No. 2018-1218

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CLEVELAND CLINIC FOUNDATION, CLEVELAND HEARTLAB, INC.,

Plaintiffs-Appellants,

v.

TRUE HEALTH DIAGNOSTICS, LLC,

Defendant-Appellee.

On Appeal from the United States District Court for the Eastern District of Virginia, in No. 17-198, Judge Leonie M. Brinkema

BRIEF OF LAW PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT

David Lund
Adam Mossoff
ANTONIN SCALIA LAW SCHOOL
GEORGE MASON UNIVERSITY
3301 FAIRFAX DRIVE
Arlington, VA 22201
(703) 993-9577

Scott A.M. Chambers
Matthew D. Zapadka
PORZIO, BROMBERG & NEWMAN P.C.
1200 NEW HAMPSHIRE AVE., N.W. SUITE 710
Washington, D.C. 20036
(202) 517-6318

Attorneys for Amici Curiae Law Professors

February 28, 2018

A full list of the Amici is included at the end of the brief.

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *amici curiae* state the following:

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

Law Professors – See Appendix A

2. The names of the real party in interest represented by us is: Not

applicable

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

Not applicable

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

PORZIO, BROMBERG & NEWMAN P.C.,

Scott A.M. Chambers, Matthew D. Zapadka

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b).

Although this case does not appear to satisfy this Court's definition under Fed. Cir. R. 47.4(a)(5) and 47.5(b), this Court previously decided *The Cleveland Clinic Foundation et al. v. True Health Diagnostics LLC*, Appeal No. 16-1766, which involved different patents covering similar technology.

Dated: February 28, 2018

/s/ Matthew D. Zapadka
Scott A.M. Chambers

Matthew D. Zapadka
PORZIO, BROMBERG & NEWMAN P.C.
1200 NEW HAMPSHIRE AVE., N.W. SUITE 710
Washington, D.C. 20036
(202) 517-6318

Attorneys for Amici Curiae Law Professors

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

RULES

OTHER AUTHORITIES

INTEREST OF *AMICI CURIAE*[1]

The *amici curiae* are professors who teach and write on patent law and policy. As patent law scholars, they are concerned that the law properly promotes and secures protection for inventions in all technologies, including medical diagnostics and biotechnology. They have no stake in the parties or in the outcome of the case. The names and affiliations of the members of the *amici* are set forth in Appendix A below.

SUMMARY OF ARGUMENT

The district court's decision in *The Cleveland Clinic Foundation v. True Health Diagnostics, LLC*, No. 17-cv-198, 2017 WL 3381976 (E.D. Va. Aug. 4, 2017), represents an improper application of 35 U.S.C. § 101. The parties address the relevant innovation covered by Cleveland Clinic's patents, as well as the application of the Supreme Court's and the Court of Appeals for the Federal Circuit's § 101 jurisprudence; accordingly, *amici* offer additional insight concerning the legal and policy problems with the trial court's decision: innovation in improving the assessment of a patient's risk of developing cardiovascular disease is an

[1] No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting this brief; and no person other than amici, their members, or counsel contributed money intended to fund preparing or submitting this brief. Consent has been sought from each party, none of whom opposed the filing of this brief. FED. R. APP. P. 29(c)(5).

invention that the patent system is designed to promote, and thus it should be eligible for patent protection. Barring a properly reasoned, factually-based determination that either a claimed method-of-treatment invention covers a law of nature or, under step two of the *Alice-Mayo* test, that it would be considered routine or ordinary by a person having skill in the art, a district court should not find claims to be ineligible subject matter under § 101 on a motion to dismiss. *See Berkheimer v. HP Inc.*, __ F.3d at ___, No. 2017-1437 (Fed. Cir. 2018). The district court's decision in this case conflicts with the Patent Act as an integrated statutory framework for promoting and securing innovation in the life sciences, as construed by both the Supreme Court and this court.

The Supreme Court has recognized that the plain meaning of the language of § 101 indicates that the scope of patentable subject matter is broad. *See Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980). This is why the Supreme Court consistently has held that "[t]he § 101 patent-eligibility inquiry is only a threshold test." *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). Accordingly, this "threshold test" is necessarily followed by the more exacting statutory requirements of assessing a claim as a whole according to the standard of a person having skill in the art as to whether it is novel, nonobvious, and fully disclosed as required by the *quid pro quo* offered to inventors by the patent system. *Id.*

Unfortunately, courts have been focusing on out-of-context statements in the Supreme Court's recent § 101 cases that have led those courts to inexorably apply the two-step "*Alice-Mayo* test" in an unbalanced and legally improper manner. *See Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). Courts are dissecting claims into particular elements and then construing these elements in highly generalized terms with no evidentiary support. Thus, as happened in this case, a district court all too often merely asserts a conclusory finding that the claim—actually, specific elements dissected out of the claim as a whole—covers ineligible laws of nature or abstract ideas.

