

No. 18-277

In the
Supreme Court
of the **United States**

URVASHI BHAGAT
Petitioner,

v.

ANDREI IANCU, DIRECTOR, UNITED STATES PATENT
AND TRADEMARK OFFICE,
Respondent.

*On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Federal Circuit*

**Amicus Brief of Independent Inventors, Healthcare
Professionals and Paul Gilbert Cole In Support of
Petitioner Urvashi Bhagat**

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In the Supreme Court of the United States

Urvashi Bhagat, *Petitioner*, v. Andrei Iancu, *Respondent*.

Motion to File Amicus Brief Out of Time

Counsel for Amici states the following:

Respondent Iancu, through the U. S. Department of Justice, provided notice to Counsel at 3:39PM on **October 3, 2018**, that Respondent would not oppose entry of the Amicus Brief at issue. Because of the timing, Counsel was forced to revise and re-print the Amicus Brief to reflect Respondent's permission. Despite Counsel's best efforts, Counsel was unable to physically deliver, or cause to be delivered, the required paper copies by midnight of October 4, 2018.

The required paper copies were delivered about 3:00PM on October 5, 2016, which is less than 48 hours after Respondent gave notice of their permission.

Further, Counsel states that it was his understanding under the Supreme Court's Rules that the paper copies could be timely filed three calendar days after electronic filing. Counsel apologizes for this misunderstanding.

Counsel further asserts that no prejudice was caused by the one-day delay in delivering the required paper copies.

WHEREFORE Counsel respectfully requests that this Court grant Amici permission to file their brief out of time.

Burman York Mathis, Esq.
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Questions before This Court

This case raises fundamental issues concerning patent eligibility under 35 U. S. C. § 101, including:

Is the standard of patentability expressed under *Funk Brothers*¹ moot or inapplicable in light of the 1952 Patent Act and the Supreme Court's decision of *Bilski v. Kappos*?² More specifically, does a "process" under § 101 require a "transformation," and is the standard of "invention" used in *Funk Brothers*' holding applicable to patent eligibility under 35 U. S. C. § 101?

Also, did the Patent Trial and Appeal Board (PTAB) and Federal Circuit err by not construing the language of § 101 according to its ordinary, contemporary and common meaning?

In addition, *Amici Curiae* ask an additional question of this Court:

Did the PTAB and Federal Circuit err by not considering the claims as a whole in both its § 101 and § 102 rejections.

¹ *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)

² *Bilski v. Kappos*, 561 U.S. 593 (2010)

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I. Identity and Interests of Amici Curiae

The Amici Curiae comprise U.S. Inventors, which is a nationally-recognized inventor association, joined by individual inventors, healthcare professionals specializing in the science of nutrition and businessmen. Amici Curiae include thousands of members. On behalf of all members, Amici Curiae promote policies that foster innovation, growth and a competitive marketplace for innovation. Amici Curiae members have a strong stake in the proper functioning of a predictable U.S. patent system. Amici Curiae's members also have a particularly strong interest in the development of appropriate standards for evaluating patent-eligibility under 35 U.S.C. § 101.

Paul Gilbert Cole is a practicing UK and European patent attorney, is a council member of the Chartered Institute of Patent Attorneys (CIPA), is a visiting professor in IP Law at Bournemouth University in the UK, and has been writing about and teaching patent law for some 40 years. Mr. Cole is concerned with the integrity of the legal system and the correctness of the consequential guidance that is given to patent examiners in the USPTO. It is his professional opinion that this Court should grant certiorari because the decision below does not conform with 35 U. S. C. § 101 or equivalent international standards of patent-eligibility.

Accordingly, Amici Curiae respectfully urge the Court to grant leave to file the present Brief, to grant Urvashi Bhagat's Petition and to reverse the decision below. Amici Curiae have no stake in the parties or in the outcome of the case beyond the deleterious effects of the instant Decision.³

³ No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or

The names and affiliations of the Amici Curiae are set forth in the Appendix.

II. Reasons to Grant Certiorari

A. The Federal Circuit's Holding Violates Supreme Court Precedent Established in *Bilski v. Kappos* and *Diamond v. Diehr*.

