

No. 2017-2508

**United States Court of Appeals
for the Federal Circuit**

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY
INNOVATION LTD., MAX-PLANCK-GESSELLSCHAFT ZUR
FORDERUNG DER WISSENSCHAFTEN E.V.,

Plaintiffs-Appellants,

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA
MAYO MEDICAL LABORATORIES, MAYO CLINIC

Defendants-Appellees.

Appeal from the United States District Court for the District of
Massachusetts in No. 15-cv-40075-IT, Judge Indira Talwani

**BRIEF OF FREENOME HOLDINGS INC. AND
ACHILLION PHARMACEUTICALS, INC. AS
AMICI CURIAE IN SUPPORT OF NEITHER PARTY**

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April 22, 2019

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CERTIFICATE OF INTEREST

Counsel for the Amici certify the following:

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

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2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

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:

None.

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:

Meredith M. Addy, AddyHart P.C.
Sherry M. Knowles, Knowles Intellectual Property Strategies LLC

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). (The parties should attach continuation pages as necessary).

None.

Dated: April 22, 2019

By: /s/ Sherry M. Knowles
Sherry M. Knowles

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INTEREST OF THE *AMICI CURIAE*

Amici Curiae are U.S. companies who have an interest in ensuring that the balance of powers and limitations in our tripartite government as established by the U.S. Constitution are honored.¹ Specifically, *Amici Curiae* have an interest in ensuring that Congress' pronouncement of the scope of patent eligible subject matter defined in 35 U.S.C. §101 and under the U.S. Constitution, Article I, section 8, clause 8 is strictly applied.

Freenome Holdings, Inc. uses artificial intelligence to recognize disease-associated patterns among billions of circulating, cell-free markers to produce accurate, non-invasive blood tests for very early cancer detection.

Achillion Pharmaceuticals, Inc. has three drugs in human clinical trials for the treatment of orphan diseases of the complement Alternative Pathway, including C3 glomerulopathy and paroxysmal nocturnal hemoglobinuria, and has a research program to develop drugs for additional complement-related disorders. The treatment of these complex diseases may benefit from companion personal diagnostic assays.

¹ No counsel for a party authored this brief in whole or in part and no person other than *amici* or their counsel made a monetary contribution to its preparation or submission. The parties have indicated that they do not oppose the filing of this brief.

SUMMARY OF THE ARGUMENT

Amici Curiae urge the Court to carry out its constitutional duty to properly construe the words of 35 U.S.C. §101 and then apply them to this case. Specifically, the Court may not remove words from a statute before applying it to the facts. The Court also may not apply a statute in a manner that is wholly inconsistent with the text of the statute. Further, the Court may not apply judicial exceptions to any statute, much less the patent eligibility statute. Recognizing that the Court is bound to apply Supreme Court precedent, at a minimum, *Amici* ask the court to recognize in the opinion the tension resulting from application of the judicial exceptions to override the language of §101.

ARGUMENT

I. Proper Statutory Construction of 35 U.S.C. §101 Requires Recognition of “Discoveries” as Patent Eligible Subject Matter

Article I, Section 8, Clause 8 of the U.S. Constitution gives *Congress* the sole power to “promote the Progress of Science and the Useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” The Constitution grants Congress full discretion to decide how to promote this progress.

Whoever *invents or discovers* any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. §101 (1952) (emphasis added). Congress unambiguously chose to promote the progress by motivating conduct that “invents” *or* “discovers” in the disjunctive.

Where the Constitution grants sole authority to Congress to create law, the federal courts are limited to statutory construction: “time and again ... courts must presume that a legislature says in a statute what it means and means in a statute what it says there.” *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (citing several supporting cases and adding: “When the words of a statute are unambiguous, then, this first canon is also the last”). When the statute’s language is plain, “the sole function of the courts is to enforce it according to its terms.”

Caminetti v. United States, 242 U.S. 470, 485 (1917); *see also Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000). This assumption is “elementary” to judicial analysis of statutes. *Caminetti*, 242 U.S. at 485.

The Supreme Court even analyzes the grammatical structure and punctuation. *See D.C. v. Heller*, 554 U.S. 570, 598 (2008) (analyzing the placement of a comma in the Second Amendment); *Lockhart v. United States*, 136 S. Ct. 958, 962 (2016) (quoting a book by Justice Scalia about limiting clauses and phrases which “should ordinarily be read as modifying only the noun or phrase that it immediately follows”); *see also Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 229 (2008) (where the dissent criticized the majority as improperly placing “implicit reliance upon a comma at the beginning of a clause”). Despite its thorough analysis, however, the Court cannot change Congress’ statutory language.