This has led lower courts to create an unduly stringent and restrictive patent eligibility test under the *Alice-Mayo* test, as evidenced by the district court's decision in this case. This contradicts the Supreme Court's decisions in *Chakrabarty* and *Bilski* that § 101 is only a threshold inquiry identifying broad statutory categories of patent-eligible inventions. This improper application of the *Alice-Mayo* test inevitably leads to § 101 rejections of patentable method inventions, as the district court in this case rejected an innovative invention in the bio-pharmaceutical sector that the patent system is designed to promote.

Furthermore, the improper treatment of the § 101 inquiry as a pure question of law requiring no evidentiary findings whatsoever, especially when the parties

expressly dispute as to what a person having skill in the art would consider routine or ordinary, conflicts with the Supreme Court's and this Court's decisions that the application of the patentability requirements in the Patent Act present questions of law with underlying questions of fact. *See Teva Pharm. USA Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 838 (2015) (claim construction); *KSR v. Teleflex*, 550 U.S. 398 (2007) (nonobviousness under § 103); *Berkheimer*, __ F.3d at ___, No. 2017-1437 (Fed. Cir. 2018) (patentable subject matter under § 101); *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343 (Fed. Cir. 2016) (indefiniteness under § 112); *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014) (enablement under § 112). This has sowed indeterminacy in patent eligibility doctrine, as inventors and companies in the innovation industries are left with little predictability concerning when or how courts will dissect claims and make conclusory assertions that they are patent ineligible under § 101.

ARGUMENT

I. The Supreme Court has affirmed that the scope of the exceptions to patent eligibility is narrow.

Courts have been improperly applying the *Alice-Mayo* test. This has resulted in patent eligibility doctrine under § 101 for product and process inventions in the life sciences and bio-pharmaceutical fields that is overly restrictive; too many inventions are considered by courts to fall under the exceptions to patent eligibility.

Thus, it is necessary to explicate again the plain language of § 101 and the Supreme Court's interpretation of the statutory mandate of § 101.

Section 101 provides for the issuance of a patent to "[w]hoever invents or discovers any new and useful process, machine manufacture or composition of matter or any new and useful improvement thereof." The expansiveness of the terms demonstrates that the subject matter covered by the patent laws should be given wide scope. Although laws of nature, physical phenomena, and abstract ideas are not patentable and treated as judicially-defined exceptions to the statutory rule, the scope of these exceptions is narrow. *See, e.g., Alice*, 134 S. Ct. 2347 at 2354 ("[W]e tread carefully in construing this exclusionary principle [of finding claims patent-ineligible under § 101] lest it swallow all of patent law.").

The Supreme Court has repeatedly cautioned against an overly restrictive interpretation of the patent laws, which are enacted by Congress according to the constitutional purpose of promoting progress of the useful arts. Courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *Diamond* 447 U.S. at 308 (*citing United States v. Dubilier Condenser Corp.*, 289 U. S. 178 (1933)). This is particularly true for § 101. The Supreme Court has repeatedly noted the harms that will flow from unduly restricting subject matter eligibility according to the exceptions. *See, e.g., Alice*, 134 S. Ct. 2347 at 2354.

Patent claims on diagnostic methods, including the specialized laboratory methods at issue here, present a particularly salient concern. Such claims are easy to analytically dissect and overgeneralize into individual foundational laws of nature or natural phenomenon, or restate at such a high level of generalization to be regarded as conventionally-known techniques in the art. That is not because such inventions comprise laws of nature or natural phenomena themselves, but because all diagnostic method claims seek to discover information about a subject, including those seeking to diagnose conditions in humans.

