical, and medical services industries. The Court's decision will potentially impact thousands of issued patents and pending applications relevant to those industries.

> ***"One of the greatest challenges facing the personalized medicine industry is obtaining funding for the necessary clinical research…. The availability of patent protection is essential to obtaining that funding. A ruling that novel and nonobvious diagnostic methods are ineligible for patent protection would cripple the nascent personalized medicine industry, to the detriment of the public."*** (p. 24)

Section 101 Is Very Broad – and the Prometheus Patent Should Not Be Excluded Under It.

- "[Section 101] has been construed broadly by this Court to exclude only three categories of invention: laws of nature, physical phenomena, and abstract ideas. The diagnostic methods claimed by Prometheus do not fall into any of these excluded categories." (p. 2)

The Patent Office Has Been Granting Patents for Similar Types of Inventions for Decades.

- "Prometheus's methods, like many other patents directed to personalized medicine, therapeutic treatment of humans, and diagnostic methods, utilize the natural metabolic process of the human body, but those natural processes are not what is 'claimed' and therefore should not serve as a basis to deny patent protection. Simply put, the mere involvement of a natural metabolic process in claims directed to personalized medicine, therapeutic treatment of humans, or diagnostic methods should not be used as a basis to deny patent protection to that whole class of inventions, especially where the U.S. Patent and Trademark Office ('PTO') has been granting patents on these types of inventions for decades and where the patent statute explicitly recognizes them." (pp. 2-3)

The Patent Statute Accounts for the Policy Concerns Raised by Mayo.

- "Petitioners raises a host of policy concerns in an attempt to convince this Court that the diagnostic claims in this case should not be eligible for patent protection under 35 U.S.C. § 101. The flaw in Petitioners' arguments, however, is that Congress has already balanced the competing policy concerns associated with diagnostic method claims and enacted specific provisions to address those concerns. And rather than amend section 101 of the patent statute, Congress enacted other provisions to take those concerns into account." (p. 4)

Mayo's Claims that the Prometheus Patent Would Create Liability for Doctors Is a Ruse -- the Patent Statute Expressly Precludes Patent Infringement Lawsuits Against "Medical Practitioners."

- "In its brief, Mayo complains that diagnostic method patent claims prevent 'doctors from using their best medical judgment,' 'force doctors to spend unnecessary time and energy to enter into license agreements,' 'divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations,' and 'raise the cost of health care while inhibiting its effective delivery.'… The patent statute, however, expressly precludes patent infringement lawsuits against medical doctors and the health care institutions with which they affiliate for performing certain medical activities, thereby negating these concerns." (pp. 4-5)

- "Mayo's concerns regarding doctors being required to search patent files or obtain patent licenses are illusory. Furthermore, these provisions of section 287(c), providing relief from infringement for certain activities by medical practitioners, would not be necessary (and in fact would be meaningless) if these types of activities were not otherwise considered eligible for patenting under section 101." (pp. 6-7)

Congress Could Have, But Did Not, Limit Patentability Under Section 101 in the Recently-Enacted *America Invents Act*.

- "On September 16, 2011, the President signed the Leahy-Smith America Invents Act (hereinafter referred to as the 'America Invents Act' or 'AIA')…. [T]he AIA was 'a 6-year work in progress,'… Congress amended many provisions of the patent statute, but notably Congress declined to amend section 101, even though the process included numerous occasions for it to consider policy issues concerning patentable subject matter." (p. 7)

- "Congress in that legislation affirmatively excluded certain types of inventions from patent eligibility, but it did not exclude patent protection for diagnostic method inventions. In connection with diagnostic method inventions, the balance struck by Congress at this time is only that a study of a limited subset of such inventions be conducted by the Director. In light of that balance, it would be inappropriate for this Court to conclude otherwise in this case." (p. 9)

Prometheus's Method Claims Are Patent Eligible under Section 101 and This Court's Precedent.

- "Prometheus's claims require administering a drug to a patient and measuring that patient's ability to transform the drug into its metabolite. Both of these steps are the result of human intervention and do not occur in nature. The 'wherein' clauses of the claims which follow these steps apply the results of these man-made steps to allow a determination whether an adjustment in the treatment is necessary. The distinction between a claim to a mere principle and a claim to a process which applies the principle to effect a useful result, has long been recognized by the Court." (pp. 10-11)

- "To be sure, Prometheus's patent claims, like many other patent claims related to the therapeutic treatment of humans, rely on the natural metabolic processes of the human body (much like many mechanical devices rely on the natural process of gravity). The mere fact that an invention exploits natural metabolic processes, however, cannot be used as a basis to render this whole

class of inventions ineligible for patent protection." (p. 11)

- "Over a long line of cases, this Court has explained that abstract ideas, laws of nature, and natural phenomena are not eligible for patent protection under § 101, but a practical application of one of these principles may be patented." (p. 11)

- "Prometheus's patent claims are directed to practical applications of metabolic processes to achieve a useful result, namely determining the optimum treatment range for a particular individual based on his or her personal metabolic rate. Such a diagnostic process can minimize the hazardous side effects of available medicines while at the same time optimizing their healing effect on a personalized basis…. Prometheus's process claims pass the physical transformation threshold for patent eligibility." (p. 12)

Any "Correlation" in Prometheus's Method Is Not a Law of Nature or a Physical Phenomenon.

- "[T]he 'law of nature' category that this Court has excluded from patent protection is directed at the most fundamental of physical principles. When such laws of nature are harnessed by human ingenuity into correlations that can be applied in practical and useful methods, such as methods of diagnosing or treating disease, patent protection should be available, and neither this Court nor Congress has ever said otherwise." (p. 14)

- "Here, the inventors determined that metabolite levels below a certain amount (one variable) indicated a need to increase drug dosing (the other variable), and that metabolite levels above a certain amount (one variable) indicated a need to decrease dosing (the other variable). Those correlations are subject to interpretation and revision, as evidenced by Mayo's arguments. Laws of nature and physical phenomenon, on the other hand, are not subject to the interpretation of the observer; they are truisms." (pp. 14-15)

- "The PTO has long recognized the patentability of diagnostic claims, including those that apply a biological correlation. Indeed, Petitioners' own patent portfolio includes many patents directed to biological correlations." (pp. 15-16)

Narrowing the Availability of Method-Based Patents Would Harm the Medical Research Industry.

- "[N]arrowing the interpretation of section 101 to exclude claims that include a biological correlation, like those in Prometheus's patents or for that matter in Mayo's patents, would have an unintended and chilling effect on the medical research industry." (p. 17)

- "Medical research and diagnostic companies spend billions of dollars annually to develop new methods for diagnosing or predicting a susceptibility to disease, as well as new methods of making and testing drugs in order to ensure their safety and efficacy…. Patent protection for diagnostic and therapeutic processes is necessary to ensure that the companies investing in medical research are adequately compensated for large development and regulatory costs." (p. 17)

- "Patent protection provides a necessary incentive for others to invest in similar research and

development, leading to increased economic health as well as advancing the general well being of the public." (pp. 17-18)

Patent Protection Is Vital to the Personalized Medicine Industry.

- "The impact of patent protection varies from industry to industry, but it is particularly critical to medical research industries such as pharmaceuticals, biotechnology, and personalized medicine. Medical research companies spend billions of dollars annually to develop new methods for diagnosing or predicting susceptibility to disease as well as new methods of making and testing drugs in order to ensure their safety and efficacy." (p. 22)

- "Diagnostic tests to identify increased risk of disease, to allow early detection of disease, and to ensure safe and/or effective administration of drugs are vital to improving the health and quality of living throughout the world. Patent protection for diagnostic processes is necessary to ensure that the companies investing in medical research are adequately compensated for large development and regulatory costs and to provide incentives for others to invest in similar research and development." (pp. 22-23)

- "Personalized medicine designs therapies around a given patient's unique physiology, such as a particular patient's ability to metabolize a particular drug…. This approach to treatment avoids the high costs (in terms of lives and dollars) of the traditional trial and error approach to diagnosis and treatment." (p. 23)

Petitioners' Many Complaints Are Appropriately Addressed by Other Provisions of the Patent Statute.

- "[Many of petitioner's claims] are not presently before this Court. More importantly, they are not appropriately addressed under section 101 of the patent statute—the patent statute has other provisions that squarely address these concerns with requirements that the claimed invention is new, nonobvious and clearly disclosed." (p. 18)

BRIEF OF THE INTELLECTUAL PROPERTY OWNERS ASSOCIATION:

Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and a total of over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. IPO represents the interests of all owners of intellectual property.

"IPO believes that this Court's precedent appropriately interprets the broad standards for patent-eligible subject matter set forth in Section 101 of the Patent Act. The Court should decline to use this case to erect further, extra-statutory barriers to patent-eligible subject matter that would disrupt those standards, particularly in the field of medical diagnostic techniques, where innovation relies on broad patent protection. The construed claims in this case recite transformative methods of medical treatment that should fall within the broad scope of patent-eligible subject matter." (p. 17)

Congress and the Courts Designed Patent Law To Be Broad – Section 101 Is a Low Threshold and Should Not Be Merged with the More Stringent Patentability Requirements such as Novelty or Non-Obviousness.

- "Congress and Courts alike have broadly defined the types of inventions that may be eligible for patent protection." (p. 2)
- "[T]he Petitioners appear to be asking this Court to use Section 101 beyond its intended purpose as a permissive threshold for filtering patent-eligible subject matter. Repeatedly, Petitioners' Brief suggests that the claimed invention should not be patentable because it involves methods that are well-known to doctors, thereby implicating issues of novelty or obviousness." (pp. 5-6)
- "Section 101 merely defines the field of patent-eligible subject matter." (p. 7)
- "[T]he Court should apply Section 101 in its proper purpose as a permissive threshold, and leave for another day the questions of whether the substantive conditions of patentability are met for the claimed invention." (p. 8)

A Broad Scope of Patentability Is Particularly Important for Medical Treatments.

- "This Court has long recognized the need for patent law to incentivize innovation and the public disclosure of such innovation. This need is particularly crucial in the field of medicine, given the potential life-changing importance of its breakthroughs and the rapid pace of discoveries in the industry. This Court's precedent appropriately acknowledges that in 35 U.S.C. §101 a broad scope of patent-eligible subject matter well serves this goal." (p. 3)
- "This Court has repeatedly recognized that a permissive approach to subject matter eligibility serves an important role in promoting technological innovation in our country." (p. 8)

- "This Court also has acknowledged that this approach is consistent with the intent of our country's founders and Congress: 'Congress took [a] permissive approach to patent eligibility to ensure that "ingenuity should receive a liberal encouragement."'" (p. 8) (quoting Writings of Thomas Jefferson)

- "The incentive that patent protection creates is particularly important with the rapid pace and unpredictability of medical treatments. The field of diagnostic medicine continues to develop, and scientists increasingly have been able to diagnose, predict, and treat medical conditions that were not long-ago unknown." (p. 9)

- "[T]he promise of patent protection has led to the development of high-profile innovations like a prognosis for colon cancer…, a test for HIV/AIDS…, and a test for breast and ovarian cancer…. These medical advances depend heavily on the strong protection of intellectual property rights." (pp. 9-10)

- "Patent protection for medical innovations has jump-started growth in the biotechnology industry, especially in small-to-mid size companies that rely heavily on patented technologies…. Developing a discovered correlation into a marketable diagnostic technology is extremely costly, and requires the efforts of venture capitalists, developers, managers, laborers, technologists, manufacturers, marketers, and distributors. Patent protection encourages this diverse group of people to cooperate." (p. 10-11)

- "As in other fields, the eligibility for patent protection for medical treatment methods creates the incentive for inventors to disclose the innovation to the public in exchange for such protection. Correspondingly, the profit potential that may flow from the exclusive rights of an enforceable patent covering a medical invention provides the incentive for parties to work together to bring an innovation to market…. If the patent eligibility of medical diagnostic tools is questioned—or eliminated—funding for risky and expensive projects will be less forthcoming, and in turn, advances in medical diagnostic testing will be less forthcoming as well." (p. 11)

- "A change in the broad application of Section 101 not only would upset settled expectations in the medical field, but it could have a destructive impact on the continued advances in medicine that have led to society-improving breakthroughs. Only if scientists, doctors, and investors can rely on broad access to patent protection will we continue to benefit from the incredible innovation in this field that our society has enjoyed in the last several decades." (pp. 11-12)

Transformative Methods of Medical Treatment and Diagnostics Should be Patentable.

