SUPPLEMENTAL WRITTEN TESTIMONY OF

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IN RESPONSE TO

QUESTIONS FROM SENATOR BLUMENTHAL

COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

ON

"THE STATE OF PATENT ELIGIBILITY IN AMERICA, PART I"

JULY 26, 2019

Questions for the Record for Ms. Sherry M. Knowles, Esq.
Senate Committee on the Judiciary
Subcommittee on Intellectual Property
Hearing on "The State of Patent Eligibility in America: Part I"
June 4, 2019

QUESTIONS FROM SENATOR BLUMENTHAL

1. Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system.

   a. What impact will broadening the subject matter that can be patented have on industry?

   b. What impact will broadening the subject matter that can be patented have on consumers?

   c. Could the proposed reforms increase consumer prices? If so, in what industries or on what products?

Introductory Comments

This written testimony supplements the written testimony I submitted to the Senate Judiciary Committee, Subcommittee on Intellectual Property, on June 3rd, 2019, as well as my oral testimony to the Subcommittee on June 4th, 2019.

I would like to thank Senator Blumenthal for providing these follow-up questions that focus on the balance between motivating innovation and protecting consumers. My area of expertise is the pharmaceutical and biotechnology industries, and thus I will answer Senator Blumenthal's questions as applied to the drug industry.

Senator Blumenthal has been very active in his goal to reduce drug prices. His questions at their core pertain to the relationship between patents and consumer prices. At the end of my comments, I will provide a few brief thoughts on this, although this is not the main subject of the patent eligibility discussion at hand, but I know of interest to Senator Blumenthal.

With immense respect, I would like to first kindly challenge two of the implicit assumptions in the questions presented.

"Striking the appropriate balance between encouraging innovation and protecting consumers is a key goal of our patent system"

The goal of the patent system is solely to motivate innovation which is new and non-obvious over what currently exists as prior art. The patent system is unrelated to consumer protection. Our patent system has worked very well since the country's founding to produce the leading nation in the world in innovation, which has dominated its competition.

Not only is the patent system unrelated to consumer protection, it should not be applied in a manner that overtly disadvantages, or discriminates between, one industry over another. This would likely be a violation of the United States' obligation as a signatory in 1994 of the Trade Related Aspects of Intellectual Property ("TRIPS") of the World Trade Organization ("WTO") as part of the Uruguay Round of the General Agreement on Tariffs and Trade ("GATT").

According to Section 5, Article 27.1 of the TRIPS Agreement, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial design." This is sometimes referred to as the "anti-discrimination" clause of TRIPS.

Article 27.3 allows members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans. Article 27.3 does not exclude improvements to drugs themselves, which are new compositions of matter, formulations or drug combinations. No developed country in the world relies on the Article 27.3 exception to limit patent rights in the pharmaceutical sector, including Europe, China, Russia, Japan, South Korea, Canada, Australia, Israel, and others. The United States would fall behind in its ability to compete if it does so.

India is an example of a country that relies on the exception via the controversial Section 3(d) of the Indian Patents Act of 1970 (as amended). The Indian law excludes from patent eligible subject matter new forms of a known substance that do not increase efficacy, all methods of treatment and other aspects of pharmaceutical improvement innovations. Many are convinced that the Indian Section 3(d) law violates TRIPS. The Indian Supreme Court specifically referred to the fact that Section 3(d) is interpreted to reduce drug prices (See, *Novartis v. Union of India and Others* (Supreme Court of India, Civil Appellate Jurisdiction, Civil Appeal Nos. 2706-2716 of 2013; April 1, 2013).

If Congress uses patent law to restrict protection on selected pharmaceutical innovations as a means to control drug pricing, it will be aligning our country with India instead of the developed world.

"Broadening the subject matter that can be patented"

The questions presented refer to the effect of "*broadening*" the subject matter that can be patented. With kindness, the current issue faced by the Subcommittee on Intellectual Property is not whether to *broaden* the scope of Section 101. It is whether to *restore* the application of patent eligibility to what it always has been historically, as repeatedly codified by Congress starting with the Patent Act of 1790. The Supreme Court has veered off of the literal text of the statute and taken it upon itself to create common law to rewrite Section 101 by ignoring words and creating judicial exceptions, contrary to Art. I, Sec. 1, Cl. 8 of the U.S. Constitution.[1]

I co-authored an article that was published in January 2019 which tracks the legislative history of patent eligibility from the first Patent Act in 1790 through the America Invents Act of 2011, and compares it to the parallel but inconsistent development of case law on patent eligibility by the U.S. Supreme Court. See, Sherry Knowles and Anthony Prosser, Unconstitutional Application of 35 U.S.C. §101 by the U.S. Supreme Court, 18 J. Marshall Rev. Intell. Prop. L. 144 (2018). This extensive legal research establishes that the Supreme Court has *narrowed* the scope of patent eligibility without statutory basis or constitutional authority. In just four months, this article has been downloaded by almost 700 unique IP addresses (not individuals), indicating an extraordinary interest in the judicial activism shown by the U.S. Supreme Court.

The issue at hand is therefore whether to *restore* patent eligible subject matter to the text of the current statute and historic scope that made our country excel among others, or whether to *restrict* it as done by the Supreme Court created common law without authorization from Congress or the Constitution.

[4]#Congress should be weary of the power currently exerted by the U.S. Supreme Court to ignore the actual text of statutes and create judicial exceptions as they feel fit, under its Court made doctrine of "Statutory Stare Decisis". Even if a Senator or Representative happens to agree with the creation and narrowing of patent eligibility law by the Supreme Court in this instance, the next time the Court may do the same thing to a statute that the Senator or Representative was a Co-Sponsor of, which would not be as well received. As a policy and to protect the exquisite balance of powers between Congress and the Judiciary, and the power of Congress generally, Congress should insist that the Supreme Court respect the literal words of its statutes. Congress can amend the statutes when necessary, but not allow them to be implicitly amended by the Courts without control by the legislative branch.

With indulgence from the Senator, I would like to rephrase the questions to refer to "restoring" instead of "broadening"

With that introduction, I turn to the questions presented.

a. What impact will restoring the subject matter that can be patented have on industry?

Restoring patent eligibility to its historic and statutory textual scope will motivate additional medical solutions to treat and diagnose cancer and other serious diseases, which translates to saving and extending lives. This may in turn translate to lower healthcare expenses due to a decrease in long hospital stays, repetitious procedures and extended end of life care. In particular, I refer Senator Blumenthal to Section VII of my Written Testimony submitted June 3, 2019 titled "Effect of Supreme Court's Development of Unconstitutional Case Law on Us Personally", pages 27-30, which provides a detailed response to this question.

I note there was extraordinary confusion over the holding and meaning of the Supreme Court decision in *AMP v. Myriad* (569 U.S. 576 (2013); "Myriad") during the three days of Subcommittee testimony, and thereafter in the press. I would like to detangle this and clarify both the decision and its ramifications.

Human genes and DNA in the body have NEVER been patent eligible in the history of the United States because they are not manmade and are not new. The *Myriad* decision did not address whether genes and DNA in the body are patent eligible because it is common ground that they are not and have never been.

Opponents of the 101 amendment refer to "human genes" or "genes" in an uninformed or careless manner without indicating whether they are talking about human genes in the body or isolated gene segments outside of the body. The distinction is critical, and confusion causes uninformed panic.

The *Myriad* decision SOLELY addressed whether isolated gene segments outside of the body are patent eligible. The actual holding of the *Myriad* decision is that "a naturally occurring DNA segment is not patentable merely because it has been isolated".

The Supreme Court *Myriad* holding is inconsistent with the Congress' Section 101 statute because isolated genetic material outside the body is due to human intervention and is thus manmade. The decision is based on the Court's judicial exceptions to the statute, not the language of the statute as passed by Congress.

This decision threw the baby out with the bathwater, because it was interpreted to hold that all isolated natural materials, whether from the human body, a bacteria, a plant or whatever, are not patent eligible subject matter. These materials have played an essential part in medicine as antibiotics, anticancer agents, and in personal diagnostics. The downstream effect of *Myriad* was devastating in all of these categories. As I said in my testimony on June 4, research on isolated natural materials to cure diseases including cancer has come to a dead stop in the U.S. I refer to pages 27-30 of my June 3rd, 2019 Written Testimony for supporting statistics.

As I stated in my written testimony June 3rd, 2019 (page 29), there are almost 270,000 women each year in the United States diagnosed with breast cancer and almost 42,000 women die each year from the disease. I am a breast cancer survivor whose life was saved by two isolated natural products that would not have been be patent eligible under the *Myriad* law. If *Myriad* had been the law in the United States years ago, I would not be giving testimony because I would have already died. It is critical that we restore the scope of patent eligibility to the pre-*Myriad* standard, to revive the full scope of research and development on personal diagnostics and isolated natural products that may hold the secrets to extending and saving lives.

Because of the human genome project, the human genome is now public. Therefore, there is diminishing ability, if at all, in researching or getting a patent on isolated non-disease based naturally occurring gene segments out of the body. The only isolated gene segments of remaining interest are those linked to diseases. Research should be properly motivated to find these links and develop diagnostics and products that can help us, our families, friends and co-workers.

b. What impact will restoring the subject matter that can be patented have on consumers?

In the pharmaceutical and biotechnology areas, consumers are patients.

The impact of restoring the subject matter that can be patented on patients is that new medical solutions may be invented that save or extend their lives. The highest public interest is life itself.

It is essential to disconnect motivation for creating new medical solutions from drug pricing and distribution. If the drug or diagnostic is not invented because there is no motivation to do so, the pricing and distribution problem goes away because the solution will not exist.

A great example is found in the *Myriad* case. The Supreme Court highlighted that certain universities and institutions were not able to provide BRAC1/BRAC2

testing because of the *Myriad* patent. However, there was NO evidence in the *Myriad* case that these universities or institutions (i) had independently collected or investigated the massive data necessary to discover the altered BRAC genes or their relationship to breast cancer or (ii) developed the diagnostic test and obtained FDA approval. In other words, these universities and institutions did not carry out the "extensive effort" to create the invention and product. There was no evidence that a breast cancer diagnostic based on the BRAC1/BRAC2 gene alterations would have ever been invented or developed unless *Myriad* did so with the expectation that its market would be protected. Women in the United States would have missed out on a diagnostic that has undoubtedly saved lives.

The *Myriad* Court made a fundamental error by skipping over the need to motivate the basic research to later market accessibility and pricing.

c. Could the proposed reforms increase consumer prices? If so, in what industries or on what products?

The proposed amendment to Section 101 addresses whether and how many new medical solutions will be created by inventors. It does not address pricing.

Brief Comments on Drug Pricing Pending Legislation

Senators Cornyn and Blumenthal have co-sponsored a bill that would use the Federal Trade Commission to surveil pharmaceutical companies and selectively reduce their patent terms under certain circumstances (Affordable Prescriptions for Patients Act of 2019). Senator Cornyn stated in a press release that "Using practices that would make the robber barons of the gilded age blush, Big Pharma has crushed competition and stifled access to cheaper generic drugs to squeeze billions out of families, businesses and the Government." Senator Blumenthal has said "Through common sense reforms, this bipartisan bill will empower the FTC to fight back against drug companies' most egregious and monopolistic practices. It represents an important step in reining in Big Pharma's greed and puts the industry on notice—enough is enough.

I would like to kindly provide thoughts on this. I have not been paid for, nor have I discussed, my testimony with any company, including a pharmaceutical company. These are my own views.

If Big Pharma has been making robber barons blush, one would think that their profits, and thus as a surrogate, their stock prices would be disproportionate

among other industries. Based on publicly available data and research, this is not the case.[2]

Comparison of Pharmaceutical and Technology Stock Performance and U.S. Patent Portfolio sizes

Using online research figures from Schwab.com, I compared the three-year performance of pharmaceutical company stock and technology stock. I then compared these numbers to how many granted U.S. patents and published pending U.S. patent applications these companies have (based on numbers from www.freepatentsonline.com)[3]. The results are shown in Tables 1 and 2 below.