The Supreme Court's decision in *Bilski v. Kappos*, 561 U.S. 593 (2010) set forth a number of important legal principles that the United States Patent and Trademark Office (USPTO) and the Federal Circuit have ignored for the last eight years. The first principle is the abrogation of the machine-or-transformation test as the sole test for patent eligibility under § 101. The second principle, related to the first, is this Court's recognition that there was no definition of the word "process" that requires a machine or transformation for patent eligibility under § 101. Yet it is the position of the USPTO and the Federal Circuit that some "transformation" is necessary for a process under § 101.

A correct holding reversing the decision below does not require a reversal of *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). A reversal merely

submitting the brief. No person other than the *Amici Curiae* or its counsel made a monetary contribution to its preparation or submission.

Amici Curiae provided notice to Petitioner Bhagat on September 21, 2018, of intent to file on behalf of Petitioner Bhagat, which is at least 10 days prior to the October 4, 2018, filing deadline as required under rule 37(2)(a). Amici Curiae also initially provided notice to Respondent on September 21st and again on September 22nd. Both Petitioner and Respondent have provided their consent.

requires recognition that the 1952 Patent Act substantively changed the statutory standard of patent-eligibility, and that proper claim construction principles discussed in *Bilski* render the holding of *Funk Brothers* moot or inapplicable. That is, there is no issue of *stare decisis* with regard to *Funk Brothers*. There is no decision or underlying principle for the Supreme Court to stand by because Congress, using its authority under Article I, Section 8, of the Constitution, changed the standard of patent-eligibility nearly seventy years ago.

In view of the change of statutory law since *Funk Brothers* was decided, it is the Amici's position that the decision below embodies an erroneous categorical rule that treats Petitioner's claims as falling outside the scope of § 101 by ignoring the ordinary, contemporary and common meaning of the statutory wording in 35 U. S. C. § 100 and 35 U. S. C. § 101.

Another reason to reverse the decision below is because, despite the rule set forth in *Diamond v. Diehr*⁴ and repeated in *Alice Corp.*,⁵ neither the USPTO nor Federal Circuit are yet convinced that claims under § 101 must be analyzed *as a whole*.

B. The Federal Circuit's Holding Is Detrimental to the Science of Nutrition

This case is an analog to *Bilski*. While *Bilski* addressed the patentability of business methods, this case addresses the patentability of nutrition science. However, unlike *Bilski*, which was directed to an extremely old process, *Bhagat* is directed to a new, specifically-tailored innovation to nutrition.

⁴ *Diamond v. Diehr*, 450 U.S. 175 (1981)

⁵ *Alice Corp. PTY, Ltd v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014)

The Federal Circuit does not apparently consider the science of nutrition important enough to warrant patentability consistent with the statutory language of § 101. Instead, the Federal Circuit has added an additional burden of some vague idea of “transformation” not found in the Patent Law and expressly disclaimed as a requirement to patentability in *Bilski*.

Innovation should be liberally encouraged in the science of nutrition as nutrition addresses a wide variety of preventable chronic diseases costing this country hundreds of billions of dollars every year.

While the science of lipids has barely been scratched, there are established studies indicating that inappropriate amounts/ratios of omega-6 and omega-3 oils in Western diets cause increased risks of cancer, cardiovascular disease, and inflammatory and autoimmune diseases. See, e.g., Simopoulos, Artemis, *The Importance of the Ratio of Omega-6/Omega-3 Essential Fatty Acids*, 56 *Biomedicine & Pharmacotherapy* 365-79 (2002). See also, William Harris et al., *Omega-6 Fatty Acids and Risk for Cardiovascular Disease*, 119 *Journal of the American Heart Association* 902-907 (2009).

Accordingly, the science of nutrition promises potential benefits for individual well-being, public well-being and national economics.

However, despite the known and unknown benefits of nutrition science, the Federal Circuit takes an unreasonable position that, without some nebulous standard of transformation, a new, useful and non-preemptive invention/discovery related to nutrition is not patent-eligible. By insisting on applying the machine-or-transformation test, the Federal Circuit created yet another categorical rule that “frustrate[s] the purposes of the patent law.” *Bilski*, 561 U. S. at. 605 (citing *Chakrabarty*).