This is why the Supreme Court specifically warned lower courts and the United States Patent and Trademark Office ("PTO") against an overly restrictive application of § 101 in determining patent-eligibility for claimed inventions. *See Mayo Collaborative Services*, 566 U.S. at 71. Most recently, in its 2012 decision addressing the patentability of a diagnostic method in *Mayo Collaborative Services v. Prometheus Laboratories,* the Supreme Court warned "that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id*. This is a very common refrain throughout the Supreme Court's § 101 jurisprudence. *See, e.g., Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354-55 (2014) (stating that "an invention is not rendered ineligible for patent simply because it involves an abstract concept" in some of its distinct

claim elements); *Mayo*, 566 U.S. at 71-72 (recognizing same); *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) ("[A]n application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."). The Federal Circuit may need to better articulate this basic premise in applying the *Mayo-Alice* test in assessing the patent eligibility of inventions.

Neither Congress nor the Supreme Court intended to dissuade research in the field of natural products for any uses. There are millions of natural products and processes that incorporate natural phenomena existing in nature for billions of years, but innovative scientific and therapeutic applications continue to evolve, and should be rewarded with patent protection. Limiting the commercial value of these products by withdrawing their potential to be patented will force biotechnology and pharmaceutical firms to restrict or eliminate their innovation in these fields.

II. The exceptions to § 101 are narrow because it is a "threshold test."

The exceptions to subject-matter eligibility are narrow, ensuring the doctrine is limited to its narrow purpose: § 101 is a threshold test. *See Bilski*, 561 U.S. at 602. This permits the other sections of the Patent Act to test the scope of the advancement and the adequacy of the disclosure, as intended by Congress. *See id.*

The distinction between the function of the threshold test and the function of the remaining patentability requirements was explicitly recognized in *Diamond v. Diehr*, 450 U.S. at 188 ("Arrhenius' equation is not patentable in isolation, but when

a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold by § 101."). The question in *Diehr* was how the Arrhenius' equation was incorporated into a claimed invention comprising a new rubber-curing process. *Id*. Once it was established that the patent claim as a whole covered a new method of curing rubber, the Supreme Court properly recognized that the § 101 inquiry was at an end. *Id*. Given the structure and function of the Patent Act, this is the sensible interpretation of the patentability provisions as an integrated statutory framework.

Moreover, the determination of the nature of the process, of the invention, and of what is routine or ordinary in the art is a factual question. *Berkheimer*, __ F.3d at ___, No. 2017-1437 slip op. at 6. This factual question was well-presented in *Diehr*, which was on appeal from a denial of the patent application at the PTO. In this case, which was decided on a motion to dismiss, there were underlying factual questions that remain unanswered and which can be resolved only at a later stage in the litigation.[2] Consistent with the "threshold test" of § 101, courts must avoid invalidating patents without receiving evidence and providing well-reasoned opinions that reach the appropriate legal conclusion on the basis of this evidence. For a court to treat a § 101 determination as a pure question of law that can be

[2] As discussed further *infra*, proper application of the *Alice-Mayo* test will require analysis of factual questions, particularly at step two.

resolved on a motion to dismiss does violence to the integrated statutory framework of the Patent Act by converting § 101 from a threshold test into the sole legal criterion of patentability.

III. Claims challenged under § 101 must be analyzed "as a whole" to ensure the individual claim terms are not construed in isolation as the invention.

The district court ignored the mandate from the *Alice* Court that "we consider the elements of each claim both individually and 'as an ordered combination.'" *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 566 U.S. at 79). This proposition—that courts should assess claim elements individually and as a whole—has been improperly construed by lower courts in the disjunctive, *i.e.*, as equally acceptable alternative approaches in construing claims under § 101. The *Alice* Court, however, used the conjunctive "and," and not an "or"; thus, both methods of claim construction are required by the *Alice-Mayo* test. In considering Appellant's claims as "an ordered combination," *id.*, the claimed methods for diagnosing artherosclerotic cardiovascular disease have several underlying factual questions.

The claimed laboratory methods require human intervention and manipulation of chemical and biological products to diagnose cardiovascular disease, which immediately suggests factual questions regarding the prior use, if any, of those interventions and manipulations. The district court in this case repeated the same error of many other courts when it analyzed particular claim terms and declared that

each of these terms fall within the natural law exception. *See Cleveland Clinic*, 2017 WL 3381976 at *8. It recognized that the "strongest argument [was] that the ordered combination of steps in these claims has not been previously used for this particular purpose," but then brushed this aside by citing prior § 101 decisions that also failed to follow the mandate of the *Alice-Mayo* test to do this analysis. *Id*. The district court abdicated its responsibility to follow the proper *Alice-Mayo* test, to inquire further about the prior use of the steps, and to identify factual questions and apply the appropriate presumptions based on the Federal Rules of Civil Procedure.