Table 1: PHARMACEUTICAL COMPANIES		
NAME	3 YEAR STOCK PERFORMANCE	U.S. GRANTED AND PENDING APPLICATIONS
Abbvie	+19%	4,245
Merck	+29%	25,211
BMS	-21%	7,821
Pfizer	+10%	8,662
Sanofi	+5%	8,544
Astra Zeneca	+13%	5,016
GlaxoSmithKline	-1.30%	3522

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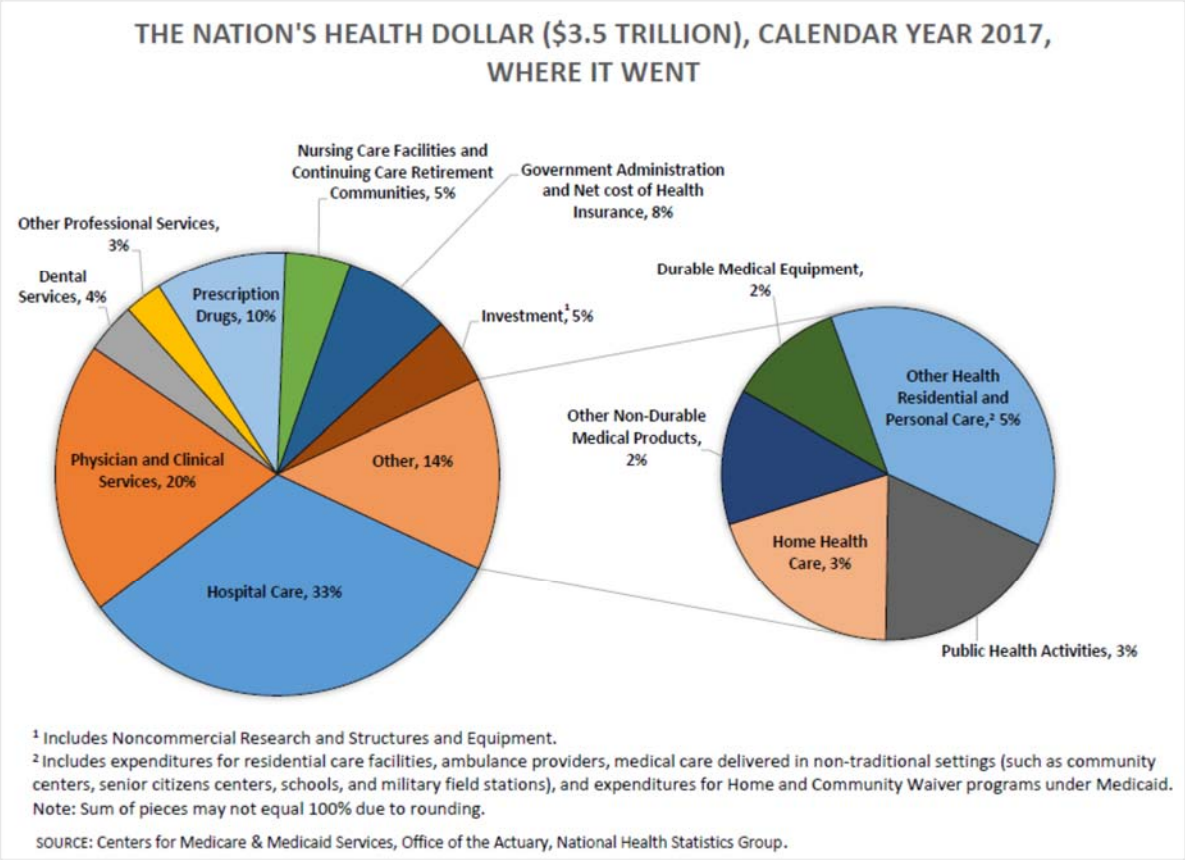
Table 2: TECHNOLOGY COMPANIES		
NAME	3 YEAR STOCK PERFORMANCE	U.S. GRANTED AND PENDING PATENTS
Google	+447%	55,890
Amazon	+173%	14,413
Facebook	+70%	11,875
Microsoft	+175%	93,891
Apple	+112%	47,773

Tables 1 and 2 indicate that over a three-year period, technology stocks have performed much better than pharmaceutical stocks. Further, these Tables indicate that in general, technology companies hold many more patents in their portfolios than pharmaceutical companies. The lower performance of pharmaceutical stocks does not support a huge profit margin as suggested, if stock price is used as a rough surrogate for profitability or stock purchaser confidence in future profitability.

The pending Cornyn Blumenthal bill specifically references pharmaceutical "patent thickets". However, Apple was granted 44 patents in one day (May 29, 2018) by the U.S. Patent Office. Further, Adcolony.com reported that "10 fast facts for the iPhone's 10th Anniversary" on January 10, 2017 by 2017, Apple had filed more than 200 patents on its iPhone technology. These are just among a few examples.

America's Healthcare Expenditure and Drug Costs

I attach an article by Steven Moore published in Healthcare, July 10, 2018, titled Where does $3.3 Trillion Go? (INV.us). The article provides a good discussion of the percentage of U.S. healthcare spend on prescription drugs, which it estimates at around only 10% of total costs. It also provides a good discussion of the money made by the insurance industry as a middle-man in drug costs.



How can the U.S. Reduce Drug Prices?

Instead of trying to use the patent system, which is designed solely to motivate innovation and protect investment, to reduce drug costs, I respectfully suggest that Congress look into the staggering cost of drug development and human clinical trials leading to drug licensing by the U.S. FDA. If it costs less or takes less time to get the product to market, the time to return on investment decreases and the price can decrease accordingly. The huge cost of drug development should be tackled head-on.

According to a 2016 report, the pre-tax capitalized cost per drug approval is 2.6 billion dollars (in 2013 dollars) (DiMasi, J.A., Grabowski, H.G., and Hansen, R.W., *Innovation in the pharmaceutical industry: New estimates of R&D costs*; Journal of Health Economics; Vol. 47, May 2016, pages 20-33). The authors reviewed the R&D costs of 106 new drugs from 10 biopharmaceutical companies. They found a 12% approval rate on drugs that start development. The costs of failed drug candidates were included. The pre-tax out-of-pocket cost per approval was

$1.395 billion. The authors also reported that the total capitalized cost increased at an annual rate of 8.5% above general inflation.

If it takes this much money (and an 88% risk of failure per drug development initiation) to get a drug to market (and usually 10-12 years of corporate time if a new chemical entity), that will undoubtedly be reflected in the cost.

The structure of the regulatory review process should be reevaluated to find ways to reduce the cost and time of drug development. The industry may not be able to meaningfully reduce the number of drug failures in clinical trials because these are not predictable. However, perhaps the structure of the final, large scale Phase III clinical trials can be adjusted in appropriate cases to be a Conditional Approval with strong FDA surveillance, and with some payment for the drug by the patients. This would get the drugs to the patients faster and would reduce the cost of drug development because the drug developer will begin to get recoupment of its investment at an earlier time.

America's Healthcare Expenditure – Where Does $3.3 Trillion Go?

by Steven Moore in Healthcare Jul 10, 2018

Getting an accurate count of how much Americans spend on healthcare every year and the specific items they purchase, like prescription drugs, is tricky.

Think about it like this. If you are a small business owner or anyone else who itemizes their expenses, you have tough calls to make.

For example, I use the mobile app Mint to track and sort my expenses. If I purchase internet access on a plane, does it go under "Business Services" or "Travel?" If I buy a bottle of wine for a

business acquaintance, does it go under “Alcohol and Bars” or “Gifts?”

Imagine doing this type of thing for all $3.3 trillion Americans spent on healthcare in 2016.

Three point three trillion dollars is the most commonly used estimate of healthcare spending in 2016. The National Health Expenditure Accounts are published annually by the Centers for Medicare & Medicaid Services (CMS), a division of the U.S. Department of Health and Human Services.

Story continues below

While I find it difficult to fully trust an organization which can’t even abbreviate its own name correctly, most people do trust CMS.

The summary of America's healthcare expenditure is called the National Health Expenditure (NHE). CMS publishes a chart showing the percentage of the $3.3 trillion that goes to hospital care (32%), dental services (4%), home health care (3%), prescription drugs (10%), physician and clinical services (20%) and several other categories.

Centers for Medicare & Medicaid Services 2016 National Healthcare Expenditure

CMS also publishes a seemingly unlimited number of spreadsheets to support their aggregate charts. I downloaded a zip file containing a spreadsheet that claimed to have historical data for healthcare spending since 1960.

With 544 lines and 58 rows of data, this claim seemed well-founded at first. Turns out not all categories are available for every year, but 2003 through 2016 is complete, and a fifteen year history is probably most helpful in examining the rate of change in healthcare spending. Hospital prices in 1960 is trivia. Hospital prices over the last 15 years are data.

Many other estimates of America's healthcare expenditure are derivative of the CMS number, and show different results of types of spending depending on how they are calculated.

Some are not based on the CMS findings. America's Health Insurance Plans (AHIP), the insurance industry's lobbying association, has an estimate that is largely based on commercial databases.

AHIP – Where Does Your Health Care Dollar Go?

Note some of the differences between the AHIP study and the CMS NHE report. Drug expenditures, according to AHIP, are 130% more than the government estimate. Hospital expenditures are half of the CMS report estimate. Physician and Clinical Services is 20% according the CMS. AHIP makes Doctor Services and Clinic Visits separate categories, and the two combine for 42.2% of the health spend.

Interestingly, AHIP claims health insurers get about 12 cents of America's healthcare dollar, while CMS gives insurers about 7% of the 2016 healthcare spend.

Why the extreme variances?

From a political perspective, it is worth thinking about AHIP's role as an advocate for health insurance companies, and who they compete with in the public policy arena when comparing the CMS numbers to AHIP's estimate. (SPOILER – health insurance companies are in constant legislative combat with doctors and drug manufacturers) Nobody wants to be seen by policy makers as taking too much of the pie, or having their prices rise at too fast a rate.

From a methodological perspective (which may also be political), AHIP's choices are odd. They surveyed 5 for-profit insurance companies and 25 not-for-profit insurance companies. Out of the top ten health insurers, accounting for 207,010,000 people, or 71% of the 292 million with health insurance in America, three are non-profit. Those three non-profits account for 31,000,000 insurance subscribers, or 15% of the top ten.

AHIP's methodology shows how they chose the 5 for-profit insurers and 25 not-for-profit insurers, but not why. Their sample uses about 17% for-profit companies, when more than 75% of Americans are insured by for-profit companies.

Similarly, AHIP uses only claims by patients under the age of 65. Also very odd since we know that the majority of healthcare spending comes at the end of life.

I found this with an hour's worth of Google searching. AHIP knows this. Their sampling is skewed to produce an outcome. Why would health insurers do this?

Likely because the CMS numbers show that over the last 15 years, the cost of health insurance has been one of the fastest growing costs in healthcare. Faster than pharmaceutical manufacturers and faster than physician services. The cost of Big Insurance is rising faster than their traditional legislative sparring partners, pharma and the docs. They don't want the attention.

National Healthcare Expenditure Price Increases by Category '03 through '16

Expenditure Category	Mean Annual Percent Increase	Difference From NHE Mean
Total National Health Expenditure (NHE)	5.00%	0.00
Hospital Care	5.51%	0.51
Physician and Clinical Services	4.65%	-0.35
Other Professional Services	5.24%	0.24
Dental Services	3.81%	-1.19
Other Health, Residential, and Personal Care	5.71%	0.71
Home Health Care	6.27%	1.27

Nursing Home & Retirement Facilities	3.68%	-1.32
Prescription Drugs	5.20%	0.20
Other Non-Durable Medical Products	4.02%	-0.98
Durable Medical Equipment	4.27%	-0.73
Government Administration	4.75%	-0.25
Net Cost of Health Insurance	6.24%	1.24
Government Public Health Activities	3.39%	-1.61
Research	2.91%	-2.09
Structures and Equipment	3.70%	-1.30

An IVN extrapolation based on CMS findings.

Another analysis of the pharmaceutical drug manufacturers receipts from the NHE comes from the Berkeley Research Group (BRG). Funded by the Pharmaceutical Research and Manufacturers Association (PhRMA), the drug manufacturer's lobby, the BRG study shows that prescription drug spending accounts for 14% of the NHE, compared the the CMS 10%.

While the BRG research shows a larger pharmaceutical piece of the healthcare pie, it also shows that the share actually going to pharmaceutical manufacturers is shrinking. The BRG study shows

that brand manufacturers realize about 47% of the money spent on pharmaceutical drugs.

Berkeley Research Group

SHARE OF 2015 NET DRUG EXPENDITURES REALIZED BY MANUFACTURER AND NON-MANUFACTURER STAKEHOLDERS

So we have a government study and two competing studies from industry associations displaying conflicting information. This is probably the time for me to share a battle-worn test I learned from more than a decade in DC. How do you know if a lobbyist is lying? Her lips are moving.

That being said, if the Berkeley Research Group is lying, they are doing a much better job of it than AHIP. While the AHIP study methodology has several points, noted above, that stick out as odd at first glance, the PhRMA study passes the smell test.

The non-manufacturer stakeholders referenced in the chart above have been coming under a lot of scrutiny. That $142.8 million (and maybe more) largely goes to pharmacy benefit managers (PBMs). PBMs are little-known entities that have come to virtually control retail pricing of prescription drugs. And that is all they do. They don't try to make pharmaceutical drugs better, they don't ship prescription drugs, they don't sell prescription drugs to consumers, they simply set the prices. And the top three players in the industry, all Fortune 25 companies, make about $300 billion annually doing so.

The PBMs are subsidiaries of a retail pharmacy, CVS, a pharmacy by mail, Express Scripts and the nation's largest insurance company UnitedHealth.

So how much of America's health care spend does Big Pharma realize? Depends on who you ask. Either 10% (CMS), 14% (PhRMA) or 23.3% (AHIP). And you can probably find more estimates. In fact, the links in this article all have the tools you need to research further and make your own decision. If you have a different analysis, send it my way. We'll likely publish it.