C. The Federal Circuit's Inability to Follow Supreme Court Precedent Is Detrimental to Innovation

The effects of the Federal Circuit's decision upon innovation are perilous. *Funk Brothers* may have been correctly decided under the patentability standards of 1948 when patent eligibility was determined by 35 U. S. C. § 31. However, today *Funk Brothers* is a relic that must be cast off. Decisions such as *Funk Brothers* were the impetus of the 1952 Patent Act, which was passed to rid the country of the stifling effects *Funk Brothers* and other such cases had on innovation.

By reverting to pre-1952 standards of patent eligibility while ignoring Supreme Court precedent, the Federal Circuit's jurisprudence threatens the stability and reliability of the patent system.

There is a quote found in the preface of *Nonobviousness – the Ultimate Condition of Patentability* (page v), a book that discusses patent-eligibility under § 101 as much as obviousness under § 103, that is particularly relevant.

“[I]nventors and businessmen will be interested in the patent system only so long as they can reasonably understand the patent laws and rely on their stability. Indeed, when the government grant of a patent cannot reasonably be relied upon throughout the nation, then the patent system becomes a cruel hoax. An increase in trade secrecy and a decrease in innovation would be the result.

The prevention of such a result has seldom been more important. There is no doubt that we must now encourage innovation. The reliability of patents has an important role to play in achieving that result. . . . While a reliable patent system

is not the whole answer, it is, nevertheless, a vitally important part of the answer.” – Donald W. Banner, Commissioner of Patents and Trademarks (March 1979)

Since the *Bilski* decision, the U. S. patent system has dropped to No. 12 in patent protection and “joins a handful of other countries that are not thought of as being particularly intellectual property friendly.”⁶ The United States Chamber of Commerce’s Global Innovation Policy Center reports that the U. S. presently “faces a growing level of uncertainty for innovators, particularly in relation to patent protection.”⁷ The Federal Circuit now uses the vague idea of “invention” to justify conclusory statements having no basis in preemption or the statutory language of § 101. See, e.g., *In re Villena*, Appeal No. 17-2069 (Fed. Cir. 2018). The Federal Circuit also advocates trade secrecy over patent protection. *SAP America v. Investpic*, 890 F.3d 1016, 1024 (Fed. Cir. 2018).

Innovation is waning, and even the head of the USPTO recognizes that the patent system is unstable.⁸

Amici assert that these detrimental effects are not caused by the lower courts following Supreme Court precedent. To the contrary, as will be discussed below, these detrimental effects are caused by the lower courts failing to follow statutory law, standard claim construction practices and this Court’s precedent.

⁶ <https://www.ipwatchdog.com/2018/02/08/u-s-patent-system-falls-12th-place-chamber-global-ip-index-2018/id=93494/>

⁷ http://www.theglobalipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_2018.pdf at p. 157

⁸ <https://www.law360.com/articles/1032230/uspto-head-calls-for-new-path-to-restore-patent-stability>

D. Other Issues

Regarding the anticipation rejection, *which does not extend to every claim*, it is of critical importance that this Court correct the Federal Circuit's violation of Petitioner's due process rights under § 706 of the Administrative Procedure Act (APA) that Congress mandated, and address the claims as a whole in its anticipation rejection as well as its patent-eligibility rejection. Because addressing the "claims as a whole" requirement under § 101 fully addresses the anticipation rejection, little additional effort is required to address the anticipation rejection.

III. Argument

E. Applicable Law

1. *The Legislature, Not the Courts, Determines the Scope of Patent Eligibility*

Article I, Section 8, of the United States Constitution states "*Congress* shall have power . . . to promote the progress of science and useful arts" (emphasis added).

To this end, *Congress* enacted several different acts over time including the 1952 Patent Act.