- "[T]he U.S. Court of Appeals for the Federal Circuit construed the asserted claims as methods of treatment, requiring a specific application of a correlation of metabolites in the body that requires a transformation of matter to a different state. The Federal Circuit held that the asserted claims represent patent-eligible subject matter under 35 U.S.C. § 101. Under this Court's precedent, such methods of treatment are patent eligible subject matter. Respondent's arguments to the contrary should be rejected, for they seek to draft new, extra-statutory exceptions onto Section 101 of the Patent Act or confuse patent-eligibility under Section 101 with the conditions for patentability under Sections 102, 103 and 112." (p. 4)

- "[T]his Court's precedent recognizes that applications of laws of nature, natural phenomena, and abstract ideas, which are new productions from these elements, are patent-eligible." (p. 12)

- "Transformative methods of treatment should be patent-eligible. In the context of a specific category of disease, a novel method for the application of a naturally-occurring correlation with treatment steps that involve transformations of the body is eligible for patent protection." (p. 13)

- "[M]ethods for treatment of a specific disease, that require transformation of bodily components based on administration of a drug, do not pre-empt all uses of any natural correlations or mathematical formulas. Thus, Respondent's claims are directed to a 'process,' which Congress in 35 U.S.C. §101 and this Court in the cases discussed above have defined as a type of invention that may be eligible for patent protection." (p. 16)

BRIEF OF HEALTH LAW, POLICY, AND ETHICS SCHOLARS:

Amici are scholars of health law, policy, and ethics. They have devoted their careers to the study and promotion of public health. Their perspective reflects a broad utilitarianism that seeks the greatest good for the greatest number. The foundational public health principle affirms one simple objective: to prevent avoidable suffering and death.

> ***"Amici write to advocate caution in the Court's resolution of this question and offer Hippocrates' own counsel: First, do no harm. Patent protection for medical process inventions has resulted in long-term benefits to public health, benefits that result from both private investment, and increased public knowledge. This Court should not limit the arsenal of incentives available to combat future health threats."*** (p. 3)

Medical Process Patents Advance Public Health.

- "[P]atent eligibility for claims to medical diagnostic and treatment processes prevents avoidable suffering and death. Steady improvement in medical treatment methods, especially for complicated, risky, and painful therapies, is vital. Advancement at some short-term cost is better than no advancement. The removal of long-standing incentives to improve disease treatment could do enormous damage to medical progress. This Court should not limit the arsenal of incentives available to combat future health threats." (p. 1)

- "A long-term, population-based approach to patent policy offers compelling reasons to maintain the patentability of medical diagnostic and treatment processes: those inventions save lives over time. Their patentability encourages sensible private investment in medical advances and fosters widespread public dissemination of medical discoveries." (p. 3)

Section 101 Authorizes Medical Process Patents.

- "The Founders enshrined in the Constitution their empirical judgment that patents promote societal progress." (p. 4)

- "[A]t each opportunity, Congress has maintained its expansive view of patentable subject matter, to the benefit of American progress." (p. 4)

- "[F]or over 100 years, Congress has declined invitations to exclude medical treatment methods from Section 101." (p. 6)

- "The AMA lobbied Congress to exclude medical procedure patents from the Patent Act's protection…. Congress rejected medical lobbyists' initial attempts to restrict patentable subject matter… [and] created Section 287(c)(1) to grant immunity from patent infringement suits to both '"medical practitioners" and "related health care entities": when they engage in protected "medical activity."'… The very premise of the AMA's efforts that resulted in Section 287(c)(1) is that Section 101 permits medical process." (p. 7)

Medical Process Patents Encourage Private Investment.

- "Patent law protects medical diagnostic and treatment innovations for the same reason it protects all types of inventions: patents spur progress." (p. 8)

- "Innovation in disease treatment is complicated and expensive. At the frontiers of medical science, the balance between risk and reward weighs heavily against making any effort. Research and development merely initiate the costly process of bringing an effective therapeutic intervention to market. Production, clinical trials, regulatory compliance, distribution, monitoring and insurance for adverse outcomes, and physician education all draw on limited investment resources." (p. 8)

- "In this economically constrained environment, patents preserve the financial feasibility of investments in medical research. Private investors allocate resources based on whether the end result can be commercialized and patented, not whether medical technology will be advanced. Innovative medical methods are cheaply reproduced by others, and without some promise of exclusivity, investment fades." (pp. 8-9)

- "Patents on diagnostic tests provide incentives for scientist-inventors to innovate beyond the basic, government-funded research for which no patent can be sought, and apply that theoretical research to a useful product. That useful product is the benefit upon which the patent quid pro quo is based." (pp. 9-10)

- "[M]edical process patents appropriately align investment incentives to expected consumer value: The patentee's profits as a monopolist are tied to demand. If an innovation is of no use to people, the innovation will not lead to private investment. But a patentable innovation that is of considerable use to sick people, for example, will likely produce a return and justify appropriate capital investment in research." (p. 10)

Medical Process Patents Increase Public Knowledge.

- "Medical patents encourage widespread and immediate dissemination of medical knowledge. That is their entire purpose—patents offer the potential for limited financial rewards ex ante, but in exchange, they require full disclosure ex post." (p. 11)

- "[T]he patent system may better facilitate dissemination of medical knowledge than publication in professional journals. Under U.S. patent law, the inventor must not only disclose the invention, but explain it in such full, clear, and succinct terms as to enable any person skilled in the art to replicate it.… Medical journals have no such requirement. Nor do they publish all data submitted to them—the peer review process necessarily narrows the spectrum of publishable research." (p. 13)

The Ethical Concerns Raised by the Medical Associations Are Shortsighted or Misdirected.

- "The 'ethical' objections raised by the medical associations reflect a misplaced emphasis on the short-term concerns of individual patients at the expense of long-term public welfare." (p. 3)

- "A physician's commendable sensitivity to an individual patient's immediate welfare can distort her perspective on long-term policymaking…. Physicians and their professional associations may value individual autonomy and patient-specific protections from potential conflicts of interest more than the general health and well-being of the community." (pp. 18-19)

- "[T]he AMA has long grounded its opposition to medical process patents in concern for the individual patient under the care of the health professional…. The AMA's admirable fidelity to the individual patient's rights and needs has misled it in this instance to a counterproductive position on patent policy." (p. 20)

- "[F]or other types of patents the medical associations recognize the contributions to patient health and welfare made possible by innovations protected under the Patent Act…. [M]edical process patents promote patient health and welfare. From a medical perspective, the relevant question should be whether the invention promotes public health. The medical associations provide no reason to distinguish among different kinds of medical innovations amenable to patent protection." (pp. 21-22)

The Medical Associations' Practical Concerns Should Be Directed to the Executive or Congress.

- **"**To the extent the PTO is not advancing the evident purpose of the statutory nonobviousness and novelty requirements, the AMA's complaint is with the Executive or, failing that, Congress. These administrative complaints are not a basis to misconstrue 35 U.S.C. § 101." (pp. 23-24)

- "To the extent medical process patents raise unique cost-related or other ethical concerns, Congress is free to act." (p. 26)

BRIEF OF NOVARTIS CORPORATION:

Novartis Corporation is an indirect wholly-owned subsidiary of Novartis AG, a Swiss holding company, whose affiliates around the world provide healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, the Novartis companies offer a diversified portfolio to best meet patient and social needs: innovative medicines, eye-care products, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools, over-the-counter health aids, and animal-health products.

> ***"The identification of biomarkers that help predict the efficacy of particular therapies permits physicians to tailor a treatment regimen for a particular patient. Such tailoring, in turn, lowers healthcare costs…. Personalized medicine achieves significant efficiencies—and dramatic improvements in results and quality of life—by identifying which therapeutics will work for a particular patient, and which might be less effective. Crucially, this is done without physicians having to engage, as they have traditionally, in the expensive, time-consuming, often empirical, and sometimes painful or tragic process of racing against the clock to determine whether a patient will respond favorably to a therapy."*** *(p. 18)*

Patents Are Necessary for Healthcare Companies Like Novartis To Protect Its Investments in Developing Medical Innovations.

- "Like any healthcare company, Novartis relies on patents to protect its many innovations in patient care. Absent an ability to protect its investments with valid patents, healthcare companies like Novartis would lack the necessary incentive to make the extraordinary financial out-lays required to bring medical innovations to market." (p. 2)

- "A reversal of the judgment below would threaten the patent-eligibility of therapeutic and diagnostic processes under §101 of the Patent Act, 35 U.S.C. §101. This would have a chilling effect on the advancement of the health-care solutions developed by the Novartis companies and others. In turn, this would have a devastating impact on those who depend on such developments (and on the investments which make those developments possible) for their health and for the support of their local economies." (p. 2)

- "Novartis and many other healthcare companies are expending hundreds of millions of dollars to identify new biomarkers and apply their detection to new diagnostic and therapeutic methods…. Although driven by the desire to improve healthcare, the prospect of patent protection also provides an important incentive to expend—and the necessary protection to fund—the time and effort necessary to make biomedical discoveries and translate them into new medical procedures that help patients." (p. 19)

- "The protections afforded by patent-eligibility also fuel the very economies where companies have or intend to have a presence. Novartis's decision to expand its operations in Cambridge, Massachusetts, is a case in point. Despite the present economic crises, the company expects to spend $600 million to bolster its research operations and strengthen partnerships with local universities and biotechnology start-ups…. It also estimates hiring an additional 200-300

employees over the next five years, which would bring the total Novartis workforce in Cambridge alone to about 2,300. Such investments would be jeopardized without access to patent protection, and a potential for return on that investment. And yet it is these very types of investments that will be critical not only to preserving the health of Americans, but also to sustaining our economy." (p. 21)

The Ability To Detect or Measure Biomarkers Makes Personalized Medicine Possible, and the Resulting Therapeutic- and Diagnostic-Processes Are Patent-Eligible Under § 101.