About the Author

Steven Moore

Steven Moore lived through the Obamacare debate as a chief of staff to a member of the House Ways and Means Committee and as a House leadership staffer. In addition to his work on Capitol Hill, he has professional experience in about a dozen countries. Moore also holds a graduate degree in international business.

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Introductory Comments

This written testimony supplements the written testimony I submitted to the Senate Judiciary Committee, Subcommittee on Intellectual Property, on June 3rd, 2019, as well as my oral testimony to the Subcommittee on June 4th, 2019.

I would like to thank Senator Hirono for providing these important follow-up questions. My area of expertise is the pharmaceutical and biotechnology industries, and thus I will answer Senator Hirono's questions as applied to the drug industry.

I am pleased to note that Senator Hirono is also a member of the Subcommittee on the Constitution of the Senate Judiciary Committee, which has as one of its responsibilities the assurance of the proper balance of powers between the three branches of government. I would like to draw Senator Hirono's attention to a law review article I co-authored which was published in January 2019 (Sherry Knowles and Anthony Prosser, Unconstitutional Application of 35 U.S.C. §101 by the U.S. Supreme Court, 18 J. Marshall Rev. Intell. Prop. L. 144 (2018)). For the Senator's convenience, I attach a copy for review. In just four months, this patent law review article has been downloaded by almost 700 unique IP addresses, which is unusual for such a publication. It emphasizes the deep concern Americans have for the overreaching conduct of the U.S. Supreme Court in the area of patent eligibility and how it is encroaching on the balance of powers between Congress and the Court, in apparent violation of the Constitution.

In the case of *Marbury v. Madison (*5 U.S. 137 (1803)), the U.S. Supreme Court held that it can review the constitutionality of federal statutes. However, who oversees the constitutionality of U.S. Supreme Court decisions? That must be the responsibility of Congress, and it should fall to the Subcommittee on the Constitution of the Senate Judiciary Committee.

I would welcome the opportunity to meet with Senator Hirono to discuss this article and the misalignment of the balance of powers between the Courts and Congress. This subject is central to Senator Hirono's responsibilities for both the Subcommittee on the Constitution and the Subcommittee on Intellectual Property.

I answer Senator Hirono's questions in bolded text below.

1. **Last year, Judge Alan Lourie and Judge Pauline Newman of the Federal Circuit issued a concurring opinion to the court's denial of *en banc* rehearing in *Berkheimer v. HP Inc.*, in which they stated that "the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems."**

   Do you agree with Judges Lourie and Newman? Does § 101 require a Congressional fix or should we let the courts continue to work things out?

Yes, I fully agree with Judge Lourie and Judge Newman. The Supreme Court has shown no interest in fixing this problem, and in fact it created the problem and is content to leave the status quo. This is confirmed by the fact that the Supreme Court has recently denied its 43rd petition for certiorari in the case of *Villena v. Iancu* (S. Ct. docket 18-1223). It is also of note that among the cases for which petitions for certiorari have been filed, two that were sent to the Solicitor General by the Supreme Court for an opinion both upheld patent eligibility (Vanda Pharmaceuticals, Inc. v. West-Ward Pharma; 887 F.3d 1117 (Fed. Cir. 2018); Berkheimer v. HP; 881 F.3d 1360 (Fed. Cir 2018)).

2. **The Federal Circuit rejected a "technological arts test" in its *en banc Bilski* opinion. It explained that "the terms 'technological arts' and 'technology' are both ambiguous and ever-changing." The draft legislation includes the requirement that an invention be in a "field of technology."**

   a. **Do you consider this a clear, understood term? If so, what does it mean for an invention to be in a "field of technology"?**

   b. **The European Union, China, and many other countries include some sort of "technology" requirement in their patent eligibility statutes. What can we learn from their experiences?**

   c. **Is a claim that describes a method for hedging against the financial risk of price fluctuations—like the one at issue in the *Bilski* case—in a "field of technology"? What if the claim requires performing the method on a computer?**

   d. **What changes to the draft, if any, do you recommend to make the "field of technology" requirement more clear?**

The term "in any field of technology" is not a clear, understood term in the United States because of its required interpretation through a series of U.S.

Supreme Court decisions that are utterly confusing and inconsistent. However, if these Supreme Court cases are abrogated, as provided for in the draft text of the amendment, then this term may be restored to its common sense and well-understood meaning.

The term "in any field of technology" is used in Section 5, Article 27.1 of the Trade Related Aspects of Intellectual Property ("TRIPS") of the World Trade Organization ("WTO"), which the United States is a signatory of. According to the TRIPS Agreement, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial design.

The term is also used in Article 52(1) of the European Patent Convention to define the scope of patent eligible subject matter ("European Patents shall be granted for any inventions, in all fields of technology, as long as they are new, involve an inventive step, and are capable of industrial application").

European practitioners and other signatories of TRIPS do not have a problem with the term "in all fields of technology." It is noncontroversial.

Why was it agreed language in TRIPS, and is functioning fine in Europe and other countries but not in the U.S.? The answer is that U.S. practitioners and lower courts are required to interpret "technology" according to the reasoning of the Supreme Court decisions in their line of incoherent cases on patent eligibility. European practitioners are not tethered to these illogical befuddling decisions, and thus are free to use the term in a sensible way in the normal course.

I refer Senator Hirono to a general discussion of these cases in our law review article referred to above. However, to highlight just one example of the problems, I compare the 1978 case of *Parker v. Flook* (437 U.S. 584) (where the Supreme Court ruled the innovation did not describe a patent eligible technology) to the 1981 case of *Diamond v. Diehr* (450 U.S. 175) (where the Supreme Court ruled the innovation did describe a patent eligible technology).

In *Parker v. Flook*, the inventor claimed an industrial process that uses an algorithm to modify a catalytic hydrocarbon cracking process. It was useful in the processing of petroleum distillate and to crack (break down) raw hydrocarbon material. The Patent Examiner acknowledged it was a useful method within the technological arts, but rejected the claims under Section 101 because of the use of the algorithm to control temperature. The Federal Circuit reversed, holding that the

claim was patent eligible because it covered an industrial process which employed an algorithm and a computer to control temperature variations to keep the process on track (as raw materials are not consistent, the temperature of reaction can vary) (559 F. 2d 21, 1977)). In other words, the inventors were not claiming a mathematical formula per se. The Supreme Court reversed, holding that "a method for updating alarm limits during catalytic conversion, in which the only novel feature is a mathematical formula, is not patent eligible under 101 of the Patent Act". Thus, the Supreme Court focused on the algorithm itself used in the computer instead of the fact that the invention was an improvement in an industrial chemical engineering process using equipment to create a chemical product, which is, according to any common sense definition "an area of technology". The Court also confused patent eligibility with the novelty requirement by focusing on a "novel feature" in the eligibility analysis, which is improper.

Just three years later, the Supreme Court decided *Diamond v. Diehr*. The invention involved a process for molding raw, uncured synthetic rubber into a cured product, using a feedback mechanism to control temperature and to determine the cure time. Just like in *Parker v Flook*, the *Diehr* process involved a chemical engineering set-up that reacted a raw material to form a final chemical product using a controlled feedback loop through a computer with repeated temperature measurements.

There was no significant difference in the processes of *Flook* and *Diehr*. They both engineered a raw product into a final product with a temperature feedback loop using industrial equipment. Yet the Supreme Court held that the *Flook* claim was not patent eligible and the *Diehr* claim was patent eligible. And the S. Ct consistently refers back to them to "teach" the courts and practitioners the difference, even though on close study there is none. We can't run a leading economy and take important business decisions based on these false distinctions.

There is one major difference between *Flook* and *Diehr*. The members of the Supreme Court changed. In *Flook*, Justice Stevens wrote the opinion for the majority, consisting of Brennan, White, Marshall, Blackmun and Powell, with a dissent from Stewart, Burger and Rehnquist. Three years later, in *Diehr*, Justice Rehnquist wrote the opinion with Burger, Stewart, White and Powell, and with a dissent from Justice Stevens, Brennan, Marshall and Blackmun. So simply having two Justices, White and Powell, change sides, made the difference. From then on, the American people had to be convinced that two similar industrial processes were fundamentally different, and that one does not constitutes "technology" and the second one does constitute "technology". It would have been understandable if *Diehr* had overruled *Flook*, but the Court did not do that. Instead, the Court simply

tried to distinguish *Flook* in a non-satisfactory way, leaving the patent eligibility of future commercial technology uncertain.

Another comparison of inconsistent Supreme Court decisions is the early case of *LeRoy v. Tatham* (55 v. 156 (1853)) and the case of *Funk Brothers Seed Co. v. Kalo Inoculant Co.* (333 U.S. 127 (1948)), which has caused immeasurable damage. I refer you to our law review article for a discussion.

These are examples of why the term "technology" doesn't work in the United States but works in other countries. U.S. Practitioners and courts are hopelessly and rightfully confused by these currently binding precedents.

The term "in any fields of technology" should remain in the draft text as long as the Supreme Court cases are abrogated, which would allow the U.S. to use the term in the same way it is used in Europe and under TRIPS. If the Supreme Court cases are not abrogated, then the term should be removed to separate the amended text from the unfortunate and confusing Supreme Court decisions, and it should be so stated in the amendment.

Once unshackled from the inconsistent Supreme Court decisions, the term technology would apply, as it does in Europe and other countries, to any innovation that has a tangible, physical component. The analysis would then smoothly proceed to a consideration of novelty, obviousness, enablement and written description.

In addition, it would be advisable to insert the word "applied" in front of "discoveries". To date, the U.S. has had to rely on legislative history to interpret that discoveries are limited to anything that is manmade. The draft language for 100(k) does refer to "through human intervention", however, it would further improve clarity to add the term "applied".

3. **Sen. Tillis and Sen. Coons have made clear that genes as they exist in the human body would not be patent eligible under their proposal.**

   Are there other things that Congress should make clear are not patent eligible? There are already statutes that prevent patents on tax strategies and human organisms. Are there other categories that should be excluded?

There was extraordinary confusion over the holding and meaning of the Supreme Court decision in *AMP v. Myriad* (569 U.S. 576 (2013); "Myriad") during the three days of Subcommittee testimony, and thereafter in the press. I would like to detangle this and clarify both the decision and its ramifications.

Human genes and DNA in the body have NEVER been patent eligible in the history of the United States because they are not manmade and are not new. The Myriad decision did not address whether genes and DNA in the body are patent eligible because it is common ground that they are not and have never been patent eligible.

Opponents of the 101 amendment refer to "human genes" or "genes" in a sloppy manner without indicating whether they are talking about human genes in the body or isolated gene segments outside of the body. The distinction is critical, and confusion causes uninformed panic.

The *Myriad* decision SOLELY addressed whether isolated gene segments outside of the body are patent eligible. The actual holding of the *Myriad* decision is that "a naturally occurring DNA segment is not patentable merely because it has been isolated".

The Supreme Court *Myriad* holding is inconsistent with the Congress' Section 101 statute because isolated genetic material outside the body must be due to human intervention and is thus manmade and eligible. The *Myriad* decision is based on the Court's judicial exceptions to the statute, not the language of the statute as passed by Congress.

Instead of amending the draft of Section 101 to state that genes as they exist in the human are not patent eligible, Congress should educate the public that genes in the body have never been patent eligible. If the draft is changed to state that genes as they exist in the body are not patent eligible, Congress should be careful to note that this is not a change in the law.

The *Myriad* decision threw the baby out with the bathwater, because it was interpreted to hold that all isolated natural materials, whether from the human body, a bacteria, a plant or whatever, are not patent eligible subject matter. These materials have played an essential part in medicine as antibiotics, anticancer agents, and in personal diagnostics. The downstream effect of Myriad was devastating in all of these categories. Research on isolated natural materials to cure

diseases including cancer has come to a dead stop in the U.S. I refer to pages 27-30 of my June 3rd, 2019 Written Testimony for supporting statistics.

As I also said during my oral testimony June 4th, 2019, I am a breast cancer survivor whose life was saved by two isolated natural products that would not be patent eligible under the *Myriad* law. If *Myriad* had been the law in the United States years ago, I would not be giving testimony because I already would have died.

Because of the human genome project and other publications, the human genome is now public. Therefore, there is diminishing ability, if at all, in researching or getting a patent on isolated naturally occurring gene segments out of the body. The only isolated gene segments of remaining interest are those linked to diseases. Research should be properly motivated to find these links and develop diagnostics and products that can help us, our families, friends and co-workers.

4. **I have heard complaints that courts do not consistently enforce Section 112 with respect to claims for inventions in the high tech space.**

   a. **Are these valid complaints?**

   b. **Do the proposed changes to Section 112 adequately address those complaints and limit the scope of claims to what was actually invented?**

   c. **Are you concerned that the proposed changes will make it too easy for competitors to design around patent claims that use functional language?**

I am not an expert in high tech patents and therefore I will kindly defer these questions to those who are experts in this field. I do note that draft Section 112(f) would have significantly different effects in the high tech and the pharmaceutical/biotech areas, and for that reason, should be the subject of further discussions.