Arguably, the two most significant changes of the 1952 Patent Act were: (1) to codify the holding of *Hotchkiss v. Greenwood*, 11 How. 250 (1850), so as to define patentability (not "invention") in terms of nonobviousness under 35 U. S. C. § 103; and (2) to replace the word "act" under then 35 U. S. C. § 31 with "process" under § 101 while defining the word "process" in § 100.

Section 101 states: "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 . . . ” (emphasis added). Relevant to the word “process,” Congress defined the word in § 100 (b) as follows: “The term ‘process’ means process, art or method[.]”

While it is fully within the courts’ powers to identify exceptions under § 101, it is not within the courts’ powers to *de facto* rewrite a single word of the statutory patent laws, or to replace congressional intent with biases that the courts feel better suited to patent law. That is, *it is not within the constitutional powers of the courts to place a single additional burden on patentability that Congress did not sanction in its statutes.*

While courts may interpret particular words in view of congressional intent, the Supreme Court repeatedly declared that “[u]nless otherwise defined, ‘words will be interpreted as taking their ordinary, contemporary, common meaning.’” *Bilski v. Kappos*, 561 U.S. at 603. “Our task . . . is the narrow one of determining what Congress meant by the words it used in the statute; once that is done, our powers are exhausted.” *Diamond v. Chakrabaty*, 447 U.S. 303, 318 (1980).

2. The Federal Circuit’s Decision Must Comply with the Statutory Requirements of the Administrative Procedure Act

Proceedings of the Board are governed by the APA, Title 5, §§ 551 et seq. *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998). Section 706 of the APA recites:

“To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, *interpret constitutional and statutory provisions*, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

...

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) *arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law*” (emphasis added).

The Supreme Court’s decision in *Dickenson v. Zurko*, 527 U. S. 150 (1999) stressed “the importance of not simply rubber-stamping agency fact-finding.” *Id* at 162. “The APA requires meaningful review[.]” *Id*.

Under the APA, the Board is obligated not only to come to a sound decision, but to fully and particularly set out the bases upon which it reached that decision. *Sang-Su Lee*, 277 F.3d at 1342. The USPTO “must set forth its findings and the grounds thereof, as supported by the agency record[.]” *Id*. “Judicial review of a Board denying an application for patent is thus founded on the obligation of the agency to make the necessary findings and provide an administrative record showing the evidence on which the findings are based[.]” *Id*. Factual inquiries “must be based on objective evidence of record.” *Id*. at 1343. “[R]eview of an administrative decision must be made on the grounds relied on by the agency.” *Id*. at 1345. “If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers.” *Id*. at 1345-46.

Petitioner Bhagat has every right to expect the USPTO and Federal Circuit to follow statute and established case law. It is a basic principle of fairness and due process that the government must follow the government’s own rules.

F. The USPTO Failed to Address the Claims as a Whole Both under § 101 and § 102

The *Diamond v. Diehr* decision held that, in determining patent eligibility, “claims must be considered as a whole” *Diehr*, 450 U.S. at 188. *Mayo v. Prometheus* later clarified that, not only must claims be considered as a whole, but that all claim limitations must be considered individually and “as an ordered combination.” *Mayo*, 132 S. Ct. at 1298. *Alice Corp.* repeated this rule. *Alice*, 134 S. Ct. at 2350, 2351, 2355 and 2359.

When addressing claims as a whole, words cannot be simply written out of a claim. “[T]he words of a claim are generally given their ordinary and customary meaning [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AHW*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321. (internal quotation marks omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

Turning to the instant decision, the PTAB and Federal Circuit both failed to address all claims limitations individually and as a whole, ordered combination. Exemplary claim 65 is reproduced below:

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4: 1 or greater,

contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein *at least one casing comprises an intermixture of lipids from different sources*, and wherein

(1) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.

The PTAB expressly stated that it gave the limitation "*at least one casing comprises an intermixture of lipids from different sources*" zero weight because the word "casing" was not defined in the specification. Appx 5a-6a. While Petitioner's specification does state that "the compositions comprising the lipid formulation disclosed herein may be administered to an individual by any orally accepted form" (see Appx 6a), this at most means that the word "casing" can be broadly construed, *not completely ignored*.