- "[P]ersonalized medicine uses biomarkers to correlate an *individual's* genetic makeup with particular diseases; to identify whether the *individual* will be compatible with particular therapies that work for some, but not all, patients; or to pinpoint the dosage range over which a therapy will exhibit a combination of maximal efficacy and safety for the *individual*." (p. 3)

- "Those techniques—new and infinitely useful—are processes that are patent-eligible under §101. They lie squarely within the 'useful arts' that delineate that section's broad and dynamic scope…. Indeed, these new techniques are directed to perhaps the most 'useful' endeavor of all—directly enhancing the quality of, or even sustaining the very existence of, human life." (p. 3)

- "To be sure, therapeutic- and diagnostic-process claims invariably hinge on laws of nature, which themselves are not patentable and, hence, belong equally to all. But such claims, to be valid, do more than simply inscribe natural laws. Rather, they invariably *use* such laws to solve otherwise intractable problems relating to patient diagnosis and treatment." (p. 4)

- "It is all too easy to dismiss the relationships being identified in this new era of personalized medicine as discoveries of the laws of nature…. But the discovery of those relationships and their utility in treating diseases can represent a critical advance in the important art of making the unhealthy healthy, or providing the individual who is prone to disease with immunity to its effects. Where a new and useful process for identifying those who are at risk of disease or most likely to benefit from a particular treatment is discovered, it represents a true advance in the art of medicine and technology. When a process claim clearly calls for the detection or measurement of a relevant bio-marker, such claim language should suffice for the claim to be patent-eligible under §101." (pp. 19-20)

- "Personalized medicine can be the difference between life and death. It directly enhances the quality of, or even sustains the very existence of, human life. It is hard to imagine a more 'useful' invention than a process applying newly discovered natural relationships to that end." (p. 29)

- "The diagnostic-process claims at the heart of personalized medicine are the result of the same kind of intellectual exertion and have the same utility as machine-age processes, even though they are couched in the language of molecular biology rather than that of mechanics and electronics." (p. 29)

- "As this Court has repeatedly held, processes *applying* laws of nature, natural or physical phenomena, or abstract ideas are patent-eligible under §101, because they do not *preempt* these

fundamental principles of science." (p. 4)

- "[O]ne may not patent a law of nature itself, but may patent an *application* of it for 'new and useful' ends. This should not be viewed as an unusual balance to strike; virtually any useful patent claim must ultimately rely on laws of nature to generate useful results." (p. 9)

- "[D]iagnostic-process claims, like the therapeutic-process claims at issue here, are not simply directed to a law of nature itself, but to a practical application of a law. They invariably require the detection of a biomarker and take advantage of a natural correlation between that bio-marker and a disease to make a diagnosis and thereby inform a course of treatment, if needed or desired. Hence they do not offend §101." (pp. 9-10)

Section 101 Should Continue To Have a Broad Scope.

- "Section 101 of the Patent Act has an intentionally and historically broad scope. This Court has repeatedly affirmed that breadth and never has held that medical diagnostic or therapeutic processes are categorically ineligible for protection under that section. It should decline Mayo's invitation to break from that tradition now." (pp. 2-3)

- "[W]hen the Patent Act requires recalibration, Congress has responded—but not by revising §101. That bedrock provision has remained unchanged since 1952, when it was codified at its present location within Title 35. Indeed, even with the recent enactment of the Leahy-Smith America Invents Act of 2011, Congress adjusted the finer filters of §§102, 103, and 112, but not the coarse filter of § 101." (p. 14)

- "Asking §101 to do the work of [sections 102, 103, and 112] is to propose an answer that is far worse than the problem. It would force a procrustean solution on the courts and the country. It would disregard the text and structure of the Patent Act, which encourages the kind of innovation, investment, and activity that leads to the development of the useful arts. With the stroke of a pen, it would decree that diagnostic and therapeutic innovations, which are the fruits of immense financial and intellectual investment, are *not* patent-eligible. Doing so would have the readily foreseeable and undesirable consequence of depriving American patients of much-needed medical innovation and the American economy of much-needed activity." (pp. 5-6)

- "Constricting §101 so tightly that therapeutic- and diagnostic-method claims would be summarily precluded from patent-eligibility would not only usurp the filtering function of these other sections of the Patent Act, but also effectively invalidate a plethora of patents directed to such subject matter. Furthermore, it would endanger the pharmaceutical and biotechnology industries, patients throughout the United States, and the American economy." (p. 7)

- "Indeed, denying patent protection would retard the unfolding revolution in healthcare stimulated in large part by personalized medicine. Without the promise of patent protection, the necessary incentive to make the intensive and costly investment in the research and development of therapeutic and diagnostic processes would instantly disappear, as would the benefits such an investment provides to our economy." (pp. 7-8)

BRIEF OF GENOMIC HEALTH, INC., VERACYTE, INC., XDX, INC., BIODESIX, INC., TARGET DISCOVERY, INC., THE COALITION FOR 21ST MEDICINE, AND BAYBIO:

Amici are each active participants in the personalized medicine field. Amici are vitally interested in the success of personalized medicine. Each is involved at the forefront of this great, new frontier. Experience in the trenches has given Amici a unique perspective regarding the difficulties inherent in commercializing this emerging technology, and the recognition that patent protection is critically important to attract and retain private investment and drive future innovation.

> ***"[T]housands of patents for innovations in the area of genetics and personalized medicine were sought and obtained over the last two decades. Reliant on the ability to patent their discoveries, private enterprise invested heavily in personalized medicine and freely disclosed invention-related data to the public. The resulting patent-protected investments have created a nascent industry that, if allowed to continue to thrive, promises to dramatically reduce ballooning health care costs while improving lives."*** (p. 5)

This Court's Precedent Supports the Patent Eligibility of Personalized Medicine Claims.

- "For many years patents have been awarded for innovations in the personalized medicine area. The reliable issuance of such patents has been based on a solid legal foundation formed by this Court's precedent." (p. 4)

- "Key decisions of this Court wisely, and broadly, approved of patenting in the area of genetics as well as for concrete processes that use scientific principles at their heart." (p. 4)

- "Many inventions in the personalized medicine area arise from the discovery of a relationship between the genetic profile of a person and the optimized diagnosis and treatment of that person for a specific disease. This is frequently referred to in the briefing before the Court as a 'correlation.' There should be little doubt that it is inventive to identify and apply these correlations to a concrete process to improve the diagnosis and treatment of the unhealthy for a particular disease. It takes both inspiration and perspiration to create these inventions." (p. 10)

Personalized Medicine Holds Great Promise, But Innovation and Ultimately Patient Care Will Suffer Without Patent Protection.

- "Personalized medicine has the potential to revolutionize patient care by allowing physicians to design targeted treatments that both reduce the cost of healthcare and improve patient outcomes." (p. 12)

Enforceable Patent Protection Is Critical to Investment in Personalized Medicine.

- "The Congressional Research Service arm of the Library of Congress has documented that a key driver for research and development in medical technology is enforceable patent protection." (p. 14)

- "[L]ed by American ingenuity and entrepreneurialism, this sector could serve as an economic engine for decades to come if the fruits of investment are sheltered from copying through enforceable patent protection." (pp. 5-6)

- "Despite the mass expense and risk of creating a new diagnostic test from scratch, copying such a test can be remarkably easy. Once the relationship is proven, the validation data disclosed, the test approved, and the conventional wisdoms overcome, a new test can be simple and cheap to clone. The primary bulwark against such copying is enforceable patent protection." (p. 6)

- "[I]t would be particularly unfair and destabilizing to invalidate the thousand of patents that have already issued, those in process, or those currently motivating ongoing or planned research and investment. But, more than that, it would be a devastating blow to the promise of personalized medicine to compromise patent protection for this industry just as it is beginning to make a significant impact on patient care and helping to reduce the staggering cost of our health system." (pp. 6-7)

- "Diagnostics companies have invested based on the settled expectation that, if able to obtain clinical acceptance and payer reimbursement, novel tests would be protected from competitor copying for the remainder of their patent terms. As a result, in the United States personalized medicine has budded and blossomed into a $11.2 billion market that employed more than 40,000 people in 2005." (p. 14)

- "The patent system is essential to protect and drive biomedical innovation because it is the protection from copying for novel diagnostics that attract financial investment. This is especially true for diagnostic tests, which like pharmaceuticals, are easily imitated." (p. 15)

- "Personalized medicine reduces – and can eliminate altogether – the need for expensive, but reimbursable procedures that have long been staples of the healthcare economy. The revenues from these traditional procedures may be viewed as lifeblood for elements of the medical establishment and others who prosper from the status quo, including many of the amici supporting petitioner. This explains the medical establishment's concern about the disruptive changes to their business that will follow from a patent-incentivized personalized medicine industry." (p. 17)

- "Given the high costs of R&D, private funding is critical to the future of personalized medicine companies, many of whom have relatively limited resources with which to navigate the long and expensive research, development, and commercialization cycles required in this area. Investors are keenly aware that patent exclusivity is absolutely necessary to have any hope of recouping the huge amount of investment necessary to launch a single successful product." (p. 17)

- "There is no basis to believe that academia, or the public sector, can nourish personalized medicine as effectively as can patent-protected private sector investment. Suggestions to the contrary by those against patents simply defy common sense." (p. 18)

- "Eliminating biomedical process patents, or creating uncertainty about their enforceability would likely cause a fatal crack in the industry's already-weakened foundation, setting back hopes for a new era of targeted and thus less expensive medicine." (p. 21)

BRIEF OF THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS:

AUTM is a non-profit professional association with the objective of addressing the concern that inventions funded by the United States government were not being commercialized effectively. AUTM is the largest association of university technology transfer professionals, with a membership of more than 3,600 intellectual property managers and business executives from 45 countries. AUTM's members represent more than 350 universities, research institutions, teaching hospitals, and government agencies worldwide, as well as hundreds of companies involved with managing and licensing innovations derived from academic and non-profit research. AUTM's mission is to ensure that basic, early-stage scientific research is translated into commercial products for the public benefit.

> ***"Without the availability of patent protection to fuel the engine of tech transfer, medical research in academic laboratories would more often sit on the shelf, and the number and diversity of innovative discoveries entering the product development pipeline would decline."*** (p. 9)

Through the Patent System, Universities and Other Research Institutions Are Able To Transfer Early-Stage Research to the Private Sector for Further Development and Commercialization.