5. **There is an intense debate going on right now about what to do about the high cost of prescription drugs. One concern is that pharmaceutical companies are gaming the patent system by extending their patent terms through additional patents on minor changes to their drugs.**

   Would the proposed changes to Section 101 and the additional provision abrogating cases establishing judicial exceptions to Section 101 do away with the doctrine of

obviousness-type double patenting? If so, should the doctrine of obvious-type double patenting be codified?

The doctrine of obviousness-type double patenting has significant legal issues that should be the subject of a separate discussion.

The U.S. Patent Office states that a rejection for "non-statutory-type" double patenting is based on a "judicially created doctrine" grounded in public policy and which is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. This is problematic for at least these reasons:

(i) The term "non-statutory-type" double patenting is an admission that this rejection is not authorized by a congressional statute. Congress is the only branch of the government authorized to create substantive patent law.

(ii) The "judicially created doctrine" of obviousness double patenting is *ultra vires* because the U.S. Constitution does not grant power to the courts to create patent law, regardless of the underlying public policy. Any assertion of statutory stare decisis cannot be used to bootstrap the unauthorized judicial creation of substantive patent law to judicial self-authorization.

(iii) The terms "patentably distinct" and "patentably indistinct" do not exist in Chapter 35 of the United States Code.

(iv) There has been no clear delegation of authority under *Chevron U.S.A., Inc. v. Natural Resource Defense Council*, 467 U.S. 837 (1984) to the U.S. PTO to generate an entire body of regulatory

law on obviousness type double patenting and associated terminal disclaimers.

As an administrative agency, the U.S. PTO is limited to making rules pursuant to a constitutionally valid delegation of power from Congress. While Congress has delegated authority to the U.S. PTO to make certain rules (for example the PTAB regulations, see *Cuozzo Speed Technologies, LLC v. Lee,* 136 S. Ct. 2131 (2016)), no statute exists that delegates the authority to make or implement a rule on non-statutory obviousness-type double patenting. The United States Court of Appeals for the Federal Circuit (CAFC) has confirmed on several occasions that Congress did not vest the U.S. PTO with any general substantive rulemaking power. The U.S. PTO is instead vested with the power to make procedural rules and to apply statutes passed by Congress. Thus, promulgation of rules related to obviousness-type double patenting and insistence on the submission of a terminal disclaimer that can affect patent term and ownership runs contrary to prior court holdings that have found agency action outside the scope of a clear delegation of authority provided by Congress to be unconstitutional.

Even if Congress had delegated authority to the U.S. PTO to promulgate a rule on non-statutory obviousness-type double patenting, which it has not to date, the current MPEP guidance and rules are procedurally defective under the Administrative Procedure Act (APA; 5 U.S.C. 500-596). The APA has strict procedural requirements that agencies must follow to make new rules. The requirements of either APA § 553, 556, or 557 applies to all substantive rulemaking by the U.S. PTO. At a minimum these rules require that a notice of proposed rulemaking is provided for substantive rules, and a comment period allowed and then the final rule must be published in the Federal Register. The U.S. PTO has not published proposed or final rules on the meets and bounds of non-

statutory obviousness-type double patenting in the Federal Register. And it is well established that the MPEP does not have the force of law and is internal guidance only. It is not a substitute for the notice and comment provisions of the APA for substantive rules.

Tracing obviousness-type double patenting to the first MPEP (§ 9-4-1 MPEP 1948) the rule still fails to meet the procedural requirements of the original Administrative Procedure Act, which even in 1946 required publication in the Federal Register (60 Stat. 237, 238, 1946). In fact, to the best of my knowledge there has never been a rule implementing the law on non-statutory obviousness type double patenting in the Federal Register that complies with the APA. And notwithstanding, the U.S. PTO cannot do so because by definition there is no clear delegation from Congress on this matter because there is no statute on this matter.

Because of the failure to follow the framework of our legal structure to create and authorize a body of law on non-statutory judicially created obviousness type double patenting, the informal doctrine that is applied is not grounded in specific laws that provide adequate strict guidance or limits. As a result, we see "doctrine creep" which is a broadening of the scope of OTDP in uncertain ways which adversely affects inventors, entrepreneurs and investors.

The fundamental legal problems with obviousness-type double patenting should be discussed, including whether it can or should be fixed retroactively in a manner that is consistent with our laws.

Notwithstanding, since the changing of the patent term to 20 years from the filing date from 17 years from the date of issue, there is less need for such a doctrine because the expiration date of a patent is based on its filing date not the issue date.

6. **In its *Oil States* decision, the Supreme Court explicitly avoided answering the question of whether a patent is property for purposes of the Due Process Clause or the Takings Clause.**

   What are the Due Process and Takings implications of changing Section 101 and applying it retroactively to already-issued patents?

I am against changes to the patent laws that retroactively remove patent rights, or even that reinstate patent rights that were invalidated under admittedly bad law. The United States has the biggest economy in the world and U.S. businesses have to make decisions on a daily basis that affect future business plans and economic forecasts. These decisions must be made based on well-settled, long term law that they can rely on so that the decisions will be accurate over a long period of time. This is especially true in the pharmaceutical and biotech business.

It takes 10-15 years from drug discovery to first commercial sale. The risk of loss of invested capital and employee time over this 10-15 year period is staggering because only a very small number of drug candidates make it all the way through to market. Business decisions have to be made whether to progress a drug candidate based on a range of potential risks, including uncertainty in large population human efficacy and toxicity, regulatory administrative burdens, predicted competition in the market place by similar drugs, and the strength of the developer's patents which are critical to repay the investment and make a return as required by its shareholders. These decisions simply cannot be made in a shifting legal framework that over this long time period turns a good business decision into a bad business decision and with a likely loss of investment. Given the required long-term nature of drug development, it is essential that the industry has a long-term consistent law to follow.

Even bad law is better than shifting law. Businesses can make decisions based on bad law that remains over the period of investment. Businesses get turned

upside-down when midstream the law changes and the investment to that point has to be questioned and reevaluated from scratch.

THE JOHN MARSHALL
REVIEW OF INTELLECTUAL PROPERTY LAW

UNCONSTITUTIONAL APPLICATION OF 35 U.S.C. § 101 BY THE U.S. SUPREME COURT

SHERRY KNOWLES AND DR. ANTHONY PROSSER

ABSTRACT

"A or B" is inconsistent with "A not B." This describes why the application of 35 U.S.C. § 101 by the U.S. Supreme Court is inconsistent with the U.S. Constitution, and thus unconstitutional. This article tracks the legislative history of patent eligibility from 1790 to 2011, and the parallel but inconsistent U.S. Supreme Court case law during this period. In following its own case law, the Court has shown extraordinary judicial activism, has penciled out two words of the federal statute ("or discovers"), and has penciled a word out of the U.S. Constitution ("discoveries").

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UNCONSTITUTIONAL APPLICATION OF 35 U.S.C. § 101 BY THE U.S. SUPREME COURT

SHERRY KNOWLES AND DR. ANTHONY PROSSER

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I. INTRODUCTION

"A or B" is inconsistent with "A not B." This describes why the application of 35 U.S.C. § 101 by the U.S. Supreme Court is inconsistent with the U.S. Constitution, and thus unconstitutional.

The U.S. Constitution is among the most brilliant documents ever crafted. It is the supreme law of our land and alone creates the carefully balanced tripartite framework for the federal government. As well said by James Madison, "In framing a government which is to be administered by men over men you must first enable the government to control the governed, and in the next place oblige it to control itself."[1]

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*."[2] Thus, the U.S. Constitution does two things: it grants the power to create the laws that promote the progress of science solely to Congress, and it associates inventors with discoveries. The U.S. Constitution does not use the word "patent," and it does not tell Congress what kind of advances should be promoted to progress science.

Congress has used its exclusive power under Art. I, Sec. 8, Clause 8 to declare how the country will promote the progress of science, by defining the scope of subject matter that the country will motivate through the use of a temporary government-granted monopoly. This is often referred to as the patent eligibility statute. The current version of the statute is 35 U.S.C. § 101, which 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, subject to the conditions and requirements of this title.[3]

And here we come to "A or B," which is "invents or discovers." Section § 101 unambiguously refers to "invents" and "discovers" in the disjunctive. Thus, according to its plain meaning, Congress has used its exclusive grant of power from the U.S. Constitution in Art. I, § 8, cl. 8 to promote the progress of science by a grant securing for a limited time the exclusive right to either an invention or a discovery. Both

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[1] THE FEDERALIST NO. 51, at 322 (James Madison) (Clinton Rossiter ed., 1999).

[2] U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

[3] 35 U.S.C. § 101 (2012) (emphasis added).

words "inventors" and "discoveries" are used in the U.S. Constitution.[4] And, both inventions and discoveries have resulted in important fundamental advancements of society.[5] It is not out of the pale to conclude that it is in the country's best interest to promote the progress of science by motivating and temporarily rewarding both of them.

Where the U.S. Constitution grants sole authority to Congress to create law in an area, the U.S. Supreme Court is limited to statutory construction.[6] The Supreme Court as recently as 2000 has stated that "when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms."[7] The court has stated "time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there."[8] This assumption is "elementary" to judicial analysis of statutes.[9] The Supreme Court even respects the grammatical structure of sentences.[10] Thus, sometimes statutory interpretation can turn on the very punctuation used by Congress.[11]

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[4] U.S. CONST. art. I, § 8, cl. 8.

[5] *Invention*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (3d ed. 1961). The term "invention" is commonly defined in dictionaries either in circular fashion as the act of inventing or alternatively, according to the patentability requirements of novelty, non-obviousness, adequate description, and enablement. It has also been referred to as an act of ingenuity or genius and not of ordinary skill. In contrast, discovery has been used to refer to learning how something works. Congress has clarified its intent that these terms are limited to things made by man, which is not necessary for definition of invention but affirms Congress' intent that its use of the term discovery in the statute refers to *applied* discoveries, in other words, an application made by man of what something is or does; *see* H.R. REP. NO. 82-1923, 2d Sess., 6 (1952). Examples of marketed pharmaceutical drugs (or drug combinations) that are synthetic and fall into the category of invention include Crestor, Lipitor, Advair, Symbicort, Januvia, Atripla, Viagra, Cialis, Ritalin, and Revlimid. Examples of marketed drugs that have been discovered in nature and then isolated and used in a non-naturally occurring form with important therapeutic uses include penicillin, tetracycline, epogen, adriamycin, insulin, vincristine, vinblastine, streptomycin, and Vitamin B_{12}. Clearly, both categories have improved health, promoted the progress of science, improved our standard of living, and saved countless lives.

[6] *See* Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A., 530 U.S. 1, 6 (2000); Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253-254 (1992); Caminetti v. United States, 242 U.S. 470, 485 (1917).

[7] *Hartford*, 530 U.S. at 6.

[8] *Connecticut*, 530 U.S. at 253-254 (citing several cases in support and going further to state that "When the words of a statute are unambiguous, then, this first canon is also the last" and the "judicial inquiry is complete").

[9] *Caminetti*, 242 U.S. at 485 ("It is elementary that the meaning of a statute must, in the first instance, be sought in the language in which the Act is framed, and if that is plain, and if the law is within the constitutional authority of the lawmaking body which passed it, the sole function of the courts is to enforce it according to its terms.").

[10] *See* D.C. v. Heller, 554 U.S. 570, 598 (2008) (affirming the Court of Appeals' opinion that in part relied on the placement of a comma in the Second Amendment); *see also* Lockhart v. U.S., 136 S. Ct. 958, 962 (2016) (quoting a book on statutory construction by Scalia regarding the interpretation of limiting clauses and phrases which "should ordinarily be read as modifying only the noun or phrase that it immediately follows").

[11] *See* Ali v. Fed. Bureau of Prisons, 552 U.S. 214, 229 (2008) (where in the opinion of the four-judge dissent, the majorities holding improperly placed "implicit reliance upon a comma at the beginning of a clause").

Supreme Court Justice Ruth Bader Ginsburg was recently asked on The Colbert Report TV show whether a hot dog is a sandwich. She replied, "You tell me what a sandwich is and then I'll tell you if a hot dog is a sandwich."[12] This is an example of strict statutory construction—the Court must read the literal words of the statute and apply them to the facts. Under the Constitution, as illustrated by Justice Ginsburg, it is the requirement and limitation of the Supreme Court to construe the literal meaning of every word of 35 U.S.C. § 101 and apply it to the facts at hand. This is the case whether the court agrees with the wording of the statute or not.[13]

Notwithstanding its legal prohibition, the U.S. Supreme Court has created its own parallel law in the area of patent eligibility. The Supreme Court case law on this subject, which has taken on the nature of common law, is directly inconsistent with the wording of 35 U.S.C. § 101. It runs roughshod over the U.S. Constitution. In following its own case law, it has penciled out two words of the federal statute ("or discovers") and penciled a word out of the U.S. Constitution ("Discoveries").