The PTAB does not assert that the prior art or any natural phenomenon satisfies the limitation of *a single casing comprising an intermixture of lipids from different sources* – even under the broadest reasonable interpretation standard.

That is, rather than applying the "widely accepted" and "commonly understood" meaning of the word "casing," or even an unreasonably broad construction of the word, the PTAB and Federal Circuit wrote the word out of the claim entirely. This is inappropriate under § 101 and inappropriate under § 102.

For this reason alone, § 706 of the APA mandates that the PTAB's § 101 and § 102 rejections must be set aside.

IV. The Petitioner's Alleged "Product-by-Process" Claims Include a Process under § 101

A. There Are Two Types of Patent Eligibility Analysis under § 101

Assuming that an invention is new and useful, there is a distinct difference in patent eligibility analyses under § 101 that is often overlooked.

The first type of analysis is whether something is patent-eligible under § 101 by virtue of the definitions recited in § 100. An example of such an analysis is found in *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007) (holding that an electromagnetic carrier *per se* is not a process, machine, manufacture or composition of matter as defined by § 100). *In re Nuijten* reflects an example of a man-made invention that, as a categorical rule (not categorical exception), falls outside § 101.

The second type of analysis, which was addressed in *Alice Corp.*, is a determination of whether a claim constitutes an *exception* to § 101 by preempting a law of nature, natural phenomena or an "abstract idea." *Alice Corp.* commands courts to construe the abstract idea narrowly noting that the non-abstract "[poses] no comparable risk of pre-emption[.]" *Alice Corp.*, 573 S. Ct. at 2355.

The Federal Circuit's holding in the present case is not based on preemption, but instead is based upon the idea that, under a product-by-process construction (see Appx 29a), Petitioner's claims do not include a "process" under § 101.

B. The Claims Constitute a Process under § 101

Amici are aware that the USPTO and Federal Circuit agree that the present claims are directed to a product-by-process. Amici disagree with this product-by-process construction as does the Petitioner. However, even assuming that the present claims possibly may be construed as a product-by-process, the Federal Circuit's holding is still erroneous as Petitioner's claims would include a process under § 101.

As stated above, one of the major changes to the patent laws in the 1952 Patent Act was to replace the word "act" under then 35 U. S. C. § 31 with "process" under § 101 while defining the word "process" in § 100. As is also stated above, "[u]nless otherwise defined, 'words will be interpreted as taking their ordinary, contemporary, common meaning.'" *Bilski v. Kappos*, 561 U.S. 593, 603 (2010).

As was further recognized by the *Bilski* decision, there is no known meaning "of the definitional terms 'process, art or method' that would require these terms to be tied to a machine or to transform an article." *Id.*

Turning to the idea of the ordinary, contemporary and common meaning of the word "process" as related to patent law, *Black's Law Dictionary* (6th Ed. 1990) at p. 1205 defines "process" to mean: (1) an "art or method by which any particular result is produced;" (2) a "means or method employed to produce a certain result or effect;" and (3) "a definite combination of new or old elements, ingredients, operations, ways, or means to produce a new, improved or old result[.]"

Clearly, "a definite combination of new or old elements, ingredients, operations, ways, or means to produce a new, improved or old result" describes Petitioner's claims when

treated under a product-by-process construction. Appx. 5a-6a. A categorical rule differentiating Petitioner's claims from other forms of processes is improper. Such "categorical rule[s] denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.'" *Bilski*, 561 U. S. at. 605 (citing *Chakrabarty*).

C. *Bilski* Holds That § 101 Does Not Require a Transformation, and Thus Funk Brothers Is Moot or at Least Inapplicable

As is stated by the Federal Circuit (Appx 12a, 14a):

"The Board held that admixture with other natural products of known composition was *not shown or stated to change the nature of the compositions*, citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) ('The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. . . . They serve the ends nature originally provided and act quite independently of any effort of the patentee.')

The Board found, and we agree, that the Applicant has not shown that the claimed mixtures are a '*transformation*' of the natural products, or that the claimed mixtures have properties not possessed by these products in nature" (emphasis added).