- "At its core, the function of the United States patent system is to drive innovation. This purpose is grounded in the U.S. Constitution…" (p. 5)

- "Universities and research-based institutions play a critical role in achieving the goals of the patent system and promoting innovation through the technology transfer process. Tech transfer is an important means by which scientific discoveries and inventions are transferred from universities to private-sector organizations for development, commercialization, and practical application. These are expensive, time-consuming, and risky investments that universities cannot make." (p. 5)

- "Technology transfer ('tech transfer') licensing activity fuels innovation, particularly for biomedical technologies, but this success is dependent upon the clear, consistent, and correct interpretation of the patent laws, including § 101's patent-eligibility standard. The fundamental purpose of tech transfer is to translate academic research into practical application, and tech transfer relies on the patent system to operate effectively. Patent rights are the currency of the tech transfer process, allowing early-stage research to be moved from universities and research institutions to the private sector for development and commercialization." (pp. 3-4)

- "A broad, encompassing standard of patent eligibility, as intended by Congress and supported by this Court's precedent, is important to encourage innovative research and development, particularly in nascent biomedical fields like personalized medicine and established, but rapidly-evolving, fields like diagnostic testing." (p. 4)

- "Eliminating entire categories of inventions and discoveries at § 101's eligibility threshold, as Petitioners urge, would reduce the number and diversity of inventions entering the product development pipeline and defeat Congress's intent to use the patent system to move discoveries from the research laboratory to the clinical setting." (p. 4)

- "Petitioners' request for a sweeping new, narrow interpretation of § 101 would radically change the patent system and undermine efforts to encourage the development and commercialization of pioneering research conducted in our nation's universities." (p. 7)

- "The development and commercialization path is long, arduous, and expensive. Patents are assets through which a university can pass on intellectual property rights to small and frequently young companies focused on practical application of the technology. These companies, in turn, can pass them along to larger companies when greater capital is required to complete product development. The availability of intellectual property protection provides incentives to each entity along the development pathway to continue investing their capital as needed to bring a new invention to market." (pp. 7-8)

- "After filing patent applications on a promising new technology, a university actively seeks to license out to the private sector the applications and patents covering the technology. Most typically, the patent rights are licensed out exclusively, to a single licensee. Unlike universities, these companies have capital they can invest at risk in product development. With the promise of limited-term exclusionary rights afforded by the patent system, these companies have economic justification to undertake the time-consuming and expensive studies needed to test the observed results of a university's research… This framework has greatly benefited the public by allowing universities the means to achieve practical application of early-stage scientific research. It takes advantage of market efficiencies to leverage public and private resources, helps create jobs, improves public health outcomes, and stimulates the economy. At the same time, universities use the revenues realized through licensing to help advance scientific research and education, a further benefit to the public." (pp. 8-9)

In Enacting the Bayh-Dole Act, Congress Recognized that the Patent System Is Critical To Spurring Commercialization of University Research for the Public Good.

- "In 1980, Congress responded to widespread concerns that the United States was losing its technological advantage and economic competitiveness in the global marketplace due to a perceived lack of innovation. It recognized that federal agencies that funded university research had imposed significant obstacles to commercialization of medical innovations and other new technologies growing out of government-sponsored research…. Congress chose to overcome these… through enactment of the University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh-Dole Act…" (pp. 11-12)

- "Through Bayh-Dole, Congress expressly recognized that the promise of patent exclusivity was critical to incentivizing private sector investment in university technology. The importance and success of the Act has been borne out in the three decades since its passage." (p. 12)

- "Congress provided a procedure by which universities and other non-profit research institutions are allowed to retain legal title to inventions made using federal research funds. The provisions of the Act encourage universities to file patents on the full range of their inventions and then collaborate with small businesses and other commercial enterprises to promote the development and utilization of the federally-funded discoveries… Disqualifying entire categories of innovative medical research from patent protection, as would be the result of Petitioners' proposed narrowing of patent eligibility, would defeat Congress's purpose in enacting Bayh-

Dole." (pp. 13-14)

- "The success of the Bayh-Dole Act in meeting its objectives is tangible and overwhelming. Since the Act took effect, more than 6,000 U.S. companies have been formed based on university discoveries; 4,350 university-licensed products are on the U.S. market; and 5,000 licenses between universities and industry are currently in effect." (p. 14)

- "[O]f particular significance to the present appeal, more than 153 new medical products have been commercialized based on research funded by the U.S. government since enactment of the Act…. Adopting Petitioners' narrow view of patent eligibility under § 101 on the theory that patents play an unnecessary role in fostering medical research would undermine Congress's reliance on the patent system through Bayh-Dole as the means to promote and assure the practical application of university-based research and innovation. Consistent with Congress's goals, this Court should reaffirm a standard of patent eligibility that broadly encompasses all fields of technology, including those not yet conceived or even imagined." (pp. 14-15)

- "Tech transfer, in short, is a vital component of the innovation process. Imposing new limits on patent eligibility, as Petitioners propose, would set back the highly successful university-industry collaboration that has benefited the public over more than three decades since enactment of the Bayh-Dole Act." (p. 20)

Petitioners Ignore the Economic Realities That Play a Central Role in Bringing New Technologies to Market, as Their Own Actions Demonstrate.

- "Petitioners assert that Mayo Labs developed an improved product, and could have offered it at a lower price than the Prometheus product, but for the fact that Mayo Labs was blocked from launching it by Prometheus's patent lawsuit…. This assertion turns the patent bargain—early disclosure of inventions in exchange for a limited patent monopoly—on its head…. The very reason Mayo Labs could develop a purportedly improved product and potentially offer it at a lower price point was that Mayo Labs was able to take advantage of the work disclosed by the inventors of Prometheus's patented methods, without incurring the initial investment Prometheus itself had made when it licensed the technology from the inventors." (pp. 20-21)

- "If patents are not available in fields like personalized medicine, inventors will be motivated to maintain critically significant data and discoveries as trade secrets in proprietary databases rather than disclose it to the public in patent applications…" (p. 21)

- "In this case, the inventors who worked at a Canadian teaching hospital entered into a licensing agreement with Prometheus. Prometheus then further developed and commercialized the inventors' method of treatment, making the test available to countless more patients than would otherwise have had access to it. Indeed, there was no commercial test of this type accessible to patients at all before Prometheus's product entered the market. This is exactly how tech transfer is meant to work." (p. 22)

- "Not surprisingly, it is Mayo Labs—a for-profit subsidiary of Mayo Clinic—that would have offered the 'improved' test. This arrangement underscores that product development and commercialization is market driven, and that the economic profit motive is central to the ultimate

goal of providing patients with access to innovative medical technologies. Given this, Petitioners' complaints that the Prometheus patents operate as 'bottlenecks on innovation competition' preventing others from 'independently developing competing processes or products' ring hollow…. Those complaints certainly do not support the restrictive standard for patent eligibility under § 101 that Mayo proposes." (pp. 22-23)

- "Mayo itself has obtained patents on methods and kits for determining the level of thiopurine methyltransferase activity in a biological sample, which presumably would have provided its "improved" test with patent protection from other competing laboratories interested in developing their own improvements to the test, and even today it has more such patents pending at the USPTO." (p. 23)

Petitioners' Policy Arguments Are Properly Addressed to Congress, Not This Court.

- "Petitioners' many policy arguments regarding the proper balance between incentivizing innovation and limiting… should be directed to Congress, not this Court." (pp. 23-24)

The Prometheus Claims Fall Within § 101's Broad Patent-Eligibility Standard.

- "Mayo's own purported improvement on the Prometheus method underscores that the claimed method simply represents one group of inventors' practical solution to the problem based on their understanding of the drugs' effect on the human body; the claimed method is not an absolute truth, law of nature, or natural phenomenon." (p. 27)

- "Adopting Petitioners' reasoning would adversely affect the entire biomedical field. Studies designed to identify appropriate amounts of drugs to be administered to a particular subpopulation of patients having a specific 'biomarker' profile are costly and time-consuming, and patent protection is often needed to justify the investment in such studies. To hold that inventions directed to effective dosing based upon biomarker studies or other personalized treatment methods are ineligible for patent protection would greatly hinder the delivery of more efficient, focused, and cost-effective healthcare alternatives to patients in need." (p. 28)

BRIEF OF THE NATIONAL VENTURE CAPITAL ASSOCIATION:

The National Venture Capital Association (NVCA), with more than 400 members, is the venture community's preeminent trade association, advocating for policies that encourage innovation and reward long-term investment. NVCA's mission is to foster greater understanding of the importance of venture capital to the U.S. economy and support entrepreneurial activity and innovation. Venture capitalists are committed to funding America's most cutting-edge entrepreneurs, working closely with them to transform breakthrough ideas into emerging growth companies that drive U.S. job creation and economic growth. According to a 2011 Global Insight study, venture-backed companies accounted for nearly 12 million jobs and $3.1 trillion in revenue in the United States in 2010. NVCA and its members have an interest in preserving patent rights that have brought life-saving innovations to market and spurred economic growth and continued scientific advancement.

> ***"[R]ealizing the promise of personalized medicine – like many other healthcare advancements – is an undertaking mired by long development time-lines, government regulations, uncertain industry adoption, and a complex healthcare reimbursement system. This process can cost hundreds of millions of dollars and take several years before any return on investment is realized…. Venture capitalists, however, have historically been able to take on such long-term risk because patent protection in the underlying technology guarantees potentially large rewards if a product can be brought to market."*** (p. 3)

Realizing the Promise of Personalized Medicine Requires Patent Protection.

- "Instead of relying on the traditional trial-and-error approach to diagnosis and treatment, personalized medicine will enable more efficient diagnosis and targeted treatment. It will enable the recognition and treatment of disease even before symptoms appear, and it will identify predisposition to disease allowing for more effective preventative action…. The result: improved quality of care and reduced healthcare costs." (p. 5)

- "Most drugs prescribed are effective in fewer than 60 percent of treated patients…. Personalized medicine can identify patients in advance who will not need certain treatments or will suffer dangerous side effects. It can also lead to and accelerate the development of new treatments. Not only can new targeted therapeutics be developed, but the regulatory approval process can be streamlined by identifying and narrowing appropriate patient subpopulations for clinical trials." (p. 5)

- "This industry is in the process of a paradigm shift into the burgeoning field of personalized medicine – the tailoring of medical treatment to the individual characteristics of each patient…. The use of diagnostic correlations to select customized therapies is the foundation of personalized medicine and results in more focused and cost-efficient healthcare. Consequently, personalized medicine holds the promise of improved patient care and disease prevention, health care cost savings, and increased medical product development." (p. 2)

Venture Capital Is Needed To Overcome the Significant Challenges in Personalized Medicine.