II. Congress Has Repeatedly Granted Patent Eligibly To Applicants Who "Invent *Or* Discover"

Between 1790 and 2011, Congress repeatedly allowed applicants who either “invent *or* discover” access to the patent system. Although Congress did remove the word “discover” for a short period of time, even then, Congress referred to discoveries, multiple times, in the code. *See Patent Statutes of 1793-1836*. In 1836, Congress purposefully restored the disjunctive “invents or discovers,” which it

maintained through at least two dozen Patent Act recodifications, and it remains today. See Knowles and Prosser, *Unconstitutional Application of 35 U.S.C. §101 by the U.S. Supreme Court*, 18 J. Marshall Rev. Intell. Prop. L. 144; 144-153 (2018) (tracing the statutory development of Section 101 from its introduction through the present).

As part of the 1952 Patent Act, Congress also added a definition of “invention.” “The term ‘invention’ means invention or discovery.” 35 U.S.C. §100(a) (1952); see also Leahy-Smith America Invents Act (AIA) Pub. L. No. 112-29, 125 Stat. 284 (2011) (retaining the same definition of “invention”). Congress’ purposeful addition of “discovery” in both the statute and the definition of “invention” reinforces its intent that discoveries are patent eligible. Knowles, *supra* at 151. The Hearings before the Subcommittee of the Committee on the Judiciary of the House of Representatives pertaining to the 1952 Act confirm Congress’ this intent. Knowles, *supra* at 151-154. In fact, the Justice Department objected to the addition of “discovery” to the definition of invention on at least two occasions. First the Justice Department “recommend[ed] that no hasty action be taken toward the enactment of a statutory definition of ‘invention.’” H.R. Rep. 80-4061, 2nd Sess., 82 (1951). And then, the Justice Department argued that “under existing law discoveries, as such, are not patentable.” *Id.* Congress disagreed.

Instead, Congress noted its intent that inventions “include anything under the sun that is made by man.” H.R. Rep. No. 82-3760, 82d Cong., 1st Sess., 37 (1951); S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952). Thus, the legislative history of the 1952 Patent Act establishes that Congress used its exclusive constitutional power to include “discoveries,” as patent eligible subject matter. This is consistent with the first opinion addressing patent eligibility:

A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process.

Le Roy v. Tatham, 55 How. 156, 174-75 (1853) (emphasis added).

Given the clear legislative history, Courts may not remove words from the statute. Rather, Courts are required to apply the literal terms of §101 “[w]hoever invents or discovers...” to patent eligibility analyses. To ignore the disjunctive language of the statute in the face of repeated recodifications of the federal law is unconstitutional. *See, e.g., Knowles, supra; Ali*, 552 U.S. at 229; *Connecticut*, 530 U.S. at 253-54; *Caminetti*, 242 U.S. at 485. The terms of the U.S. patent code should be applied in the same precise, non-emotional manner that, for example, the U.S. tax code is applied. *See, e.g., Nat. Fed. of Indep. Bus. v. Sebelius, Sec’y of Health and Human Servs*, 567 U.S. 519 (2012) (Roberts, C.J.).

III. The Court May Not Create Patent Law.

Surprisingly, after over 180 years as a section of the Patent Statute,² the Courts have yet to perform a proper statutory construction of the literal words of §101 referring to “invents or discovers.” A review of these cases establishes that the statutory text has been used by the Courts primarily to introduce its judicial exceptions to the statute. *See Knowles, supra* at 154-67. Even a simple comparison of the wording of the *Alice* rubric to the exact language of Section 101 confirms basic inconsistencies. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

In fact, the Supreme Court has repeatedly admitted departure from the text of §101 in its decisions. The *Bilski* Court held:

The Court's precedents provide three specific exceptions to §101's broad patent-eligibility principles: “laws of nature, physical phenomena, and abstract ideas.” *Chakrabarty, supra*, at 309, 100 S. Ct. 2204. ***While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be “new and useful.” And, in any case, these exceptions have defined the reach of the statute as a matter of statutory stare decisis going back 150 years.***

Bilski v. Kappos, 561 U.S. 593 602 (2010), citing (*Le Roy* 14 How. at 174–75) (emphasis added). This quote not only rationalizes unauthorized judicial exceptions to a federal statute, it also confuses patent eligibility with patentability. *See, e.g.,*

² While it has been over 180 years since the Patent Act of 1836, it is almost 230 years since these words first appeared in 1790.

35 U.S.C. §101 (patent eligibility), and §§102, 103, 112 (together, patentability). The Supreme Court appears to be poised to continue application of its own inconsistent patent law because it has already done so for a long enough time.

However, Congress has repeatedly reaffirmed the “invention or discovery” standard from 1790 through 2011, and because Congress is solely authorized to create patent law, these repeated recodifications prevail over any “statutory stare decisis.” U.S. Const. Art. I, §8, cl. 8.

Justice Breyer’s concurrence in *Bilski* acknowledged the Court is acting outside of the bounds of the statute, and it can only go so far:

Any suggestion in this Court's case law that the Patent Act's terms deviate from their ordinary meaning has only been an explanation for the exceptions for laws of nature, physical phenomena, and abstract ideas. See *Parker v. Flook*, 437 U.S. 584, 588–89 (1978). ***This Court has not indicated that the existence of these well-established exceptions gives the Judiciary carte blanche to impose other limitations that are inconsistent with the text and the statute's purpose and design.***

Bilski, 561 U.S. at 603 (emphasis added).