However, as stated above there is no known meaning “of the definitional terms ‘process, art or method’ that would require these terms to . . . transform an article.” *Bilski*, 561 U. S. at 603.

Thus, *Funk Brothers* is inapplicable due to the statutory changes of the 1952 Patent Act in light of the claim construction principles discussed in *Bilski*.

V. The *Funk Brothers* Holding Relied on “Invention,” Which Congress Wrote Out of the Patent Law in 1952.

The 1952 Patent Act was enacted in response to the Supreme Court’s anti-patent sentiment in the early 1900s. This anti-patent sentiment was reported by Karl Lutz (*The New 1952 Patent Statute*, 35: 3 Journal of the Patent Office Society, 155, 156-7 (1953)), who stated the 1952 Patent Act was enacted to remove “the recent apostasy” of the Supreme Court “from the benevolent policy of the Constitution.” Indeed, the “apostasy” pre-1952 was so harsh that Justice Jackson criticized the Supreme Court’s “strong passion” for striking patents down “so that the only patent that is valid is one which this Court has not been able to get its hands on.” *Jungersen v. Ostby & Barton Co.*, 335 U. S. 560, 572 (1949).

The *Funk Brothers* decision was decided at the height of the pre-1952 “apostasy,” and its use of the word “invention” was offensive to Congress.

Indeed, the *Funk Brothers* decision holds that “a product must be more than new and useful to be patented; it must also satisfy the requirements of *invention*” (emphasis added). *Funk Bros.*, 333 U. S. at 131. “[W]e think that aggregation of species *fell short of invention*

within the meaning of the patent statutes" (emphasis added) *Id.*

However, the term "invention" is meaningless. "Invention" lacks clarity. So much clarity that the Supreme Court admitted that "the word cannot be defined in such manner as to afford any substantial aid[.]" *McClain v. Ortmyer*, 141 U. S. 419, 427 (1891).

So much clarity that Congress and vast numbers of prominent attorneys and legal organizations conspired to rid the country of the word by codifying the 1952 Patent Act. See "*Efforts to Establish a Statutory Standard of Invention: Study of the Subcommittee of Patents, Trademarks, and Copyrights of the Committee on the Judiciary*" United States Senate; Eighty-fifth Congress, First Session Pursuant to Senate Resolution 55, Study No. 7 (published 1958) (hereinafter "the 1958 Study").

As stated on page 2 of the 1958 Study, Charles Kettering, who headed the National Patent Planning Commission, remarked that "[o]ne of the greatest technical weaknesses of the patent system . . . is the lack of a definitive yardstick as to what is invention."

On page 4 of the 1958 Study, the legendary Giles Rich remarked about the difficulty of overcoming the idea of invention concluding "[s]o long as invention is there they can say it isn't good enough to be an invention." Judge Rich's words are especially relevant today. Assuming that something is new, useful, falls within the subject matter of § 101 and doesn't preempt an abstract idea, what standard constitutes "good enough to be an invention?"

As Judge Rich further noted in *The Principles of Patentability* (17:2 Journal of the Patent Office Society, 75, 87-8 (1960)):

"It has generally been stated to be the law that, in addition to being new and useful, an invention, to be patentable, must involve 'invention.' . . . Experienced patent lawyers, the Patent Office, and the courts understand 'What it means, only they never agree.'

[There are] various meaningless phrases which have been used to express this essential mystery--something akin to a religious belief[.]

In the final analysis . . . [the] requirement for 'invention' was the plaything of the judges who, as they became initiated into its mysteries, delighted to devise and expound their own ideas of what it meant, some very lovely prose resulting" (internal citations omitted).

Judge Rich's biting commentary on the word "invention" is the reason "invention" was removed as a prerequisite to patentability in favor of nonobviousness.

Judge Rich, who was one of the primary drafters of the 1952 Patent Act, went on to say:

"The Patent Act of 1952 expresses this [Section 103] prerequisite to patentability without actual reference to "invention" as a legal requirement. Nowhere in the entire act is there any reference to a requirement of "invention" and the drafters did this deliberately in an effort to free the law and lawyers from bondage to that old and meaningless term. The word "invention" is used only to refer to the thing invented. That is why the requirement of

“invention” should be referred to, if at all, only with respect to that which is dead.” *Id.* at 89.