- "The venture capital industry has made possible some of the most important technological advancements in the last several decades. Its willingness to assume great risks and invest in companies like Genentech helped establish the biotechnology industry, an industry which, year after year, provides hundreds of thousands of jobs, generates billions of dollars in revenue, and makes available to the general public countless life-saving innovations." (p. 2)

- "Significant obstacles stand in the way of personalized medicine. Research and development in this field is expensive and challenging. Tens of millions of dollars are needed to tackle the methodological and logistical challenges to validating apparent correlations between genetic markers and diseases." (p. 6)

- "Even if a company successfully overcomes the scientific and regulatory hurdles set before it, market success requires adoption by the patient and physician community…. Thus, even after the several years and tens of millions of dollars spent in R&D and the regulatory process, more time and money must be spent educating the public and establishing new medical standards of care." (p. 7)

- "Talented scientists and entrepreneurs willing to invest the time and energy to bring this exciting new technology to market will need to find significant sources of capital to overcome each of these challenges." (p. 7)

- "In the face of these obstacles and the need for tens, if not hundreds, of millions of dollars in capital, emerging personalized medicine companies do not have access to traditional avenues of funding. These companies simply would not exist without venture capital, often the only source of funding for high-risk disruptive innovations like personalized medicine." (pp. 7-8)

- "Over the past decade, venture capitalists have invested over $25 billion annually, mostly in disruptive technologies…. Approximately one-third of their investments will fail, however…. With such a high failure rate, venture investment is economically feasible only if the venture-backed companies that do succeed generate significant enough rewards. This is especially true with biotechnology, where the failure rates are particularly high due to the risks associated with development and regulatory approval." (p. 8)

- "Consequently, patent protection – which promises market exclusivity – is crucial to the success of personalized medicine companies." (p. 8)

- "Patent protection enables companies to attract venture funding. In fact, many venture firms employ professionals with direct expertise to review investment candidates, subjecting a company's patents – pending and issued – to extensive review before investing…. Such due diligence into a company's patent portfolio is compelled by economic necessity. A significantly higher percentage of venture capital backed companies that have succeeded (i.e., been acquired or gone public) have patent portfolios compared to those that have gone out of business." (p. 9)

- "[I]n biotechnology, strong patent protection correlates with the amount of R&D investments made by companies, and weak patent laws engender poor investment in R&D, diminishing a

company's probability of success." (pp. 9-10)

- "With all the other uncertainties that exist in the personalized medicine industry, patents are needed to counterbalance the extremely high risk faced by startup companies. The lack of patent protection discourages venture investment, and will leave the promise of personalized medicine unrealized." (p. 10)

- "Removing patent eligibility for diagnostic correlations removes [the] incentive [to invest] and jeopardizes the billions of dollars venture firms have already invested in personalized medicine companies in reliance on patent protection. It further removes incentives for future investment in this emerging market, threatening to halt an industry and deprive the public of the associated benefits of targeted cost-effective medical care, job creation, and economic growth." (p. 3)

- "This Court's jurisprudence on patentable subject matter simply does not support upsetting the established structure…. As broad patent eligibility has facilitated this country's continued innovative leadership, consistent with the constitutional mandate 'to promote the progress of science and useful arts,' this Court should affirm the Federal Circuit's ruling in favor of Respondent." (pp. 3-4)

Venture Capital Investment Backed by Patent Protection Leads to Important Life-Saving Innovations.

- "Because patent protection has thus far been allowed for diagnostic correlations, venture capitalists have invested hundreds of millions of dollars in personalized medicine companies. As a result, revolutionary new medical diagnostics focused on improved treatment for cardiovascular disease, cancer, and diabetes – among the leading causes of death in the United States – are now available to the public." (pp. 10-11)

- "Over the past 20 years, the venture community has actually invested $15 billion in more than 2000 deals specializing in cardiovascular disease, $14.7 billion in approximately 1600 deals focused on combating cancer, and close to $5 billion in almost 600 deals for the treatment of diabetes…. In 2008 alone, venture capitalists invested over $2.7 billion in almost 250 startups focused on human bioscience…. The potential benefit that may come from this level of investment is immeasurable. Denying patent protection now not only forfeits the billions of dollars currently invested, but jeopardizes the technologies that the investments were intended to bring to market." (p. 16)

Denying Patent Protection Threatens the Far-Reaching Benefits Made Possible by Venture Capital Investments.

- "While venture capital investments equal less than 0.2 percent of the US GDP, annually, VC-backed companies have generated revenue equal to 21 percent of the US GDP…. Venture-backed companies constituted 11 percent of private sector jobs in 2010." (pp. 16-17)

- "Venture capital's investment in new, cutting-edge high growth companies means that it plays a leading role in creating new industries which hold the potential unfettered job and revenue growth. Cutting off incentives for venture investment in personalized medicine would eliminate

a sector of venture-backed biotechnology companies. Venture-backed companies represent 74 percent of biotechnology jobs and 80 percent of biotechnology revenue…. That's over 400,000 jobs and $161 million in revenue in 2010." (p. 17)

- "A reduction of these jobs and the revenues generated by eliminating venture-backed personalized medicine companies will have significant unintended consequences on the economy. Indeed, venture-backed companies have been sustaining the economy, outperforming the total overall economy in 2009-2010." (p. 17)

- "[V]enture-backed companies that succeed and go public often re-invest in and support new and further advances. These advances go on to feed the cycle of innovation, job creation, and revenue growth. Thus, the current system has supported steady economic growth and support for new technologies and emerging industries. There is simply no policy reason to disturb the status quo." (p. 18)

- "[T]here does not exist any evidence of the feared negative effects of patents on further research. What does exist, however, is the undeniable importance of patents to the entire U.S. economy in general, and the future of personalized medicine in particular." (p. 18)

Patenting Diagnostic Correlations Does Not Preempt All Use of a Natural Phenomenon.

- "The diagnostic correlations that have already been granted patent protection (like the one covered by Respondent's patents), and those for which personalized medicine companies and researchers are seeking patents, fall within the scope of patentable subject matter. Neither Respondent nor the personalized medicine industry is trying to patent 'laws of nature.'" (p. 19)

- "Rather, what is being patented are very specific complex interrelationships between a multitude of biological markers and their correlation with specific diseases…. Patenting such work does not preempt nature; there are infinite combinations of biological markers that can be studied and possibly correlated with any number of diseases. Others are free to do that work, and indeed, patent protection would incentivize them to do so." (p. 19)

- "Petitioner's analytic approach presupposes that in determining patent eligibility of diagnostic correlations, the relevant natural phenomena should be defined as the specific correlation being claimed. If that tautology were accepted, no diagnostic correlation could ever be patentable. Indeed, taken to its logical extreme, nothing would be patent eligible – all patents preempt the scope of their claims." (p. 20)

- "A ruling that would deny patentability to diagnostic correlations would certainly have negative wide- ranging impact on personalized medicine, current economic incentives, and the overall health of the economy." (p. 21)

BRIEF OF THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO:

Founded in 1884, the Intellectual Property Law Association of Chicago ("IPLAC") is the oldest intellectual property law association in the nation. Its approximately 1,000 members represent a full spectrum of the profession ranging from law firm attorneys to sole practitioners, corporate attorneys, law school professors, and law students. Every year, IPLAC's members prosecute thousands of patent applications and litigate many patent lawsuits. IPLAC is a not-for-profit organization dedicated to maintaining a high standard of professional ethics in the practice of patent, trademark, copyright, trade secret, and associated fields of law. A principal aim is to aid in the development and administration of these laws and the manner by which they are applied by the courts and by the United States Patent and Trademark Office.

> ***"The profound truth underlying Congress' broad statement of eligibility is that it fosters more innovation. Indeed, the foundation of our patent system is the notion that the lure of a United States patent encourages creativity. Filing an application provides the applicant's quid pro quo—disclosure and ultimate publication—to the benefit of the public. Even if those applications do not issue as patents, the public benefits because of their dedication. A cramped reading of section 101 would discourage filings, and we would never know what the public lost without them." (p. 16)***

Our Constitution, Congress, and the Courts Historically Have Aimed To Encourage Innovation – Patent Law Has Been Written Broadly To Allow Inventions To Flourish.

- "The framers of our Constitution understood the importance of rewarding inventors, for limited times, for their creative endeavors. Congress then implemented a plan for protecting the rights of the inventor and promoting the advance of the useful arts by broadly drafting the patent statute without technological exclusions, ready to embrace yet unknown innovations. Thus, the language of 35 U.S.C. § 101 ('section 101') places few limits on the types of invention eligible for patent protection and reflects Congress' judgment on how best to fulfill its Constitutional mandate." (p. 2)

- "For more than a century, the Court has applied section 101 using a flexible and broad subject matter analysis to accommodate incredible, sweeping, and unforeseen advances in technology. Without such subject matter flexibility, many of the inventions that have made the United States the technology leader of the world would never have been discovered or would have been hidden from the public with no incentive for revelation or commercialization." (pp. 2-3)

- "[S]ection 101's flexibility accommodates smaller yet still deserving inventions. It is this elasticity of section 101, with few exceptions and without technological limitation, that has helped to make the U.S. patent system the strongest in the world, supporting innovation like no other." (p. 3)

- "Petitioner seeks to have the Court rule on a specific type of claim, indeed a specific claim, and determine whether this category, 'correlations between blood test results and patient heath,' can exist as patentable subject matter. This is precisely the type of specific exclusion the framers sought to avoid and that Congress through its implementation in statute carried forth. Rather than

precluding all uses of a natural phenomenon, Prometheus' claims merely seek to preempt others from using a particular application of that phenomenon, precisely the type of subject matter envisioned to be encompassed by the patent statute." (p. 3)

The Claimed Method Satisfies Congress's Broad Mandate Under Section 101.

- "IPLAC urges the Court not to disturb the broad and accessible threshold of statutory subject matter that has fostered innovation and public disclosure over a wide variety of useful arts—and importantly, in new and emerging fields of technology." (p. 4)

- "The Federal Circuit's decision is consistent with the Court's precedent over the past half century." (p. 4)

- "Devoid of limiting language, section 101 readily accommodates the rapid pace of innovation and the assimilation of new technologies, including technologies never anticipated at the time section 101 was enacted. As this Court has put it, patentable subject matter includes 'anything under the sun that is made by man.'… Thus, this Court has not seen fit to exclude particular technologies from section 101, no matter how unusual or bizarre." (pp. 5-6)

Congress Did Not Intend To Create Different Section 101 Tests for Different Claim Types.

- "Accepting Mayo's arguments in this case would lead to a rule carving out from section 101 certain types of claims—like the diagnostic methods claims at issue—and treating them differently. Indeed, Mayo all but concedes that it is seeking the development of special rules for such claims… This is precisely the approach to section 101 that the Court in *Bilski* rejected." (p. 11)

- "Rigid rules excluding types of subject matter have been rejected.... [C]arving out Prometheus' patent claims from section 101 would create a new set of preemption rules for diagnostic methods claims, while the low bar set by the 'wholly preempt' rule in *Diehr* would apply to all other patent claims…. Prometheus' claims fall within the scope of patentable subject matter under section 101." (p. 12)

Section 101 Eligibility Is Different than the Required Analysis Under Sections 102, 103, and 112 -- Satisfying Section 101 Does Not Mean a Patent Will Issue.

- "Section 101 itself ends with the foreshadowing caveat that even though a claim may be said to contain patent eligible subject matter, it still must satisfy the other requirements of sections 102, 103, and 112…. [S]imply because an invention contains patent eligible subject matter does not mean that a patent should issue." (p. 13)

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION:

The Biotechnology Industry Organization (BIO) is a trade association representing over 1,100 companies, academic institutions, and biotechnology centers. BIO members are involved in researching and developing healthcare, agricultural, environmental, and industrial products. The biotechnology industry currently has more than 370 products in clinical trials for treating more than 200 diseases. The vast majority of BIO members are small companies that have not yet brought a product to market or attained profitability. The biotechnology industry is uniquely dependent on predictable and effective patent protection for the development of new technologies. This is because investors such as venture capitalists in large measure base their decisions whether to invest in early-stage companies—thereby funding the research and development that eventually will bring new products to market—on the availability of patent protection for an asset that can be commercialized.

> ***"Like inventions in many other fields of technology, inventions in the field of personalized medicine often exploit known elements and discoveries. They do so, however, in the service of new and useful ways of diagnosing and treating patients. The inventive spark—a spark that is lit by extensive funding and research—occurs when a scientist connects the dots between these known and unknown elements, such as by using biomarkers to devise a new way of selecting patients, identifying symptoms that can be associated with a disease or using a drug to treat those patients, or selecting a drug that does not trigger adverse reactions in the patient. The result of these insights—a novel and useful method or treatment—is and should remain patent-eligible." (p. 3)***

A Broad Rule of Ineligibility Would Harm the Biotechnology Industry, Personalized Medicine, and Innovation Itself.