These patented diagnostic methods, which are more particularly characterized as laboratory methods, contain a combination of claim elements that were not routine and conventional at the time of the invention, as evidenced by the prior art's teaching away from these particular methods. *See* Plaintiff's Opposition to Motion to Dismiss, *Cleveland Clinic Foundation*, No. 17-cv-198, ECF No. 46 at 5. Regardless of whether these factual arguments could ultimately be proved at trial, summarily rejecting them at the motion to dismiss stage is categorically inappropriate. Moreover, laboratory methods will always be governed by scientific and physical laws, which makes the factual analysis of the "something more" in step two of the *Alice-Mayo* test imperative to the § 101 inquiry in this case. *See Alice*, 134 S. Ct. at 2354-55. Again, resolution of these factual questions at the pleading stage is inappropriate.

When the district court analyzed each claim limitation individually, it essentially embarked on a fact-based analysis—but it did so without considering any factual evidence. *See Cleveland Clinic*, 2017 WL 3381976 at *8-10. In considering without evidence the separate claim limitations means that the court relies ultimately on its gut reaction or basic sense of the gist of the invention. This violates a fundamental requirement in the Patent Act that has long served to ensure that innovation is properly secure under the law: the patentability tests are assessed according to the person having skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). To allow the § 101 analysis to be conducted devoid of the necessary expert input, claim construction, factual conclusions, and proper presumptions based on the Federal Rules of Civil Procedure causes the exceptions to swallow the rule under § 101.

IV. Showing that claim terms are routine and conventional is a question of fact, which is generally unsuitable for resolution on the pleadings.

The § 101 inquiry comprises a basic question of what is the invention. This is not merely a question of reading the claims, but involves deeper inquiries regarding what the invention is "directed to" at step one, and, if the claims are directed to one of the exceptions to patent eligibility, whether they add an "inventive concept" in step two. *See Alice*, 134 S. Ct. at 2355. Evaluating the technological context of an invention, especially when assessing whether someone has engaged in an inventive

step over what was routine or ordinary in the prior art, is a factual inquiry. Thus, the proper understanding of § 101 is that it is a legal question with underlying questions of fact that normally require proper resolution before declaring a patent claim ineligible under § 101. *See Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1273-74 (Fed. Cir. 2012).

This Court recently recognized this fundamental insight in the proper assessments of patent claims under § 101 in *Berkheimer v. HP*, __ F.3d ___, No. 2017-1437 slip op. at 6. The Court said that the "question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Id*. at *5. Therefore, "any fact . . . that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence." *Id*. at slip op. 12 (citing *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011)). However, this principle is not uniformly accepted on the Federal Circuit and requires continued affirmation of its correctness. *See, e.g., Aatrix Software, Inc. v. Green Shades Software, Inc.*, 2017-1452, slip op. (Fed. Cir. Feb. 14, 2018) (Reyna, J. dissenting) ("Our precedent is clear that the § 101 inquiry is a legal question.").

Other legal questions with requisite factual inquiries are fundamental in patent law. An obviousness determination under § 103 is the most common example, where courts routinely step through the factual questions of "the scope and content of the

prior art…; differences between the prior art and the claims at issue…; and the level of ordinary skill in the art…" along with secondary considerations before addressing the final question of law of obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court recently reaffirmed this fact-intensive analysis for obviousness. *KSR*, 550 U.S. at 407. In particular, when assessing the predictability of combining conventional elements, "it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." *Id.* The "overlap" between these determinations under both § 103 and § 101 has been noted by the Supreme Court, indicating the necessity to fully consider factual questions in both instances. *Mayo*, 566 U.S. at 90.

The Supreme Court has also held that claim construction is a question of law with factual underpinnings. *Teva Pharm. USA Inc. v. Sandoz, Inc.*, 135 S.Ct. 831, 838 (2015) (identifying "claim construction as a practice with 'evidentiary underpinnings,' a practice that 'falls somewhere between a pristine legal standard and a simple historical fact'") (*quoting Markman v. Westview Instruments* 517 U.S. 370, 378 (1996))). Although as a written instrument, the construction of a patent claim is ultimately a question of law, that does not mean that courts can ignore the existence or relevance of underlying factual questions. *Id.* at 837. *Teva* is

additionally relevant to the § 101 issue because it addressed the interaction of the Federal Rules of Civil Procedure with patent law doctrines. When a doctrine is a question of law with underlying evidentiary or fact-based questions, the Rules apply the same as they would in any other circumstance. *Id.* at 838. Here, that means accepting well-pleaded facts in the complaint on a motion to dismiss as true and deferring resolution of contested facts until trial.