The pinnacle of the U.S. Supreme Court's unconstitutional treatment of patent eligibility is found in the *Ass'n for Molecular Pathology v. Myriad*[14] decision, where Justice Thomas, writing for a unanimous Court, stated that: "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[15] In this passage, Justice Thomas reaffirmed the Supreme Court's view that a "discovery" is not patent eligible under § 101. In other words, according to the Supreme Court, "A not B" (an invention but not a discovery is patent eligible). This is despite the clear disjunctive wording of the statute that states that "whoever invents or discovers . . . may obtain a patent therefor" under Congress' sole authority to promote the progress of science.[16] *Myriad* is exemplary of the Supreme Court line of cases holding "A not B," and thus B is not patent eligible.

The legislative history of 35 U.S.C. § 101 below confirms that Congress repeatedly amended the patent eligibility statute from its time of enactment in 1790 to the most recent codification in 2011, and has maintained and reaffirmed its delegation of exclusive power to reward both inventions and discoveries. In contrast, the history of applying § 101 by the Supreme Court in its opinions goes from little or no statutory construction or discussion of legislative intent to the creation of "judicial exceptions" to the federal statute to full boar direct contradiction of it.

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[12] Sophi Tatum, *Ruth Bader Ginsburg Settles it for Stephen Colbert: Hot Dogs are Sandwiches*, CNN POLITICS (Mar. 22, 2018), https://www.cnn.com/2018/03/22/politics/ruth-bader-ginsburg-stephen-colbert-workout/index.html.

[13] *See* Pennsylvania v. Union Gas Co., 491 U.S. 1, 30 (1989) (Scalia, J., concurring in part and dissenting in part) ("It is our task, as I see it, not to enter the minds of the Members of Congress—who need have nothing in mind in order for their votes to be both lawful and effective—but rather to give fair and reasonable meaning to the text of the United States Code, adopted by various Congresses at various times.").

[14] 569 U.S. 579 (2013).

[15] *Id.* at 577.

[16] 35 U.S.C. § 101.

II. CONGRESS' LEGISLATIVE HISTORY ON PATENT ELIGIBILITY

Congress has historically shown a keen interest in the wording of the codified patent law, including on patent eligible subject matter. On numerous occasions prior to the Patent Act of 1952 Congress passed amendments and entirely new Patent Acts that contained small changes in word choice regarding patent eligibility.[17] Despite these various amendments and acts, detailed further below, Congress has consistently included both inventions and discoveries as patent eligible subject matter. The language on patent eligibility and the definition of invention in the Patent Act of 1952 remains intact today and was not amended by the recent America Invents Act.[18]

The Patent Act of 1790[19] is the first time Congress used its constitutional power to codify what can be patented. The Act stated that "he, she, or they, hath or have *invented or discovered* any useful art, manufacture, engine, machine, or device, or any improvement thereon not before known or used" is entitled to a patent.[20] The first Patent Act, like the Patent Act we practice under today, goes further to define rules for patentability of patent eligible subject matter. The Act required that inventions had to be useful and could only be enforced if they were novel.[21] The Act also required a majority vote between the Secretary of State, Secretary for the Department of War, and the Attorney General to conclude that the "invention or discovery" was "sufficiently useful and important."[22]

The Patent Act of 1793[23] repealed the prior Patent Act and made small changes to the definition of patent eligible subject matter. The Act states that if "they have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine manufacture or composition of matter" then they are entitled to patent protection.[24] While the word "discovered" was removed from the patent eligibility paragraph, it appears that this may have just been an oversight, as "discovery," "discovered," and "discoverer," are used throughout the remainder of the statute.[25] The addition of "new" as a limitation to patent eligible subject matter can be traced to our modern day novelty requirement under 35 U.S.C. 102.[26] The Patent Act of 1793 also removed the requirement for a vote that the invention is "sufficiently useful and important."[27] These changes, made

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[17] *See* Patent Act of 1793, Pub. L. No. 2-53, 2 Stat. 318 (1793); Patent Act of 1836, Pub. L. No. 24-357, 5 Stat. 117 (1836); Patent Act of 1842, Pub. L. No. 27-288, 5 Stat. 543 (1842); Patent Act of 1870, Pub. L. No. 41-230, 15 Stat. 198 (1870); Patent Act of 1897, Pub. L. No. 55-391, 29 Stat. 692 (1897); Plant Patent Act of 1930, Pub. L. No.71-312, 46 Stat. 376 (1930); Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (1952).

[18] 35 U.S.C. § 100 (2012) (Leahy-Smith America Invents Act (AIA) of 2011).

[19] Pub. L. No. 1-34, 1 Stat. 109 (1790) (current enacted version at 35 U.S.C. § 100 (2012)).

[20] *Id.* at 110 (emphasis added).

[21] *Id.* at 111. Section 5 of the Patent Act provided instruction for when a court could repeal a patent, including if "the patentee was not the first and true inventor or discoverer."

[22] *Id.* at 110.

[23] Pub. L. No. 2-53, 2 Stat. 318 (1793).

[24] *Id.* at 310.

[25] *Id.* at 321-323.

[26] 35 U.S.C. § 102 (2012).

[27] Pub. L. No. 2-53, 2 Stat. 318 (1793).

so quickly after the first Patent Act, clearly show that Congress was active and thoughtful in defining what could be patented.

The Patent Act of 1794[28] was passed to amend the prior Patent Act to reinstate court proceedings that had been dismissed as a consequence of repealing the Patent Act of 1790. The Act did not amend patent eligibility. The Patent Act of 1800[29] similarly left patent eligibility untouched but handled several technical matters including: (1) modifying the oath requirement;[30] (2) providing that resident aliens can apply for patents subject to some restrictions;[31] and (3) changing the infringement damage calculation from *at least* three times license fee to three times the actual damages.[32] The first Patent Act of 1832[33] provided that any patents that had been invalidated as a result of an inventor's unintentional failure to comply with the best mode or oath requirement could have their patent reinstated by the Secretary of State.[34] The second Patent Act of 1832[35] expanded patent rights to aliens who intended to become U.S. citizens (effectively removing the two-year residency requirement). While these acts do not change any patentability definitions, they do, again, refer to "discovery" or "discoveries" in their text, and demonstrate the keen interest Congress had in the details of patent law.

The Patent Act of 1836,[36] repealed all prior Patent Acts and reintroduced the disjunctive discovered or invented language at the beginning of the statute, reaffirming that both are patent eligible. In fact, Congress placed the word discovered before invented.[37] In relevant part, the Act said "That any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter" is entitled to a patent.[38] Restoring the "discoveries" language in the patent eligibility section purposefully clarified that discoveries are eligible for patent protection. The Act also established the Patent Office and the Commissioner of Patents position.[39]

Within four months of the Patent Office fire of 1836, Congress passed the Patent Act of 1837[40] to address the problems arising from the destruction of most of the Patent Office's records and models. The Act maintained the disjunctive "discovered or invented" patent eligibility scope. The Act also allowed recording of

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[28] Pub. L. No. 3-58, 2 Stat. 393 (1794).

[29] Pub. L. No. 6-25, 3 Stat. 37 (1800).

[30] *Id.* at 38 ("*Provided always*, [t]hat every person petitioning for a patent for any invention, art or *discovery*, pursuant to this act, shall make oath or affirmation . . . that such invention, art or *discovery* hath not to the best of his or her knowledge or belief, been known or used either in this or any foreign country.") (emphasis added).

[31] *Id.* "[T]he rights and privileges given, intended or provided to citizens of the United States, respecting patents for new inventions, *discoveries*, and improvements, . . . are extended and given to all aliens who at the time of the petitioning . . . shall have resided for two years within the United States." *(emphasis added).*

[32] *Id.* "[A] sum equal to three times the actual damage sustained by such patentee."

[33] Pub. L. No. 22-162, 4 Stat. 559 (1832).

[34] *Id.* at 559.

[35] Pub. L. No. 22-203, 4 Stat. 577 (1832).

[36] Pub. L. No. 24-357, 5 Stat. 117 (1836).

[37] *Id.* at 119.

[38] *Id.*

[39] *Id.* at 118-119.

[40] Pub. L. No. 24-409, 5 Stat. 191 (1837).

previously destroyed Patent Office records and raised the number of Examining Clerks from one to two.[41]

The Patent Act of 1839 also maintained the "discovered or invented" eligibility language.[42] In addition, it provided for more Examiners and codified that inventors who had first filed their patent applications overseas could also apply for a U.S. patent.[43] The speed at which Congress reacted to the Patent Office's needs in this time period is notable.

The Patent Act of 1842[44] increased the scope of patent eligible subject matter. The Act again maintained the "discovered or invented" disjunctive patent eligibility scope and added subject matter that can now be traced to modern day design patents.[45]

There were over a dozen[46] Patent Acts passed between 1842 and 1870. These Acts all maintained the broad scope of the disjunctive invention or discovery patent eligibility threshold. In 1870 Congress consolidated the patents, copyrights, and trademark laws into one lengthy law of 111 sections.[47] During this massive effort, Congress still maintained almost the exact same wording regarding patent eligibility, notably including the disjunctive invented and discovered language.[48] The Patent Act of 1897 also maintained this standard.[49]

The next major expansion to patent eligibility came in 1930 when Congress passed the Plant Patent Act of 1930.[50] The Act says in relevant part:

> Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, or who has invented or discovered and asexually

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[41] *Id.* at 191-192.

[42] Pub. L. No. 25-292, 5 Stat. 353 (1839).

[43] *Id.* at 353.

[44] Pub. L. No. 27-288, 5 Stat. 543 (1842).

[45] *Id.* at 543-544.

[46] The Patent Act of 1870 references a number of prior patents acts that were consolidated including: The Act of August 6, 1846, chapter 90, volume 9, page 59; May 27, 1848, chapter 47, volume 9, page 231; March 8, 1849, chapter 108, volume 9, page 895; March 8, 1851, chapter. 82, volume 9, page 617; August 8, 1852, chapter 107, volume 10, page 75; August 8, 1852, chapter 108, volume 10, page 76; March 8, 1858, chapter 97, volume 10, page 209; April 22, 1854, chapter 52, volume 10, page 276; March 8, 1855, chapter 175, volume 10, page 648; August 18, 1856, chapter 129, volume Il, page 81; March 8, 1859, chapter 80, volume 11, page 410; February 18,1861, chapter 87, volume 12, page 180; March 2, 1861, chapter 88, volume 12, page 246; March 8,1863, chapter 102, volume 12, page 796; June 25, 1864, chapter 159, volume 18, page 194; March 8, 1865, chapter 112, volume 18, page 588; June 27, 1866, chapter 148, volume 14, page 76; March 29, 1867, chapter 17, volume 15, page 10; July 20, 1868, chapter 177, volume 15, page 119; July 28, 1868, chapter 227, volume 15, page 168; and March 8, 1869, chapter 121, volume 15, page 298.

[47] Pub. L. No. 41-230, 15 Stat. 198 (1870).

[48] *Id.* ("That any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof.").

[49] Pub. L. No. 55-391, 29 Stat. 692 (1897) ("Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof.").

[50] Pub. L. No.71-312, 46 Stat. 376 (1930).

> reproduced any distinct and new variety of plant, other than tuber-propagated plant.[51]

Finally, after the rich history of expanding and refining (but not limiting) patent eligibility described above, Congress passed the modern day eligibility criteria in The Patent Act of 1952.[52]

> 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.[53]

The 1952 Act also added a definition for the term "invention." The Act states that: "The term 'invention' means invention or discovery."[54] While this circular definition of invention is not helpful in defining what an invention is or is not, it does emphasize Congress' insistence that discoveries are patent eligible.

The Hearings before the Subcommittee of the Committee on the Judiciary of the House of Representatives pertaining to the 1952 Act are enlightening. The congressional record shows the intent to maintain "discoveries" was purposeful. For example, The Department of Justice ("DOJ") gave testimony to Congress (Mr. Bryson presiding), with a range of comments on various proposed sections of the Act.[55] With respect to patent eligibility, the DOJ requested removal of "discoveries" from the definition of invention with the assertion that it was inconsistent with the decisions of the Supreme Court.[56] Specifically, Mr. Brown for the DOJ said that:

> Section 100 of the bill, "definitions," defines "invention" to include discoveries. While the term "discovery" is used in the patent law as synonymous with invention and it has been recognized that the act of discovery is an essential part of the invention, under existing law discoveries, as such are not patentable. . . The section might have the effect of creating doubt as to existing law on the subject of discovery and might result in opening the door to a huge new area of patents, and permit the creation of monopolies in some of the fundamental and far-reaching discoveries in the fields of chemistry, physics, medicine, mathematics, et cetera. . . The Department would be opposed to the creation of any new area of monopoly which would be exempt from the operation of the anti-trust

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[51] *Id.* at 376.

[52] Pub. L. No. 82-593, 66 Stat. 792 (1952).

[53] *Id.* at 797 (emphasis added); *see also* Pub. L. No. 112-29, 125 Stat. 284 (2011) (Leahy-Smith America Invents Act (AIA)). The America Invents Act maintains the same language for patent eligibility.