- "Announcing a broad rule of ineligibility concerning diagnostic and therapeutic methods that exploit knowledge gained from the study of biological systems would threaten harm to the biotechnology industry, and devastation to the nascent field of 'personalized medicine,' which promises substantial benefits to patients through its capacity to match focused and appropriate treatments and improved diagnostic methods." (p. 2)

- "In a time when health-care costs continue to increase, personalized medicine promises to yield substantial savings…. Personalized medicine therefore saves health-care dollars by targeting treatments to those patients most likely to respond to them…. But this important and growing field is threatened by the arguments advocated by Petitioners, and BIO therefore urges that the Court take a cautious approach in applying § 101 to the field." (pp. 2-3)

- "Rather than adopt the broad holding under § 101 that Petitioners advocate, this Court should reiterate two fundamental principles that it has applied for decades, and under which the claims at issue in this case define inventions that are patent-eligible, regardless whether they ultimately are determined to be valid." (p. 4)

- *"First,* the Court should emphasize that in reviewing a claim under § 101, courts must consider the claim *as a whole*…. The settled rule against doing so is particularly important to personalized medicine for the reasons just set forth—a personalized medicine process may and often will draw

upon known steps or components to yield an overall process that is important, valuable, and deserving of patent protection. The claim-dissection approach advocated by Petitioners would plunge the patent system into a standardless, 'eye of the beholder' system for measuring an invention's merit." (p. 4)

- "This would fundamentally erode the patent incentive for all innovators by making it impossible for inventors to know in advance whether they can secure patent rights in their inventions." (p. 4)

- "*Second*, the Court should reaffirm that, although a law of nature, natural phenomenon, or abstract idea is not itself patentable subject matter, a particular *application* of that law of nature, natural phenomenon, or idea is…. The Court should… reaffirm its prior precedents. Holding otherwise would interpose insurmountable obstacles to securing patent protection in the field of life sciences, as virtually all inventions in this field draw upon biological systems, or seek to exploit or affect their function." (p. 5)

- "The progress of the biotechnology industry over the 30 years of its existence has demonstrated that patent protection is an essential driver of innovation. The role that patents have played for this industry, and which they must play to encourage innovation in the field of personalized medicine, is exactly the role that Patent Clause envisions…. Using § 101 to broadly exclude entire categories of new and useful inventions from patent eligibility would be antithetical to this basic purpose. BIO urges the Court to deploy § 101 cautiously, because the danger of unforeseen consequences is great." (p. 5)

The Court Should Heed the Fundamental Principles It Has Previously Applied in Determining Patent Eligibility.

- "A hallmark of our patent law is that it protects, and thereby fosters, emerging technologies whose commercial potential may not yet be fully understood or appreciated." (p. 6)

- "The capacity of the patent system to foster development of new technology is proven by the history of the biotechnology industry. The inventions that have led to the growth and success of biotechnology, both as a scientific and engineering discipline and as an industry, could not have been imagined when the Patent Act was rewritten in 1952. An inclusive standard for patent eligibility has proven essential to the successful development and commercialization of over 200 biotechnology therapies and vaccines, hundreds of diagnostic tests, and pest- and herbicide-resistant crops." (pp. 8-9)

- "But, just as the patent system may encourage innovation, it carries the converse danger that court- adopted rules trimming away patent eligibility may hinder such technological advance. This concern is particularly great where personalized medicine is concerned." (p. 9)

- "A rule which calls for courts or the PTO to pick apart an invention in the way Petitioners advocate, disregarding the old and focusing only on the new or 'significant' elements, will inherently diminish and distort the importance of every invention—and especially inventions that build upon prior knowledge or discoveries but which do so through important, patentable leaps of inventive genius." (p. 9)

- "In addition, the Court should reaffirm that although natural phenomena and laws of nature are not patentable, *applications* of them certainly are.… Certain of Petitioners' arguments seem to call into question this basic rule, and any decision of the Court accepting Petitioners' invitation will have highly detrimental consequences in the biotechnology industry." (pp. 9-10)

Patent-Eligibility Must Be Determined by Considering the Claim as a Whole.

- "Petitioners urge whittling away the invention, leaving what it claims is a non-patent-*eligible* core.… The Court should reject this argument, which has no place in analyzing patent eligibility." (p. 10)

- "An analysis of patent-eligibility that starts by dissecting a claim into pieces invites litigants to focus on process steps that appear to be algorithms, decision-points, or that otherwise make use of data… But once the analysis is thus focused, preceding and subsequent claim steps naturally will appear to be no more than pre- and post-solution activity, and proper focus on the claim as a whole will be lost, and with it a proper under- standing of what the inventor actually invented." (p. 11)

- "[C]laim-dissection could call into question many process claims that use data generated from a biological system. Such claims will frequently require the gathering of information and so, as we discuss next, individual steps in a treatment protocol or diagnostic process may be familiar, using known testing techniques or isolating known compounds. But although certain of this knowledge may be familiar, the technique for applying the knowledge through treatment or diagnosis will not be. The results are new and useful diagnostic or therapeutic procedures, which the patent laws should properly recognize as patentable subject matter." (p. 12)

- "The claim-dissection approach urged by Petitioners is particularly ill-advised because the patent law already contains more focused mechanisms for evaluating the patentability of particular claims." (p. 14)

- "If biotechnology inventions are deemed patent- eligible only to the extent that they include limitations that render their invention nearly commercially irrelevant, then patent protection will be worth very little. The law does not support such a result." (pp. 18-19)

- "Biotechnology inventions are driven by expensive clinical trials, complicated laboratory tests, and computerized analysis of large amounts of data under complex algorithms. As other amici have explained, such investments can be significant, and often would not occur without the patent incentive." (p. 19)

- "The danger of these profoundly negative consequences for public health is the reason Petitioners feel compelled to argue that government and academia will step in.… This is cold comfort. In a recessionary era of steep budget cutbacks, speculation about government support is worth very little." (p. 19)

- "[M]ore importantly, this is not the system the Framers envisioned. Petitioners point to no support for the notion that patent protection should be obviated because of the potential for

alternate funding sources for research." (p. 19)

While Natural Phenomena Are Not Eligible for Patenting, New and Useful Applications of Them Always Have Been and Should Remain So.

- "Any decision that calls into question this basic principle, either expressly or by implication, will have drastic consequences for the biotechnology industry, and particularly for the types of technologies described in this brief." (p. 22)

- "[I]t is expected that the use of biomarkers will allow drug developers to conduct clinical trials of new medicines more quickly, more economically, and with smaller numbers of patients than are now required.… Biomarkers and their use in diagnosis or treatment, however, necessarily are linked to the human body's biological processes. In other words, any form of human intervention and activity that makes use of biomarkers necessarily will make use of the response of a biological system. A rule of patent law that holds these applications to be natural phenomena or principles *per se*, and thus non-patent-eligible at the threshold, will obviate patent protection in this domain—contrary to well-settled law." (pp. 23-24)

- "It is instead the product of human intervention, the result of administering a foreign agent (i.e., the drug) and undertaking a transformative test to determine the resulting level of metabolites. A process that determines and makes practical use of these non-natural metabolite levels is not a patent-ineligible natural phenomenon." (p. 26)

- "To accept Petitioners' argument would require ignoring these essential, non-'natural' aspects of the claimed process—eliminating the 'trees' (i.e., steps) of the asserted claims in a manner that would substantially transform the forest. Such an approach is inconsistent with this Court's precedents, and it poses grave risks to the biotechnology industry and the future of personalized medicine, in which known biomarkers and known correlations are frequently used in novel processes for beneficial treatment or diagnostic purposes." (p. 27)

BRIEF FOR MYRIAD GENETICS, INC.

Myriad Genetics, Inc. is a pioneer and world leader in the growing field of personalized medicine. Myriad's currently marketed personalized medicine products include innovative molecular diagnostic tests for diagnosing predisposition to disease (e.g., BRACAnalysis® testing assesses a woman's risk for breast and ovarian cancer); for optimizing a patient's therapy (e.g., OnDose®); and for determining a patient's prognosis (e.g., PROLARIS® testing helps urologists determine a prostate cancer patient's risk of recurrence and disease-specific death). Myriad's products are now used by more than 40,000 healthcare providers in the United States in the care of their patients. Myriad's past innovation and commercial success, as well as the patients whose lives are improved by our products, have benefited greatly from an appropriately strong U.S. patent system.

> ***"In reliance on the prospect of continuing patent protection for its advances, Myriad is making substantial investment in research and development and working diligently to deliver the next generation of personalized medicine products. Myriad scientists analyze thousands of specimens, searching the human body's biochemicals (DNA, RNA, microRNA, proteins, and metabolites) to identify molecular markers that correlate with disease characters and drug response…. The massive investment in researching and developing these new products and methods would not be feasible for Myriad, or for any company, without the promise of patent protection for the resulting inventions."*** (pp. 1-2)

Myriad Has Made Substantial Investments in Developing Medical Products, But Relies on Patent Protections To Recoup This Cost.

- "The cost of discovering, validating, and commercializing such personalized medicine products is significant. In the context of BRACAnalysis® testing alone, Myriad—has invested hundreds of millions of dollars in creating the innovative isolated BRCA1 and BRCA2 molecules… invested well over $200 million in raising doctor and patient awareness of hereditary breast and ovarian cancer… employs a sales force of over 350 throughout the country to educate doctors… employs hundreds of skilled customer service, billing, and medical services personnel…" p. 2)

- "This level of investment cannot possibly be made, and the resulting level of testing quality and patient access cannot possibly be maintained, absent strong patent protection, which allows a company a fair return on its investment in the inventive process." (p. 3)

- "Myriad thus has an interest in ensuring that patent claims to specific and practical diagnostic uses of correlations such as those in this case are affirmed as directed to patent-eligible subject matter. Absent such claims, there would not be adequate patent protection for future personalized medicine products, long-settled expectations would be upset, and the significant investment by Myriad and others in research and development would not be adequately incentivized." (p. 3)

Strong Patent Rights Are Needed To Ensure Recovery of the Substantial Investment Required To Fund Research, Development, and Product Delivery in Personalized Medicine.