See also, Rich, Giles, *The Vague Concept of “Invention” as Replaced by Section 103 of the 1952 Patent Act*, 46:12 Journal of the Patent Office Society, 855 (1964)).

The PTAB’s and Federal Circuit’s presumptive use of “transformation” and “invention” against Petitioner is not just an act of hubris, but a violation of statutory law, legislative intent and this Court’s direction set out in *Bilski*.

VI. The Standard of “Transformation” Is Offensive to the Statutory Standard Created by Congress

As stated above, 35 U. S. C. § 101 recites: “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 . . .” (emphasis added).

Noticeably missing from § 101 is the word “transformation” listed as a precondition to “obtain a patent therefor.”

In addition, noticeably missing from the PTAB’s and Federal Circuit’s laments about Petitioner’s claims is any discussion as to what standard of “transformation” is sufficient for patent-eligibility.

What is a sufficient “transformation?”

Take, for example, the world-changing invention of gunpowder, which is naught but a mixture of three naturally-found substances: charcoal, sulfur and potassium nitrate mixed in specific proportions. Each of these three

naturally-occurring components is not chemically changed when gunpowder is made. There is no "transformation" of naturally-occurring things as the Federal Circuit demands in order for a mixture to be patent eligible.

Assuming that gunpowder were invented today, would any justice on this Court deem the world-shaping invention of gunpowder as not patent-eligible under § 101 for lack of "transformation?"

Further, is carbon dissolved in iron sufficiently "transforming" of iron according to the Federal Circuit even though no chemical change is made?

Carbon aside, pure iron takes a variety of naturally-occurring allotropes. One naturally-occurring allotrope of iron (α) is ferromagnetic while another naturally-occurring allotrope of iron (β) is not.

Certainly, turning ferromagnetic α -iron into non-ferromagnetic β -iron sounds like a sufficient "transformation," but would most jurists consider turning α -iron into melted iron a sufficient transformation?

Note that turning α -iron into β -iron requires only heating α -iron to the point where thermal agitation of iron atoms exceeds the oriented magnetic moment of unpaired electron spins. Heat the iron more and you have melted iron.

As with "invention," there is no standard of "transformation," and "transformation" isn't a requirement of patentability under § 101 anyway.

While there may be no "transformation" in the present claims that satisfies the USPTO's sensibilities, without doubt the presently claimed formulation qualifies as a "composition of matter" under § 101. The present claims recite a man-made mixture of different chemical entities from different sources in a defined proportion, and thus

clearly falls within the ordinary, contemporary and common meaning of a "composition of matter" under § 101.

Such a finding does not depend on the casing feature but is inherent and sufficiently defined by the mixture of substances alone. Substantive qualification, as opposed to mere appearance, is reinforced by the effects produced by fatty acids upon the human body as is discussed within the bounds of the present patent application as well as discussed in independent research including, but not limited to, the omega-3 / omega-6 articles cited above.

Further, if one does not merely ignore the "casing" limitation as did the PTAB and Federal Circuit, the claims also fall within the definition of a "manufacture" according to the ordinary, contemporary and common meaning of "manufacture" as is found in § 101.

Thus, it is most disturbing that the Federal Circuit abrogated both the "composition of matter" and "manufacture" language actually found in 35 U. S. C. § 101 in favor of a vague concept having no basis in § 101.

"Transformation" is an *ultra vires* creation of the Federal Circuit having no basis in the statutory framework Congress created in the Patent Law. This amounts to the Federal Circuit *de facto* re-writing the Patent Law (to omit two categories and add one of their own to § 101), which offends the doctrine of separation of powers.

VII. Conclusion

The claims clearly fall within the statutory framework of § 101, and a decision to the contrary sets precedent dangerous to the stability and reliability of the patent system. Further, read as a whole, Petitioner's claims are not anticipated. Accordingly, the Decision below should be reversed as well-settled principles of law.

Respectfully submitted,

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App. 1

APPENDIX

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