This Court has also recognized the importance of factual questions underlying other patentability requirements that are questions of law with underlying questions of fact, such as assessing indefiniteness under § 112. *See Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343 (Fed. Cir. 2016). In *Akzo Novel Coatings*, the court was faced with the question of what a "temperature" reference in the claim meant in measuring the viscosity of a liquid. The court determined that it meant "room temperature" based on the requisite factual findings by the district court of how a skilled artisan would have conducted the test. *Id.* at 1344. Similar to the § 101 inquiry, the factual questions underlying a § 112 indefiniteness inquiry are based on determining what the invention *is*, which is instructive for understanding the proper application of the *Alice-Mayo* test.

This court's decision in *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180 (Fed. Cir. 2014) is another recent example of factual inquiries underlying a legal question of patentability; in this case, it was enablement. This Court held that

when the breadth of experimentation is contested by the parties, it is "imperative" that courts analyze those factual considerations before ruling on the validity of the patent. *Id.* at 1188 (*citing Johns Hopkins Univ. v. CellPro, Inc.,* 152 F.3d 1342, 1360 (Fed. Cir. 1998)). In *Alcon Research*, the factual question involved whether a given process was "routine." *Id.* Thus, the same kinds of inquiries as involved in step two of the *Alice-Mayo* test have already been analyzed as proper factual issues in the other patentability requirements under the Patent Act.

Lastly, failure to assess a claim as a whole—such as the PTO and other district courts have done when applying the *Alice-Mayo* test—improperly places too many patents in a precarious position by eliminating necessary factual questions in the § 101 inquiry. The fundamental factual inquiries are necessary to properly resolve § 101 questions. As is evident throughout all the patentability requirements, these factual questions are present in nearly every case. For instance, when a patent is granted because it embodies a solution that the prior art considered unworkable, impossible, or impractical, this is a necessary factual determination in resolving the "inventive concept" inquiry of step two of the *Alice-Mayo* test. Glossing over issues such as these with conclusory findings, as the district court did in this case and other courts have done in other cases in which § 101 has been resolved too early in the litigation, misapplies the *Alice-Mayo* test, misconstrues § 101 as a threshold test, and ultimately undermines the function of the patent system in promoting the useful arts.

V. The failure to consider claims as a whole has resulted in legal uncertainty that undermines the innovation industries relying on stable and effective patent rights.

The improper application of § 101 harms innovators, and is now recognized as a factor in the United States dropping from its position as a global leader in patent protection. The misapplication of the *Alice-Mayo* test, especially when disintegrating claims into their separate elements with resulting conclusory assertions of invalidity, is evidenced by inordinately high invalidation rates. As of June 1, 2017, the invalidation rate under the *Mayo-Alice* test in the lower courts is 61.7%. *See #Alicestorm: April Update and the Impact of TC Heartland on Patent Eligibility*, Bilski Blog (June 1, 2017), at *http://www.bilskiblog.com/blog/2017/06/alicestorm-april-update-and-the-impact-of-tc-heartland.html.* The invalidation rate at the Patent Trial & Appeal Board (PTAB) is similarly high in the Covered Business Method program and is 97.8%. *See id*. This follows naturally from judges and patent examiners only assessing individual claim elements, ignoring other elements that comprise the claim as a whole, and ignoring key factual questions that must be properly briefed.

Shortly after *Alice* was decided in 2014, anecdotal reports indicated increased rejections of many patent applications covering innovative therapeutic treatments and diagnostic tests under the *Mayo-Alice* test. *See* Bernard Chao & Lane Womack, *USPTO is Rejecting Potentially Life-Saving Inventions*, Law360 (Dec. 18, 2014), at

http://www.law360.com/articles/604808/uspto-is-rejecting-potentially-life-saving-inventions. Empirical data now confirms these concerns. For example, one examination unit at the PTO that reviews personalized medicine inventions (art unit 1634) is rejecting 86.4% of applications under the *Mayo-Alice* test. *See* Bernard Chao & Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Patent L. J. 10, 12, at http://patentlyo.com/media/2016/04/Chao.2016.PersonalizedMedicine.pdf.