- "The important and developing industry of personalized medicine would be seriously

jeopardized if such substantial and innovative contributions to science and medicine were denied patent protection at the doorway to the Patent Act, 35 U.S.C. § 101." (p. 3)

- "The significant investment and substantial risk involved in the innovation, development and delivery of personalized medicine products mandate strong patent protection. As with the pharmaceutical industry, personalized medicine relies on expensive and risky clinical studies to investigate, analyze, decipher, and confirm useful correlations between molecular markers and specific disease characters. Differences between pharmaceuticals and diagnostics, however, including a very different regulatory environment for molecular diagnostics, make broad patent coverage for the innovation underlying a diagnostic test critical." (p. 4)

- "Patent claims to one diagnostic use of the correlation between a particular molecular marker and a specific disease character do not hinder, and actually drive, the innovations of other diagnostically useful correlations between other markers and that disease character for use in alternative diagnostic tests. Therefore, by allowing patent claims to practical diagnostic uses of specific correlations, the Constitutional purpose of the patent law is served and society reaps the benefits." (p. 5)

- "Amicus urges this Court to sustain a strong patent incentive to continue to protect important American investment in personalized medicine by affirming the patent-eligibility of molecular diagnostic method patent." (p. 6)

- "Much like in the pharmaceutical industry, personalized medicine research and development are extremely costly and offer a very low rate of success…. A typical discovery study requires hundreds or thousands of carefully selected patient samples… [S]cientists must then sift through millions of data points in hopes of discovering a statistically significant correlation between one or more of these markers and a particular disease character. The amount of time and effort required is enormous. Additional clinical trials are required to demonstrate the clinical utility of the discovered correlation. Many trials are essentially equivalent to pharmaceutical trials in both design and scope… Even after such significant time and capital outlays, success is not guaranteed; failures far outnumber successes." (pp. 12-14)

- "Despite the similar costs and barriers to success between pharmaceuticals and molecular diagnostics, personalized medicine ironically promises investors an inherently smaller potential payoff compared to pharmaceuticals for the very same reason it reduces aggregate healthcare costs. Personalized medicine testing is often a one-time event—i.e., the test determines once and for all whether a patient will respond to a particular treatment. Pharmaceutical products, on the other hand, often have 'repeat' customers taking a daily dose for a very long time." (p. 14)

- "For molecular diagnostics, however, broader patent coverage is required because there is no regulatory framework that puts would-be generic diagnostic providers to the difficult choice required of would-be generic drug marketers. Someone looking to offer a competing diagnostic test may make trivial changes to the innovator's diagnostic process, piggyback on the innovator's clinical studies, and merely validate the technical aspects of the laboratory to satisfy CLIA requirements. Unlike in pharmaceuticals, broad claims are needed to prevent easy circumvention of the patents protecting the significant investment in a new and useful personalized medicine product." (p. 15)

- "Even greater than the cost of innovation and validation of such personalized medicine products is the cost of actually delivering them to patients." (p. 15)

- "The reason investors, both private and public, have been willing to pour such huge sums of capital into such risky ventures is the settled expectation that limited exclusivity will provide for a reasonable return." (pp. 15-16)

Claims To Diagnostic Use of Correlations Such as Those in Prometheus's Patents Are Usually the Only Patent Claims Available that Can Provide Meaningful Protection for Personalized Medicine Products.

- "While the Human Genome Project ('HGP') has provided a boon to personalized medicine by greatly facilitating the discovery of important correlations, it has simultaneously made patenting in personalized medicine much more challenging, because human genes (including most genetic variations) have been elucidated and virtually all proteins encoded by these genes are now known… Patenting of new tools or techniques does nothing to incentivize the discovery of new correlations and the development of the use of such correlations into commercial personalized medicine products. Invalidation of a claimed method for the diagnostic use of correlations—particularly at the threshold of the Patent Act—threatens to destroy the personalized medicine industry in its infancy." (pp. 17-18)

Protecting Medical Diagnosis Method Claims Accords with the European Approach and Will Incentivize Critical Domestic Investment.

- "European patents have been routinely granted on medical diagnosis method claims like those at issue in this case. Failure to protect medical diagnosis claims similarly in the United States threatens to put the U.S. at a competitive disadvantage." (p. 29)

A Time-Limited Patent Monopoly on a Particular Diagnostic Use of a Particular Correlation Does Not Wholly Pre-empt that Correlation.

- "Unlike Einstein's E=mc2 and Newton's law of gravity, the correlations in medical diagnosis process claims such as the Prometheus claims have a qualitatively narrower spectrum of applicability, and thus exert much less impact on upstream scientific and technological research. Far from granting a monopoly on 'basic tools' of a fundamental or upstream nature, such claims grant relatively narrow exclusivity over a downstream research endpoint that has matured into a process that is ready to be marketed for the benefit of the public." (p. 32)

Because There Are Numerous Possible Correlations for a Particular Disease Character, a Patent on a Particular Diagnostic Use of a Particular Correlation Incentivizes Scientists to Discover New Correlations and Develop Better Personalized Medicine Products.

- "[A]ll biological components— from individual genes to small molecules, proteins, cells, tissues and entire organs—work together through an array of interconnected biological pathways that facilitate communication among genes, molecules, and cells, to accomplish biological functions and properties of life… Disturbance of any one member of a pathway may lead to changes in not only other members of the same pathway but also members of other pathways, resulting in a disease or disorder. Likewise, a single disease or disorder can be associated with numerous

changes in many pathways…. Therefore, there can be numerous biomarkers correlating with a particular disease. Indeed, the primary goals of research and development in the field of personalized medicine are to discover such correlations and biomarkers and to use these to develop molecular diagnostic tests." (pp. 33-34)

- "With so many possible correlations to the same disease, a patent monopoly on a particular diagnostic use of a particular correlation between one biomarker and a particular disease would not preclude scientists from discovering other, potentially better correlations between other biomarkers and the same disease." (p. 34)

- "When claims drawn to the use of a particular correlation for diagnosing a particular medical condition are made patent-eligible, the roadblock of such patent claims, together with the roadmap of the disclosure required to get a patent, will actually stimulate scientists to discover new correlations that can be used to design better diagnostic tests for the same medical condition. As such, the Constitutional purpose of the patent law is served and society reaps the benefits." (pp. 34-35)

BRIEF OF CONNECT AND SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION:

CONNECT was created in 1985 by the City of San Diego and the University of California, San Diego, to stimulate commercialization of discoveries from local research institutions through education, mentoring, and by fostering a "culture of collaboration" between the research organizations, industry, capital sources, and professional service providers. CONNECT has assisted in the formation and development of more than 2,000 companies, and is regarded as one of the world's most successful and emulated regional programs linking investors and entrepreneurs with the resources they need for commercialization. The San Diego Intellectual Property Law Association (SDIPLA) is a non-profit association whose members have significant ties to San Diego's world-class research institutions, and leading wireless, biotechnology, and solar industries. Comprising about 500 registered members, the SDIPLA has grown to become one of the largest intellectual property bar organizations in the country.

> ***"[I]t is vitally important that the legal framework for obtaining and enforcing patents not ossify, but instead retain the maximum flexibility reasonably provided it by Congress to adapt to ever changing technology. A primary aim of the patent system should always be to foster, not hinder the development of new and unforeseen technologies."*** (pp. 26-27)

CONNECT and SDIPLA Are Troubled by the Rising Cost and Difficulty Associated with Obtaining and Enforcing Patents on Cutting Edge Technology.

- "CONNECT views with heightening concern the rising cost and complexity of obtaining and enforcing patents on cutting edge technologies. CONNECT is also well positioned to render an objective assessment of the effect that uncertain patentability has on the ability of a struggling new company to raise capital, particularly in the economic climate prevailing today…" (pp. 1-2)

- "[I]t is especially troubling to CONNECT that the jurisprudence underlying 35 U.S.C §101 has evolved and continues to evolve in a manner that makes it difficult, particularly, it seems, in the case of pioneer technologies, to determine at the very threshold of the patenting process, whether the claimed invention is a 'useful process, machine, manufacture or composition of matter' within the meaning of the statute." (p. 2)

- "CONNECT appreciates that inventors starting new ventures take significant professional and financial risks when leaving established jobs, investing personal savings, and filing patent applications to help capture the value of their technology. Confidence of potential investors that their inventions are eligible for patent protection is one of the most important of the criteria which must exist if inventors are to secure financial backing." (p. 2)

- "[C]larification and simplification would reduce the burden of determining whether to seek patent protection, reduce the PTO's burden in applying the statute to cutting edge technologies and lend greater certainty to the presumption of validity that attends all patents. Such improvements would necessarily reduce the cost associated with obtaining and enforcing patents as well as the costs and risks of investment in new technologies, benefitting not only innovators

and investors, but also the public who stands to reap much of the benefit of that investment." (p. 3)

- "The SDIPLA shares CONNECT's concerns regarding the burden on innovation represented by the uncertainty attending application of §101 jurisprudence and, on behalf of its members and their clients, would welcome clarification of the standards to be applied in determining threshold patent eligibility." (p. 4)

Patent Law Has Long Allowed Patents for Therapeutic Drugs, Although These Inventions Incorporate Laws of Nature.

- "The huge body of issued United States patents contains many examples of patents in which drugs are administered to subjects for therapeutic purposes and many examples of patents for determining the presence of analytes of interest in diagnosing or following the course of disease in human subjects." (p. 5)

- "All inventions are based on or incorporate laws of nature, natural phenomena or, in some cases perhaps, abstract ideas. However, application of the rule advanced by *Amici* will not result in the preemption of any fundamental principles and, consistent with the Court's pronouncements over the past 20 years, merely permits their application in situations where their use is strictly bounded by conventional claim limitations." (p. 8)

The Court Should Adopt a Rule that a Claim that Meets the Machine-Or-Transformation Test Is Patent Eligible Under 35 U.S.C. §101.

- "[T]he Court can simplify and bring greater clarity to the law applicable to the patent eligibility of the many permutations of processes inventors may bring forth, particularly when the claim in question applies a fundamental principle such as a law of nature or a mathematical formula to a known structure or process. Such welcome clarification will result if the Court deems a process claim to be patent eligible under §101 if it meets the machine-or-transformation test, even if the claim contains a recitation applying a fundamental principle to a known process." (p. 10)

- "Adoption of the rule proposed by *Amici* will, therefore, provide a legal structure in which it can be more easily determined that a claim is statutory, thus reducing the cost and uncertainty arising in the initial pursuit of patent protection, simplifying the examination process in many situations, and reducing the cost of and complexity of litigating patents on the cutting edge of technology. All of these results will ultimately benefit not only the inventor and investors, but also the public by providing a climate where better informed decisions to develop and bring new technology to the market can be made." (p. 9)

- "[A]ny opportunity to clarify and simplify the determination of patent eligibility should be diligently pursued. It is in that spirit that CONNECT and SDIPLA urge this Court to not only affirm the decision of the Federal Circuit, but also adopt the rule that a process claim meeting the machine-or- transformation test be deemed to satisfy patent eligibility requirements." (p. 26)

The Prometheus Claims Are Patent Eligible.

- "Administering drugs to subjects to treat disease is a common feature of therapeutic patents that claim methods of treatment. It should, therefore, be beyond dispute that administering a medicine should be considered to meet the transformation prong of the machine-or-transformation test, and the Federal Circuit so held." (p. 19)

- "[I]t would be a huge surprise to patent practitioners if analytical processes did not meet the machine-or- transformation test even though claims to many such procedures omit any reference to the apparatus upon which they depend or call out the transformative steps upon which they are based…" (pp. 19-20)

- "Many patents to analytical methods include a conclusion that flows from information gathered using the method…. The holders of such patents would rightly be alarmed if claims including such provisions were deemed unpatentable because they employ a law of nature or natural phenomenon, for example, color or radioactivity, as an indicator of a positive result." (p. 20)

- "In this case it cannot be disputed that the claimed process for a method of treatment is a function which the patent laws were designed to protect." (p. 21)

Patent Innovation Is Fundamentally Important, So the Court Should Improve the Administration of the Patent System by Adopting a Simple Rule for Section 101.