[54] 35 U.S.C. § 100 (2012); *see also* Pub. L. No. 112-29, 125 Stat. 284 (2011) (Leahy-Smith America Invents Act (AIA)). The America Invents Act keeps the same definition of "invention."

[55] H.R. Rep. No. 82-3760, 1st Sess., 93 (1951).

[56] H.R. Rep. No. 82-3760, 1st Sess., 94 (1951); *see also* H.R. Rep. No. 80-4061, 2d Sess., 82 (1951). The Justice Department objected to the addition of discoveries to the definition of invention on at least two occasions. First, they stated that they "recommend that no hasty action be taken toward the enactment of a statutory definition of "invention." And then they went as far as to say, "under existing law discoveries, as such, are not patentable."

> laws in the absence of clear evidence that such extension is necessary to provide adequate incentive for scientific effort. There would appear to be no such necessity with respect to the broad field of "discoveries."[57]

After Mr. Brown's testimony was read into the record, the sole response to the DOJ comments was a short "Thank you, Mr. Brown" from Mr. Bryson for Congress without comment, and a request to call the next speaker.[58] And as clear from the codified law, the DOJ's suggestion was not accepted, even after the testimony that it would be inconsistent with Supreme Court cases.

Congress also heard from Mr. Fellner, the manager of the patent department of the Salsbury's Laboratories in Iowa.[59] Mr. Fellner made comments without a prepared statement on proposed sections 101 and 103.[60] Mr. Fellner wanted to include language that had been omitted from the old bill H.R. 9133 in the new version H.R. 3760. H.R. 9133 stated, "An invention in the nature of a discovery as embodied in a new and useful art, machine, manufacture or composition of matter, or new and useful improvement thereof may be patented."[61] Mr. Fellner raised the issue of the highly controversial 1948 Supreme Court, *Funk Bros.*[62] decision, holding that the discovery of a new mixture of bacteria that had commercial application to the inoculation of various agricultural species was not patent eligible. Fellner testified that the *Funk Bros.* product solved a great problem by providing a new compatible mixture of bacteria for crop development, and he implied that the decision to reject the patent was very problematic to industry.

Congressman Willis asked, "As I understand it, from the point of view of the industry you represent, their requirements would have been met by the adoption of section 101 of the old bill, H.R. 9133, particularly using the second paragraph beginning with "an invention in the nature of a discovery?"[63] Mr. Fellner agreed. To that, Congressman Willis made the important observation:

> You do not consider that the new bill, section 101 of H.R. 3760 with the definition, accomplishes what you have in mind? In other words, is it not simply a question of some condition? Does not the definition preceding section 101, embodied in section 100, carry all the implications you used in the second paragraph of section 101 of H.R. 9133? You see, in H.R. 9133, you did not have the definition contained in section 100 of the new bill. Now with these definitions, would not they supply the purpose of the second paragraph in the old bill? What it was intended to cover?[64]

This Congressional statement urges the conclusion that the subcommittee thought that taking the extra step to add "discoveries" into the definition of invention in

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[57] H.R. Rep. No. 82-3760, 1st Sess., 94 (1951); H.R. Rep. No. 3760 at 94.

[58] *Id.* at 98.

[59] *Id.* at 116-124.

[60] *Id.*

[61] *Id.* at 117.

[62] Funk Bros. Seed Co. vs. Kalo Inoculant Co. 333 U.S. 127 (1948). This case is discussed in detail in Section II. below.

[63] H.R. Rep. No. 82-3760 at 120.

[64] *Id.*

section 100 reaffirmed its intent that discoveries are considered part of the subject matter Congress wants to motivate via the patent system.

Later on in Mr. Fellner's testimony, he was questioned by Congressman Crumpacker.

> Mr. CRUMPACKER. Does not the language of the pending bill say "whoever discovers any new and useful process, machine, manufacture, or composition of matter" may obtain a patent covering it? I would think that would specifically cover the case you referred to. And, if the Supreme Court has interpreted the words as you indicate, I do not see how including that language in the paragraph would cause them to make a different interpretation.
>
> Mr. FELLNER. I believe that the Supreme Court in that particular case did not interpret it in the way the bill here originally contemplated.[65]

After finishing his comments on *Funk,* Mr. Fellner was asked to go on to the next paragraph.[66] The overall Congressional discussion at the Hearing indicates Congress considered that by taking the step to add the discoveries to the new definition of invention in section 100 before section 101, it was affirming its intent that promoting discoveries will progress science, which should be enough. It was not.

In summary, between 1790 and 2011, Congress defined the scope of patent eligibility in the broad disjunctive "invention or discovery." It did remove the word "discovered" for a short period of time (1793-1836 (and even then referred to discoveries, multiple times, later in the text of the code)), and then purposefully restored the disjunctive "invention or discovery" eligibility scope which it maintained through at least two dozen Patent Act amendments and is maintained today. The early enactments of Congress solidified and confirmed the statutory scope of patent eligibility.[67] The Supreme Court acknowledges that:

> Early congressional enactments "provid[e] 'contemporaneous and weighty evidence' of the Constitution's meaning," Bowsher v. Synar, 478 U.S. 714, 723–724, 106 S.Ct. 3181, 3186, 92 L.Ed.2d 583 (1986) (quoting Marsh v. Chambers, 463 U.S. 783, 790, 103 S.Ct. 3330, 3335, 77 L.Ed.2d 1019 (1983)). Indeed, such "contemporaneous legislative exposition of the Constitution ..., acquiesced in for a long term of years, fixes the construction to be given its provisions." Myers v. United States, 272 U.S. 52, 175, 47 S.Ct. 21, 45, 71 L.Ed. 160 (1926) (citing numerous cases).[68]

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[65] *Id.* at 122.
[66] *Id.* at 123.
[67] Printz v. United States, 521 U.S. 898 (1997).
[68] *Id.* at 905.

III. History of U.S. Supreme Court Treatment of Patent Eligibility

The earliest U.S. Supreme Court opinion sometimes referred to by the Court in the march of patent eligibility cases is the 1852 case of *Le Roy v. Tatham*.[69] A patent was issued to John and Charles Hanson on August 31st, 1837, on a combination of machine parts to make wrought lead pipes,[70] which was later assigned to Tatham. The Patent Act of 1836, which codified the requirement for patent claims[71] to be presented in a patent specification, had just been enacted and, thus, there was very little experience by patentees or the judiciary with patent claims at the time.[72] The patentee stated that while the individual pieces of the equipment were known, their new combination allowed them to succeed in making perfect strong lead pipes.[73] The Circuit Court for the Southern District of New York had charged the jury that the originality of the machinery did not consist in its novelty, but instead, in bringing a newly discovered principle into practical application, by which a useful article of manufacture is produced and wrought pipe made as distinguished from cast pipe.[74] The Supreme Court determined that "The question whether the newly developed property of lead, used in the formation of pipes, might have been patented, if claimed as developed, without the invention of machinery, was not in the case."[75] It held that there was error in the Circuit Court's instruction, "that the novelty of the combination of the machinery, specifically claimed by the patentees as their invention, was not a material fact for the jury, and that on that ground, the judgment must be reversed."[76]

The Court said in dicta, referring to the decision of the Circuit Court:

> The word principle is used by elementary writers on patent subjects, and sometimes in adjudications of courts, with such a want of precision in its application, as to mislead. It is admitted, that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and of any other power in nature,

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[69] Le Roy v. Tatham, 55 U.S. 156 (1853).

[70] *Id.* at 171. The claim was "the combination of the following parts, above described, to wit, the core and bridge, or guide-piece, the chamber, and the die, when used to for pipes of metal, under heat and pressure, in the manner set forth, or in any other manner substantially the same."

[71] Pub. L. No. 24-357, 5 Stat. 117 (1836) (Patent Act 1836.).

[72] Le Roy v. Tatham, 55 U.S. 156 (1853); Edmund Burke, List of Patents for Inventions and Designs issued by the United States from 1790 to 1847 with the Patent Laws and Decisions of the Courts of the United States for the Same Period (J. & G.S. Gideon, 1st ed. 1847). To the best of the authors' knowledge, the Tatham patent was never given a patent number and was only cataloged in the previously-cited book issued by Edmund Burke, the Commissioner of Patents, and is not readily available for review.

[73] 55 U.S. 156 at 171.

[74] *Id.*

[75] *Le Roy*, 55 U.S. at 177.

[76] *Id.*

> which is alike open to all, and may be applied to useful purposes by the use of machinery . . . 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. [77]

Thus, the *Le Roy* case was remanded on novelty grounds, not patent eligibility, and even the early *Le Roy* Court affirmed that the practical application of a property discovered in nature is patent eligible. The later case of *O'Reilly v. Morse*,[78] faithfully quoted *Le Roy* for support that while Tatham was not entitled to a patent on what happens when hot lead cools, it was entitled to a process for making lead pipe using that principle.[79]

The first Supreme Court case on the course of deviating law from the wording of the federal statute on patent eligibility was the controversial 1948 case of *Funk Bros. Seed Co. vs. Kalo Inoculant Co.*[80] The case involved a product that included several strains of root-nodule bacteria that can be used as a mixed culture to inoculate a range of plants.[81] The previously sold products included only single strains, on the belief that the strains inhibit each other so they could not be mixed.[82] Bond discovered that there are strains of root-nodule bacteria that do not inhibit each other, and so multi-strain bacterial products are possible.[83] The Court held:

> The application of this newly-discovered natural principle to the problem of packaging of inoculants *may well have been an important commercial advance.* But once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. *There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention.* But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough. Since we conclude that the product claims do not disclose an invention or

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[77] *Le Roy*, 55 U.S. at 174-75.

[78] O'Reilly v. Morse, 56 U.S. 62 (1854).

[79] *O'Reilly*, 56 U.S. at 117 (stating that in this case, "the patentee had discovered that lead, recently set, would under heat and pressure in a close vessel reunite perfectly after a separation of its parts so as to make a wrought instead of cast pipe. And the court held that he was not entitled to a patent for this newly discovered principle or quality in lead, and that such a discovery was not patentable. But that he was entitled to a patent for the new process or method in the art of making lead pipe, which this discovery enabled him to invent and employ.").

[80] Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

[81] *Id.* at 129-131.

[82] *Id.* at 130.

[83] *Id.*

> discovery within the meaning of the patent statutes, we do not consider whether the other statutory requirements contained in 35 U.S.C. § 31, 35 U.S.C.A. § 31, R.S. § 4886 are satisfied.[84]

In the italicized language, Justice Douglas stated that a commercial product based on the application of a discovery about how nature works to produce a new and useful scientific advance cannot form the basis for a patent unless it is also an invention.[85] This statement not only directly contradicts the earlier *Le Roy* opinion, it also directly contradicts the statutory determination by Congress that any composition of matter "invention or discovery" is patent eligible. This faulty analysis formed the initial threads for the Supreme Court's parallel case law on patent eligibility, and is repeatedly cited by the Court as its authority.

Under *Le Roy*, the *Funk* multi-strain product would have been patent eligible, as it stated "A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable."[86]

The *Funk* case is also one of the first in the line of Supreme Court cases on patent eligibility that uses false examples to support its opinion. The Court stated:

> The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[87]

Here, even though the Court gave lip service in the last sentence to applications of laws of nature, it rejected the Funk invention which was exactly that. Patents are used to protect commercial endeavors that have an element made by man, and thus they attempt to cover products, processes, and manufactures with commercial uses, which are almost always based on how nature works because that is the world we live in. Even if one creates a new scientific pathway, it is fundamentally based on a discovery of how nature works.

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[84] *Id.* at 132 (emphasis added).

[85] *Id.* There was, in fact, a fatal flaw in the patent claims selected for litigation of U.S. Patent No. 2,200,532 to Kalo, however, it was not patent eligibility. The claims failed the written description and enablement requirements contained in the Patent Act of 1870 – 15 Stat. at 201, because they did not name the mutually non-inhibiting bacteria to be used in the product. The Patent also included claims that were limited to the identified useful strains of bacteria, but those were not litigated. Immeasurable damage and confusion was caused by using patent eligibility as the rationale for invalidating the patent instead of patentability.

[86] Le Roy v. Tatham, 55 U.S. 156, 174-175 (1853); *see* Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 129 (1948) (emphasizing that "We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. Bond does not create state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature.").

[87] *Funk Brothers*, 333 U.S. at 129.

Was it outside the pale that Congress would authorize the protection of a new product that is a combination of several strains of root-nodule bacteria that can be used as a mixed culture to inoculate a range of plants and advance agriculture? Of course not. Even the Supreme Court admitted this was a useful new commercial product. Would it help farmers? Yes. Did it promote the progress of science? Yes. Was it a useful application of a discovery? Yes.[88] Was the *Funk* decision inconsistent with *Le Roy?* Yes.

The 1948 *Funk* decision was issued a few years before the codification of the 1952 Act. As indicated in the above legislative history leading to the 1952 Act, the addition of the definition of invention (to include discoveries) in section 100 and inclusion of "invents or discovers" in section 101 confirm Congress' intent on the issue.