Additionally, the U.S. Chamber of Commerce recently released its well-known International IP Index for 2018. *See* U.S. Chamber International IP Index, 6th Ed., February 2018, available at http://www.theglobalipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_2018.pdf ("2018 Index"). The 2018 Index explicitly states that "the patentability of basic biotech inventions was compromised by the Supreme Court decisions in the 2013 *Molecular Pathology v. Myriad Genetics* and 2012 *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* cases." *Id*. at 8. Given the manner in which courts have been misapplying the *Alice-Mayo* test, as detailed above, the 2018 Index confirms that "[t]here is considerable uncertainty for innovators and the legal community, as well as an overly cautious and restrictive approach to determining eligibility for patentable subject matter in areas such as biotech, business method, and computer implemented inventions." *Id*.

The 2018 Index further concludes that the current state of § 101 jurisprudence in the U.S. "seriously undermines the longstanding world-class innovation environment in the U.S. and threatens the nation's global competitiveness." *Id*. For many years, the United States was number one in the Index, but it fell to 10th place last year and again fell to 12th place this year in the 2018 Index of how global patent systems provide stable and effective security for all innovators. *Id*. at 35-37; *see also* Tiffany Hu, *US Drops to 12th in Patent Protection, Report Says*, Law360 (February 8, 2018), at https://www.law360.com/ip/articles/1010617/us-drops-to-12th-in-patent-protection-report-says?nl_pk=a9dc0a3c-f8e7-433d-94fe-ac6c396d5149&utm_source=newsletter&utm_medium=email&utm_campaign=ip. Considering the very high research and development (R&D) costs and extremely long time-horizons on R&D in the bio-pharmaceutical industry, it is imperative to reverse this trend if the patent system is to continue its purpose of promoting innovative, breakthrough medical treatments that all people rely on in their day-to-day lives. Thus, this Court must direct district courts to adhere to the language of the *Alice-Mayo* test in properly considering a claim as a whole, as well as adhering to longstanding Supreme Court decisions that recognize that the § 101 inquiry is a threshold legal test that hinges upon underlying questions of fact.

CONCLUSION

Amici urge this Court to reverse the district court's decision and reaffirm its prior decision in *Berkehimer* that when factual questions regarding patent eligibility under § 101 are present, this precludes determination of a patent's validity under § 101 at the pleading stage on a motion to dismiss.

Respectfully submitted,

Dated: February 28, 2018

/s/ Matthew D. Zapadka

Scott A.M. Chambers
Matthew D. Zapadka
PORZIO, BROMBERG & NEWMAN P.C.
1200 NEW HAMPSHIRE AVE., N.W. SUITE 710
Washington, D.C. 20036
(202) 517-6318

Attorneys for Amici Curiae Law Professors

Appendix A — FULL LIST OF AMICI CURIAE*

Walter Matystik
Associate Provost and Adjunct Professor
Manhattan College

Adam Mossoff
Professor of Law
Antonin Scalia Law School
George Mason University

Kristen Osenga
Professor of Law
University of Richmond School of Law

Michael Risch
Professor of Law
Villanova University School of Law

Ted Sichelman
Professor of Law
University of San Diego School of Law

David O. Taylor
Associate Professor of Law
SMU Dedman School of Law

* Institutions of all signatories are for identification purposes only. The undersigned do not purport to speak for their institutions, and the views of *amici* should not be attributed to these institutions

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d), 32(a)(7)(B) and Circuit Rule 32(b).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 4,391 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(C), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

Dated: February 28, 2018

/s/ Matthew D. Zapadka
Scott A.M. Chambers
Matthew D. Zapadka
PORZIO, BROMBERG & NEWMAN P.C.
1200 NEW HAMPSHIRE AVE., N.W.
SUITE 710
Washington, D.C. 20036
(202) 517-6318

Attorneys for Amici Curiae
Law Professors

CERTIFICATE OF SERVICE

I hereby certify that, on this 28th day of February, 2018, I filed the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

Dated: February 28, 2018

Scott A.M. Chambers
Matthew D. Zapadka
PORZIO, BROMBERG & NEWMAN P.C.
1200 NEW HAMPSHIRE AVE., N.W.
SUITE 710
Washington, D.C. 20036
(202) 517-6318

Attorneys for Amici Curiae
Law Professors