- "The ability to patent innovation is of such fundamental importance that our founders saw fit in the Constitution to specifically grant Congress power to establish a patent system. Their prescience has been borne out by history. There is likely no other time in history when the patent system has played such a vital role in inspiring innovation and encouraging investment in leading edge technologies." (p. 26)

- "Therefore, we encourage the Court to substantially improve the administration of §101 by adopting the rule that a process claim that meets the long, well established and easily understood machine-or-transformation test is not foreclosed from patentability by incorporating into the claim an application of a law of nature, natural phenomenon or abstract idea to the process." (p. 27)

BRIEF OF SAP AMERICA, INC:

SAP America, Inc. is a leading technology company focused on developing innovative software and computer-based business solutions. The Amicus conducts significant research and development and invests heavily in commercializing innovative technologies.

> ***"The software and computer industries are a vital part of today's Information Age economy and these industries depend on patent protection for growth and innovation. A decision regarding the scope of 35 U.S.C. § 101 as applied to medical diagnostic processes could have far-reaching effects in all technology areas, including software and other computer-related technologies."*** (p. 2)

When Considering the Patent Eligibility of Medical Diagnostic Processes, This Court Should Avoid Disrupting Innovation in Cutting Edge Technologies, Including Software.

- "A flexible analysis is necessary under section 101 to avoid excluding 'emerging technologies' such as software from patent eligibility." (p. 3)
- "Software is vital to the 'Information Age' economy. In 2010, the value added to the gross domestic product ('GDP') by 'Information-communications-technology-producing industries' was $684.1 billion, or 4.7% of the total GDP." (p. 3)
- "From 2006-2010, the U.S. Patent and Trademark Office issued 10,400 patents in class 707, which is only one of the ten classes for patents related to data processing…. The list of notable companies that obtained these patents, including IBM, Microsoft, and SAP, is testament to the fact that software innovators continue to seek patent protection to further their business development efforts." (p. 4)

Section 101 Is Purposefully Broad To Encourage Innovation in Cutting Edge Technologies.

- "Court should reiterate that the scope of section 101 is purposefully broad and that this threshold test for patent eligibility must remain flexible to accommodate unforeseen inventions in all technology areas." (p. 2)
- "Categorical rules should not be espoused that would contrast with Congress's intent to accommodate the ever-changing world of technology…. [R]ecently, members of this Court cited computer programs as an example of patentable inventions that were once thought, wrongly, to be excluded from patenting." (p. 5)

This Court Should Decline Petitioners' Invitation To Introduce a "Mental Steps" Test for Patent-Eligibility.

- "Petitioner's invitation to introduce a 'mental steps' test that would contradict precedent and result in uncertainty for computer-related inventions should also be declined." (p. 2)

- "A new test excluding claim elements that encompass 'mental steps' from patent eligibility is inconsistent with the plain language of the statute and this Court's precedent." (p. 12)

- "Prometheus's claims are not purely mental steps. All of the claim steps are critical to the analysis of the claim as a whole under § 101… To the extent that Mayo encourages the application of a 'mental steps' test, this Court should reaffirm that practical applications of abstract ideas are patent eligible." (p. 12)

- "Mayo's proposed mental steps test is ill-suited for 'today's information age' and would introduce uncertainty across technologies…. Applying a mental steps test to determine whether and when software is sufficiently physical would put software claims on uncertain grounds, and is contrary to the principle that patent law should afford certainty to patentees." (pp. 12-13)

BRIEF OF THE JUHASZ LAW FIRM, P.C.:

The authors of this brief are registered patent practitioners with law and science degrees and are members of the patent firm The Juhasz Law Firm, P.C. Both Paul R. Juhasz and Chris Frerking deal with the issue of subject matter patentability for their clients on a regular basis. Mr. Juhasz has written extensively and is extensively published on the Supreme Court's Bilski decision and subject matter patentability under 35 U.S.C. §101. Amici offer the following views based on their extensive experience on this matter.

> ***"[T]he issue in Prometheus is not simply about an 'observed correlation,' as the question presented strongly suggests. Rather, it is also about a methodology including chemical transformative steps for working up a chemistry inside of the body (to enable the observation of a correlation) not unlike transformative steps that work up a chemistry outside of the body which are not excluded by the Court as to subject matter patent eligibility in chemical process patents. The fact that the 'observed correlation' is occurring on body chemistry should be of no consequence."*** (p. 11)

The Claims in the *Prometheus* Diagnostic Method Patents Must Be Looked at "As a Whole" as Is Done in Chemical, Mechanical, and Electrical Patents.

- "The diagnostic step of 'administering a drug [to a human body]' in *Prometheus* is not unlike the step of 'adding a chemical A to a chemical B' in a chemical process, which is a conventional recitation in the claims of chemical process patents…. Similarly, the step of 'determining the level of [the drug's metabolite in the body]' is not unlike 'determining the level of (e.g.) acidity of a solution,' which is another conventional recitation in the claims of many granted and enforced chemical process patents. When viewed in this way, as appears was done below by the Federal Circuit in *Prometheus*, the diagnostic method claims at issue arguably become no different than subject matter that has routinely been seen as patent eligible in chemical process claims." (p. 6)

- "Under this Court's 'claim as a whole' precedent, the transformative steps of 'administering' and 'determining' for working up a body chemistry to enable the observation of a correlation in a diagnostic method patent should be considered no differently than transformative steps in chemical, mechanical, and electrical process patents." (pp. 11-12)

- "Just as the clue to the patentability of a chemical process patent is a chemical transformation, so too one clue to the patentability of diagnostic method claims involving a chemical transformation central to the claim should be a 'transformation.' The Court's precedent in connection with transformations recited in mechanical and electrical patents further support such a conclusion." (p. 12)

The "Administering" and "Determining" Steps in the *Prometheus* Claims Are Transformations Central to the Claim, Important to the Subject Matter Patent Eligibility Determination.

- "In the case of a method claim including a transformative step, the transformation is thus an

important indicator that the subject matter may be patentable." (pp. 13-14)

- "[T]he transformative steps of 'administering' and 'determining' are 'essential' and central to the claim and so should be included in the 35 U.S.C. §101 determination, not treated as token extra-solution activity and disregarded in the 35 U.S.C. §101 analysis." (pp. 19-20)

The Clue to Patentability Should Lie in Whether Steps Central to the Claim Have a "Physical" or "Virtual" Link to a Specific Physical or Tangible Object, as the Claims in *Prometheus* Do.

- "From the *Benson-Flook-Diehr* spectrum of inventions involving a fundamental principle, the threshold for subject matter patentability may be gleaned; to wit, the existence of a link of the invention to a specific physical or tangible object." (pp. 20-21)

- "This link of data to something 'real' (either by 'physical' manipulation of a physical or tangible object, or by 'virtual' manipulation of data representing a physical or tangible object) may thus provide a useful clue to the patent eligibility of inventions involving processes…. The 'physical link' and 'virtual link' patent claim approach may thus be helpful in defining that boundary line beyond which a claim preempts a fundamental principle (i.e., a law of nature, natural phenomenon, or an abstract idea) and within which the claim does not." (pp. 23-24)

- "[T]he 'determining' and 'administering' steps [in *Prometheus*] each provide a 'physical' link to (i.e., they each 'manipulate') a specific physical or tangible object (i.e., blood). Thus, when considered as a whole, the claim that includes these steps as something more than token extra-solution activity is patentable subject matter, since the claim is drawn to manipulating a specific physical or tangible object, and is not just a natural phenomenon, abstract idea, or law of nature, or a process that completely preempts one of these." (p. 24)

- "The 'determining' and 'administering' steps in *Prometheus* plainly manipulate a specific physical or tangible object. The 'administering' step is a transformation of the human body and of its components following the administration of a particular class of drugs and the various chemical and physical changes of the drugs into their metabolites… [T]he 'administering' step generates data applied to enable adjustment of the drug dosage in the recited observed correlation. The 'determining' step necessarily also involves a manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims, or some other modification of the substances to be measured, which is necessary to extract the metabolites from a bodily sample and determine their concentration…. This transformative step likewise is not merely data gathering. Rather, it too generates data applied to enabling the adjustment of the drug dosage…" (p. 25)

- "[T]he *Prometheus* enabled adjustment of the drug dosage in the recited 'observed correlation' step in combination with the 'determining' step, and, in the case of claim 1, also the 'administering' step, provide a 'virtual link' to (i.e., they manipulate representations of) a specific physical or tangible object (i.e., blood) and so should likewise be subject matter patentable under 35 U.S.C. §101." (p. 29)

BRIEF OF THE INTELLECTUAL PROPERTY AMICUS BRIEF CLINIC OF THE UNIVERSITY OF NEW HAMPSHIRE SCHOOL OF LAW:

The University of New Hampshire School of Law (UNHLaw, formerly Franklin Pierce Law Center) has a long history of intellectual property expertise. The intellectual property faculty of UNHLaw has filed amicus briefs for this Court as well as lower courts. UNHLaw has an established Intellectual Property Amicus Brief Clinic. With faculty guidance and student participation, the Clinic seeks to file amicus briefs that will lead to the development and predictable application of intellectual property law to promote innovation and competition.

> ***"A consistent theme in this Court's decisions is that the claims of the invention at issue should be considered as a whole in a variety of contexts, and in particular where the issue is patent eligibility. This dictates that claims should not be parsed, looking only for steps that are, alone, judicially excepted subject matter."*** (p. 11)

The Court Should Provide a Comprehensive Approach to Determine What Constitutes a Patent-Eligible Process.

- "[T]here continues to be an opportunity to define a comprehensive approach to determine what constitutes a patent-eligible process…. This brief proposes an approach that is more general than the machine-or-transformation test and a) is in keeping with this Court's precedents… and b) is flexible enough to apply to new types of technology that will be developed in the future. A more comprehensive approach would benefit federal courts, the U.S. Patent and Trademark Office ('PTO'), and inventors by differentiating between patent eligible processes and patent ineligible processes." (pp. 3-4)

- "Our proposed comprehensive two-step approach is to first identify whether the claim specifies *how* to achieve a result. If the claim does so, then the second step is to determine if the claim refrains from wholly preempting the use of a judicial exception, such as a law of nature. If the claim does not preempt any judicial exceptions, then it is patent eligible. This approach is consistent with the precedent this Court has set…" (pp. 4-5)

- "We propose that a claim is patent eligible when the claim specifies *how* to achieve a result and refrains from preempting all uses of a judicial exception." (p. 14)

- "The Prometheus claims are patent-eligible subject matter under the precedence of this Court and meet the requirements of our proposed comprehensive analysis." (p. 31)

Congress Has Essentially Chosen To Leave Section 101 Alone – and the Courts Have Repeatedly Declined To Narrow Eligibility Under Section 101.

- "On September 16, 2011, President Obama signed the America Invents Act ('AIA'). Amid the continuing controversy over the scope of patent-eligible subject matter in the courts, Congress made no changes to 35 U.S.C. § 101. Thousands of patents have issued over the years in the area of business methods, medical treatment and isolated genes. In the AIA, there are only two

sections that address patent eligibility and neither modify § 101." (p. 6)

Section 101 Should Be Applied Divorced from Other Statutory Considerations.

- "We urge the Court not to infuse the patent eligibility analysis with other patentability considerations that are better suited for consideration under more appropriate provisions of the statute. For example, just because a claim is extremely broad does not mean that it is not directed to patent eligible subject matter." (p. 12)