The next case in this series and the first after the passage of the 1952 Act was *Gottschalk v. Benson.*[89] In *Gottschalk*, Justice Douglas writing for the Supreme Court held that programming a computer with a mathematical formula that converts binary coded decimal numbers into pure binary numerals is not patent eligible, because it is the use of an idea:

> The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself. It may be that the patent laws should be extended to cover these programs, a policy matter to which we are not competent to speak.

The Court was concerned with affirming such a broad scope of monopoly, but that was not their decision to make, which should be limited to strict statutory construction. The decision was heavily dependent on its own prior holding in *Funk Brothers*,[90] also written by Justice Douglas without any statutory construction or legislative intent analysis, as well as *Le Roy v. Thathan*[91] and *O'Reilly v. Morse*[92]. In

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[88] *Id.* at 135-138. The dissent of Justice Burton and Justice Jackson desired affirming the appellate court decision and upholding the patent, because in their opinion the claims satisfied the patent eligibility requirements. *See also id.* at 443-444. Justice Frankfurter in his concurring opinion opined that the invention was patent eligible but failed other patentability requirements. Frankfurter states:

> Multi-purpose tools, multivalent vaccines, vitamin complex composites, are examples of complexes whose sole new property is the conjunction of the properties of their components. Surely the Court does not mean unwittingly to pass on the patentability of such products by formulating criteria by which future issues of patentability may be prejudged. In finding Bond's patent invalid I have tried to avoid a formulation which . . . would lay the basis for denying patentability to a large area within existing legislation.

[89] Gottschalk v. Benson, 409 U.S. 63 (1972).

[90] Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

[91] Le Roy v. Tatham, 55 U.S. 156 (1853) (holding that a claim to "the use of motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer" was not patent eligible as an abstract idea). However, the patent claim could have been stricken with more fidelity to the statute with a

fact, the only reference to the wording of 35 USC § 101 in *Gottschalk* is in a footnote.[93] The *Gottschalk* opinion also commented from the "Report of the President's Commission on the Patent System," referring to problems involved in examining computer software programs and recommending that they not be patent eligible.[94] Thus the Court relied on its own earlier case law, and an un-adopted recommendation from a Committee to the President in the Executive Branch, instead of carrying out strict statutory construction or reviewing legislative intent of the only branch of government delegated the responsibility to create the law. Regardless whether one is of the belief the right decision was made in this case, the Supreme Court did not carry out the required disciplined legal process of statutory construction, and it laid the groundwork for the further deviation from the required statutory interpretation.

In the Court's opinion in *Parker v. Flook,*[95] it admitted that the decision in *Gottshalk* could not have been decided based on a literal reading of 35 U.S.C. § 101.[96] The Court focused its treatment of what is patent eligible on what constitutes a process:

> This case turns entirely on the proper construction of § 101 of the Patent Act, which describes the subject matter that is eligible for patent protection. It does not involve the familiar issues of novelty and obviousness that routinely arise under §§ 102 and 103 when the validity of a patent is challenged. For the purpose of our analysis, we assume that respondent's formula is novel and useful and that he discovered it. We also assume, since respondent does not challenge the examiner's finding, that the formula is the only novel feature of respondent's method. The question is whether the discovery of this feature makes an otherwise conventional method eligible for patent protection.
>
> The plain language of § 101 does not answer the question. It is true, as respondent argues, that his method is a "process" in the ordinary sense of the word.[9] But that was also true of the algorithm, which described a method for converting binary-coded decimal numerals into pure binary numerals, that was involved in Gottschalk v. Benson. *The holding that the discovery of that method could not be patented as a "process" forecloses a purely literal reading of § 101.* Reasoning that an algorithm, or

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holding that the claims failed the written description or enablement requirement, contained in the Patent Act of 1836.

[92] O'Reilly v. Morse, 56 U.S. 62, 136 (1853).

[93] *Gottschalk*, 409 U.S. at 64-65 (reciting 35 U.S.C. § 101).

[94] *Id.* at 70-71.

[95] Parker v. Flook, 437 U.S. 584, 587 (1978).

[96] *Id.* at 585. In *Parker*, Justice Stevens, writing for the Court, addressed the patent eligibility of patent application that described a method of updating alarm limits that included three steps: an initial step measuring the present value of the process variable (*e. g.*, the temperature); an intermediate step which uses an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value. The only difference between the conventional methods of changing alarm limits and that described in patent application was in step two.

> mathematical formula, is like a law of nature, *Benson* applied the established rule that a law of nature cannot be the subject of a patent.[97]

There was a sharp dissent from Justices Stewart, Rehnquist, and Burger:

> The Court today says it does not turn its back on these well-settled precedents, *ante*, at 2527–2528, but it strikes what seems to me an equally damaging blow at basic principles of patent law by importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness. Section 101 is concerned only with subject-matter patentability. Whether a patent will actually *issue* depends upon the criteria of §§ 102 and 103, which include novelty and inventiveness, among many others. It may well be that under the criteria of §§ 102 and 103 no patent should issue on the process claimed in this case, because of anticipation, abandonment, obviousness, or for some other reason. But in my view the claimed process clearly meets the standards of subject-matter patentability of § 101.[98]

The next in the series of U.S. Supreme Court decisions on patent eligibility was *Diamond v. Chakrabarty*[99] in 1980, where the Court addressed the meaning of manufacture under § 101 and whether genetically engineered bacteria are patent eligible. Justice Burger, for a 5-4 Court (dissenting: Brennan, White, Marshall and Powell), confirmed that the term manufacture is intentionally broad.[100] Importantly, *Chakrabarty* is one of the few[101] of this line of cases in which the Supreme Court actually uses the words "statutory interpretation" and refers to legislative history; however it construes the terms "manufacture" and "composition of matter" not "discovers."

> The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101, which provides: "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."
>
> Specifically, we must determine whether respondent's micro-organism constitutes a "manufacture" or "composition of matter" within the meaning of the statute.[5]
>
> The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of

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[97] *Parker*, 437 U.S. at 586.

[98] *Parker*, 437 U.S. at 598-599.

[99] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[100] *Chakrabaty*, 447 U.S. at 317.

[101] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001). The case of *J.E.M. v. Pioneer* likewise held that plant varieties are manufactures under 101, with similar reasoning.

> matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, § 1, 1 Stat. 319. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." Writings of Thomas Jefferson 75–76 (Washington ed. 1871). See *Graham v. John Deere Co.*, 383 U.S. 1, 7–10, 86 S.Ct. 684, 688–690, 15 L.Ed.2d 545 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952).[102]

However, the Supreme Court goes further and starts to name and institutionalize the Supreme Court's parallel interpretation of what should be patent eligible, and then rules in the positive.

> This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. See *Parker v. Flook*, 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67, 93 S.Ct. 253, 255, 34 L.Ed.2d 273 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, 68 S.Ct. 440, 441, 92 L.Ed. 588 (1948); *O'Reilly v. Morse*, 15 How. 62, 112–121, 14 L.Ed. 601 (1854); *Le Roy v. Tatham*, 14 How. 156, 175, 14 L.Ed. 367 (1853). Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." *Funk, supra*, 333 U.S., at 130, 68 S.Ct., at 441.[103]

Here we see the Court defining judicial exceptions to a federal statute. The Court states that "laws of nature, physical phenomena and abstract ideas" are not patent eligible. None of these exceptions are listed in 35 U.S.C. § 101. Instead, the Committee Reports accompanying the 1952 Act indicates that Congress intended statutory subject matter to "include anything under the sun that is made by man."[104] The Court itself, in later cases, repeatedly refers to these "carve-outs" of the statute as judicial exceptions not examples.

We also again see exaggerated and false examples of "discovery" to discredit the term. Pure unapplied mathematical relationships, such as $E=mc^2$ and the law of

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[102] *Chakrabaty*, 447 U.S. at 307-310.

[103] *Chakrabaty*, 447 U.S. at 303-304.

[104] 447 U.S. at 309-310 (citing S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)); H.R. Rep. No.1923, 82d Cong., 2d Sess., 6 (1952). It is worth noting that the inventions "include anything under the sun that is made by man" quote was made by the Commissioner of Patents when summarizing the Patent Office's understanding of the bill. This quote was then used in the report to the Senate presented by Congressman Wiley, essentially adopting the Patent Office's interpretation as correct.

gravity $F=G(m_1m_2/r^2)$ are not made by man.[105] Congress has already given clear legislative intent that such are not patent eligible. The Court needed to go no further than statutory construction and legislative intent to reach a patent eligibility decision. It did not need to create exceptions to what Congress codified. Even if one were to go to the absurd to say these mathematical principals were intended by Congress to be patent eligible as discoveries of processes of nature falling under 35 U.S.C. § 101, they would certainly be caught by the novelty standard (35 U.S.C. 102), as these laws have been in existence since the big bang, around 13.7 billion years ago. The Court should stop using senseless examples of unapplied mathematics.

In *Diamond v. Diehr*,[106] Justice Rehnquist for the Court affirmed the patent eligibility of a process for making rubber, focusing on the subject of what is the scope of "process" added to 101 in the 1952 Act.[107]

> As in *Chakrabarty*, we must here construe 35 U.S.C. § 101 which provides: "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." In cases of statutory construction, we begin with the language of the statute. *Unless otherwise defined, "words will be interpreted as taking their ordinary, contemporary, common meaning," Perrin v. United States, 444 U.S. 37, 42, 100 S.Ct. 311, 314, 62 L.Ed.2d 199 (1979), and, in dealing with the patent laws, we have more than once cautioned that "courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.' " Diamond v. Chakrabarty, supra, at 308, 100 S.Ct., at 2207 quoting United States v. Dubilier Condenser Corp., 289 U.S. 178, 199, 53 S.Ct. 554, 561, 77 L.Ed. 1114 (1933).*
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> The Patent Act of 1793 defined statutory subject matter as "any new and useful art, machine, manufacture or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat.

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[105] *Id.* Albert Einstein was a highly skilled Patent Examiner at the Swiss Patent Office in 1905 when he published four groundbreaking articles in Annalen der Physik (the photoelectric effect, special relativity, Brownian motion and mass/energy interconversion). It is the last that propounded the formula $E=mc^2$. If Einstein had thought he was working on patent eligible subject matter, he was in the perfect position at the Swiss Patent Office, and with his superior intellect and not much money in his pocket, the incentive, to file a patent application on it. He did not. The reference to $E=mc^2$ is an example used in a number of S. Ct. decisions relating to § 101 for distracting dramatic effect.

[106] Diamond v. Diehr, 450 U.S. 175 (1981).

[107] *Id.* at 177-181. The claimed process used a mold for precisely shaping uncured rubber under heat and pressure and then curing it in the mold so that the product would retain its shape and be functionally operative after the molding is completed, ensuring the production of molded articles which are properly cured. *Id.* The patentee asserted the industry has not been able to obtain uniformly accurate cures because the temperature of the molding press could not be precisely measured, thus making it difficult to do the necessary computations to determine cure time and said their contribution to the art to resided in the process of constantly measuring the actual temperature inside the mold. *Id.* at 190-193. The continuous measuring of the temperatures inside the mold cavity, the feeding of this information to a digital computer which constantly recalculates the cure time, and the signaling by the computer to open the press, created a new process.

> 318. Not until the patent laws were recodified in 1952 did Congress replace the word "art" with the word "process." It is that latter word which we confront today, and in order to determine its meaning we may not be unmindful of the Committee Reports accompanying the 1952 Act which inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952), U.S.Code Cong. & Admin.News 1952, pp. 2394, 2399. Although the term "process" was not added to 35 U.S.C. § 101 until 1952 a process has historically enjoyed patent protection because it was considered a form of "art" as that term was used in the 1793 Act.[108]

In *Bilski v. Kappos*,[109] the Supreme Court finally admitted that its judicial exceptions to the federal statute are not required by the statutory text, although it asserted that the exceptions are "consistent with" it.[110] The Court also, for the first time, rationalized its judicial exceptions to the federal statute as "*statutory stare decisis*."[111] The Court thus acknowledged that it was acting outside of the bounds of the statutory language, and suggests its position that if the Court has created and used its own patent law for a long enough time, it should be able to continue. However, as discussed above, Congress has also repeatedly reaffirmed the "invention or discovery" standard from 1790 through 2011. And, since Congress is solely authorized to create patent law, these repeated recodifications prevail. The Court's quote below also conflates the consideration of the general categories of patent eligibility (inventions or discoveries) with the separate patentable subject matter requirements of novelty and obviousness. Later court cases took this conflation in a more draconian direction.[112]

> 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*

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[108] *Diehr*, 450 U.S. at 180-182 (emphasis added).