Justice Breyer in *Mayo* then admits that the Court cannot take its own judicially created exceptions too far or else they will destroy Congress’ patent law *in toto*:

The Court has recognized, however, 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. . . Still, as the Court has also made clear, to transform an unpatentable law of nature into a

patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words “apply it.”

Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012) (emphasis added), citing *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).

Justice Breyer’s last statement, that “one must do more than simply state the law of nature while adding the words ‘apply it,’” is inconsistent with *Le Roy*, 55 How. at 174-75. And, after admitting it cannot take its own judicially created exceptions too far, the Court circularly defends the scope of the exceptions on the basis that, if the court applies the words of §101 literally, it will destroy its own parallel judicial exceptions to the code which would be inconsistent with the Supreme Court’s deviating common law.

This approach, however, would make the “law of nature” exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law [i.e., its own case law]. The relevant cases rest their holdings upon section 101, not later sections [i.e., 102, 103 and 112].

Mayo, 566 U.S. at 90 (brackets added, citations omitted). In *Mayo*, despite recognition of the problem, the Court ultimately refused to apply the literal terms of §101 in light of its “better established” deviating common law analysis. *Mayo*, 566 U.S. at 90. The Court held that “[t]hese considerations lead us to decline the Government’s invitation to substitute §§102, 103, and 112 inquiries for the ‘better established’ inquiry under §101.” *Id.* at 91-92. The “better established” inquiry – the

Court's judicial exceptions. Compliance with the Constitution and federal statute, however, is not an invitation.

In furthering this path of judicial activism, in *Myriad* Court stated that:

[G]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.

Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591 (2013), citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). It is hard to imagine a more Constitutionally contradictory statement than the Supreme Court ruling that “discoveries” cannot be patented when the very statute the Court is applying requires that any “invention or discovery” *can* be patented. The Court says “A not B” while the statute says “A or B.” And, *Myriad's* inconsistent statement that a discovery is not an invention, is all the more inconsistent with the definition of invention added in the 1952 Patent Act: “an invention can be a discovery.” 35 U.S.C. §100(a). The Supreme Court's development of §101 based on its own judicial exceptions and its associated common law precedent back to *Funk* has now led to this Court's refusal of eligibility to the commercial application of a manmade discovery, even when it explicitly satisfies §101.

IV. The Court May Not Use Judicial Exceptions to Ignore Statutory Language.

The Supreme Court has repeatedly based its patent eligibility opinions on its judicially created exceptions to the statute. *See, supra.* Attorneys for *Amici*,

however, have been unable to identify any source of law that grants the Judiciary the power to create exceptions to a federal statute, much less to use them to erase words in that statute. Under the Constitution, the Court is not delegated any authority to either create or limit a law to promote the progress of science and the useful arts created by Congress in its discretion. Even the Supreme Court has acknowledged it has not been given such authority. “This Court may not engraft its own exceptions onto the statutory text.” *Henry Schein, Inc. v. Archer & White, Inc.* (No. 17-1272; January 8, 2019). *The Court Cannot Pencil Out Two Words of Section 101.*

Through the application of its judicial exceptions, the Court has effectively penciled out two words of the statute – “or discovers.” Removing these words is contrary to Congress’ explicit statutory discretion in how it wants to “promote the progress of science and the useful arts.” U.S. Const., Art. I, cl. 8, §8.

CONCLUSION

Amici have great respect for the Federal Circuit and know the Court is committed to “faithfully and impartially discharge and perform all the duties incumbent upon them under the U.S. Constitution and the laws of the U.S.”

Amici understand that the Court cannot issue a decision that is directly inconsistent with Supreme Court precedent on patent eligibility. However, *Amici* urge the Court at least address the statutory construction of “invents **or** discovers,” the repeated recodifications of the statute, the legislative history of the 1952 Patent Act, the addition of §100(a), and also acknowledge that the Court is not authorized to apply judicial exceptions to any statute.

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CERTIFICATE OF SERVICE

I, Meredith M. Addy, a member of the Bar of this Court, hereby certify that on April 22, 2019, a copy of BRIEF OF FREENOME HOLDINGS, INC. AND ACHILLION PHARMACEUTICALS, INC. AS *AMICI CURIAE* IN SUPPORT OF NEITHER PARTY was served by electronic via CM/ECF on counsel of record:

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CERTIFICATE OF COMPLIANCE

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief was printed using a 14 point Times New Roman font.

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 2544 words, excluding the parts of the brief exempted under the Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This certificate was prepared in reliance on the word count of the word-processing system (Microsoft Word 2013) used to prepare the brief.

April 22, 2019

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