[109] Bilski v. Kappos, 561 U.S. 593 (2010). The Bilski patent application concerned methods to hedge (de-risk) investments in energy. *Id.* The method provided a technique by which an energy company can sell energy at one price to consumers based on historical averages and to another set of consumers with a different price calculation that will decrease its losses if the underlying energy cost changes unexpectedly. *Id.* The Primary Patent Examiner, Board of Patent Appeals and Interferences, Federal Circuit Court, and finally U.S. Supreme Court all rejected the claims based on patent eligibility. *Id.* The Courts could also have easily rejected the claims based on 35 U.S.C. § 102 or 35 § U.S.C. 103, as basic hedging strategies has been known for centuries.

[110] *Id.* at 593-94.

[111] *Id.* Of course, even statutory stare decisis, to the extent it is consistent with the Constitution, does not allow the removal of words from a federal statute.

[112] *See e.g.* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015) (holding that method to measure fetal DNA in the blood of a pregnant woman which avoided the previous need to invasively harvest blood from the fetus was not patent eligible); *cert. denied*, Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016).

> *statutory stare decisis going back 150 years.* See *Le Roy v. Tatham,* 14 How. 156, 174–175, 14 L.Ed. 367 (1853). The concepts covered by these exceptions are "part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none." *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130, 68 S.Ct. 440, 92 L.Ed. 588 (1948).[113]

The Court continued with its acknowledgement that it 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, 588–589, 98 S.Ct. 2522, 57 L.Ed.2d 451 (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. Concerns about attempts to call any form of human activity a "process" can be met by making sure the claim meets the requirements of § 101.[114]

This quote also reflects the Court's predilection to cite to its own earlier cases instead of the wording of the statute in what should be a strict statutory construction case. This is a theme running throughout these cases and the basis for the deviation from the required application of the literal terms of the law as passed by Congress.

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*,[115] the Court addressed whether a claim to optimizing the therapeutic efficacy of a treatment using 6-thiopurine for a gastrointestinal disorder with a discovered metabolic algorithm is patent eligible under § 101. Justice Breyer, writing for the Court, mentions § 101 at the beginning of the opinion, solely to introduce the Supreme Court's judicially created exceptions to it.[116] There is no further discussion of the statute or legislative history or intent. The whole of the opinion refers back to earlier Supreme Court precedent and the evolution of the Court's evolving common law on the subject, based on its own view of what should be patent eligible.

> Section 101 of the Patent Act defines patentable subject matter. It says: "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. *The Court has long held that this provision contains an important implicit exception.* "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond v. Diehr,* 450 U.S. 175, 185, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981); see also *Bilski v. Kappos,* 561 U.S. 593, ——, 130 S.Ct. 3218, 3233–3234, 177

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[113] *Ariosa Diagnostics*, 788 F.3d at 3225 (emphasis added).
[114] *Ariosa Diagnostics*, 788 F.3d at 3225.
[115] Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66 (2012).
[116] *Id.* at 70-71.

> L.Ed.2d 792 (2010); *Diamond v. Chakrabarty,* 447 U.S. 303, 309, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980); *Le Roy v. Tatham,* 14 How. 156, 175, 14 L.Ed. 367 (1853); *O'Reilly v. Morse,* 15 How. 62, 112–120, 14 L.Ed. 601 (1854); cf. *Neilson v. Harford,* Webster's Patent Cases 295, 371 (1841) (English case discussing same).[117]

The Court then admits that it 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." See, *e.g., Benson, supra,* at 71–72, 93 S.Ct. 253.[118]

From here, the Court digresses into economic analysis and the balance between patent protection and third party freedom to operate.

> These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." *Benson, supra,* at 67, 93 S.Ct. 253. *And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify.*[119]

The Constitution has not granted any authority to the Supreme Court to carry out economic analysis of what should be patent eligible, nor is it equipped to do so. The Supreme Court does not have the power to commission white papers, take testimony, review independent evidence, have one-on-one meetings with stakeholders or to take depositions, which are necessary to create public policy. Amicus briefs, while useful, do not take the place of these tools. The Supreme Court is arguably the worst equipped of the three branches of the government to evaluate patent policy. For this reason, our founding fathers did not give the Supreme Court the authority to set policy, although, as illustrated by the *Mayo* case, the Court has crossed that line. Creating a careful balance between the scope of incentive to promote the progress of science and impeding ancillary research is the sole domain of Congress.

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[117] *Id.*
[118] *Mayo*, 566 U.S. at 71 (emphasis added).
[119] *Id.* at 86 (emphasis added).

Further, the Court makes the surprising admission that since it is not equipped to determine which applied laws of nature should be patent eligible, it will simply reject all of them:

> Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern.[120]

The Executive Branch of the United States filed an *Amicus Curiae* in this case, urging that the Supreme Court more closely align its decision with the wording of the statute, which throws a wide net for patent eligibility and then a finer net using the requirements for patentability using § 102 for novelty and § 103 for obviousness.[121] The Court responded:

> The Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101's demands. Brief for United States as *Amicus Curiae*. The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U.S.C. § 102, that it not be "obvious in light of prior art," § 103, and that it be "full[y], clear[ly], concise[ly], and exact[ly]" described, § 112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under § 102.[122]

And, after admitting it cannot take its own judicially created exceptions too far or it will destroy patent law, the court defends the scope of its 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 Court's case 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. The relevant cases rest their holdings upon section 101, not later sections. *Bilski,* 561 130 S. Ct. 3218, 177 L.Ed.2d 792; *Diehr, supra* ; *Flook, supra* ; *Benson,* 409 U.S. 63, 93 S. Ct. 253, 34 L.Ed.2d 273.[123,124]

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[120] *Id.* at 89.

[121] Mayo Collaborative Servs. v. Prometheus Labs., *Inc.*, 2011 WL 4040414 (U.S.), 11 (2011).

[122] Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66, 89 (2012).

[123] *Id.*

[124] *Id.* at 89-90 (emphasis added). The Court also quoted to H.R. Rep. No.1923, 82d Cong., 2d Sess., 6 (1952) ("A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101*

The Supreme Court ultimately refused to apply the literal terms of § 101 in light of its "better established" deviating common law analysis.[125] It stated that "These considerations lead us to decline the Government's invitation to substitute §§ 102, 103, and 112 inquiries for the "better established" inquiry under § 101."[126] The Court's "better established" inquiry is its own case law. Compliance with the Constitution and the associated federal statute, however, is not an invitation.

The unconstitutional application of § 101 by the Supreme Court reached it apex in the 2013 case of *AMP v. Myriad Genetics*,[127] where it eliminated any shadows of "consistency" with the statutory language and instead head-on disobeyed it.

In *Myriad*, the Supreme Court considered the patent eligibility of certain isolated gene sequences which encode the BRACA1 and BRACA2 genes, the presence of which are highly predictive of the potential to get breast cancer.[128] The Court held the claims patent ineligible under 35 U.S.C. § 101.[129]

Writing for a unanimous Court, Justice Thomas focused not on the statutory language of 101 or legislative intent, but again instead, the judicially created exceptions to the statute and the economic policy reason for them, neither of which are empowered to the Court by the Constitution.

> We have "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." *Mayo,* 566 U.S., at ——, 132 S.Ct., at 1293 (internal quotation marks and brackets omitted). Rather, " 'they are the basic tools of scientific and technological work' " that lie beyond the domain of patent protection. *Id.,* at ——, 132 S.Ct., at 1293. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them." *Id.,* at ——, 132 S.Ct., at 1301. This would be at odds with the very point of patents, which exist to promote creation. *Diamond v. Chakrabarty,* 447 U.S. 303, 309, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980) (Products of nature are not created, and " 'manifestations ... of nature [are] free to all men and reserved exclusively to none' ").....As we have recognized before, patent protection strikes a delicate balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention." *Id.,* at ——, 132 S.Ct., at 1305. We must apply this well-established standard to determine whether Myriad's patents claim any "new and useful ... composition of matter," § 101, or instead claim naturally occurring phenomena.[130]

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unless the conditions of the title are fulfilled"). However, this Congressional statement actually supports the United States Amicus brief that the other sections of 35 U.S.C. (102, 103, and 112) should be determinative as long as the patent claims refers to something made by man.

[125] *Id.* at 90.

[126] *Id.* at 91-92.

[127] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

[128] *Ass'n for Molecular Pathology*, 569 U.S. at 576.

[129] *Id.* at 594.

[130] *Id.* at 589.

In a stroke of extraordinary judicial activism, the Supreme Court stated:

> groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. See *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440, 92 L.Ed. 588.[131]

It is hard to imagine a more unconstitutional statement than the Supreme Court ruling that discoveries cannot be patented when the statute it is applying states that any invention or discovery can be patented. In other words, the Court says "A not B" while the statute says "A or B." And, while the *Myriad* statement that a discovery is not an invention is inconsistent with 101, it is all the more inconsistent with the definition of invention added in 1952 in section 100 that an invention is a discovery. The Supreme Court, citing to its own judicially created exceptions to the statute and its associated common law precedent back to *Funk*, now refuses to grant a patent on the commercial application of a manmade discovery, even if it meets all of the requirements of § 101. In addition, it requires all lower courts to obey the Supreme Court instead of Congress.[132]

IV. CONCLUSION

How should the Supreme Court handle patent eligibility issues? Literally apply the statute and legislative history! It works quite well. Review the proposed claimed patent subject matter on the basis of whether it describes anything made by man and whether it is an invention or applied discovery. If so, proceed to the analysis of whether it is new and useful, and described in a manner that allows one of ordinary skill in that field to carry it out. Do not stray into economic analysis or the virtues of, or exceptions to, statutory patent eligibility or how Congress decided to exercise its discretion to promote the progress of science through a limited term monopoly versus third party freedom to operate, or the size of the created monopoly—the Court was not given that authority nor is it equipped to address it. If the decision, faithfully applying the statute, causes damage to an industry or subgroup, it is up to Congress to decide whether to fix it.

In law school, we learn that there is no right without a remedy. In the case of *Marbury v. Madison*, the U.S. Supreme Court held that it can review the

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[131] *Id.* at 576.

[132] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013). It is interesting to note that the Supreme Court was way out of its technical depth in addressing the Myriad genetic technology and made statements that sound odd to those in the field of genetics. For example, the Court held that cDNA is patent eligible because it is not naturally occurring, but isolated mRNA is not patent eligible because it is naturally occurring. However, cDNA is the simple hybrid of mRNA and is generated by using mRNA as the template, similar to a mold. Viruses, in fact, make cDNA through the use of reverse transcriptase of mRNA. The Government's Amicus Brief, which disagreed with 15 years of the well-established issuance of patents on isolated gene products by the U.S. Patent Office – yes, pitting two federal agencies of the Executive Branch (Center for Disease Control and National Institutes of Health) against the federal agency authorized to grant patents, the U.S. Patent Office – on useful isolated genes for diagnostics and therapeutics proposed this non-scientific distinction to give the Court an illusion of splitting the baby.

constitutionality of federal statutes.[133] However, who oversees the constitutionality of U.S. Supreme Court decisions? There is no private right of action in the U.S. for this. The sole remedy is to urge Congress to pass a law reversing the Supreme Court position. However, why should Congress have to pass a new law when the current law is clear on its face, just to say, we meant what we said the first time?

And when we say that there is no right without a remedy, does the term remedy mean any remedy or an effective, timely remedy? It took Congress 5-10 years to pass the America Invents Act. Does this mean the United States might have to wait another 5-10 years to force the Supreme Court to limit its patent opinions to strict statutory construction and legislative intent? And what if the law takes longer due to the preoccupation of Congress with other issues of national urgency? How many industries will be destroyed and applied discoveries not advanced for the promotion of science in the meantime? This takes us to a dark conclusion that there may be no short-term action available to force the Supreme Court to faithfully obey the Constitution.

The IPO,[134] AIPLA,[135] and ABA[136] have all proposed changes to the § 101 statute to address the issues described in this article. The IPO and AIPLA approaches are similar, which is not surprising given that many of the same people belong to both organizations. The ABA position is substantially different. The authors are strongly against the ABA position, which would codify, and thus retroactively justify, the Supreme Court's judicially created exceptions to § 101. Not only are these exceptions not necessary, but it would give the Court the impression that it can ignore the wording of a statute, create parallel and contradicting common law which is then retroactively accepted. How far would this go and into which unrelated areas?

We end where we start, with the quote from James Madison "In framing a government which is to be administered by men over men you must first enable the government to control the governed, and in the next place oblige it to control itself."[137]

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[133] Marbury v. Madison, 5 U.S. 137 (1803).

[134] *Proposed Amendments to Patent Eligible Subject Matter Under 35 U.S.C. § 101*, IPO (Feb. 7, 2017), https://www.ipo.org//wp-content/uploads/2017/02/20170207_IPO-101-TF-Proposed-Amendments-and-Report.pdf. The proposed 101 section by IPO adds a sole exception to patent eligibility. That "a claimed invention is ineligible . . . only if the claimed invention as a whole . . . exists in nature independently of and prior to any human activity."

[135] *AIPLA Legislative Proposal and Report on Patent Eligible Subject Matter*, AIPLA (May 12, 2017), https://www.aipla.org/detail/news/2018/08/27/AIPLA-Announces-Legislative-Proposal-on-Patent-Eligibility. The proposed 101 section by AIPLA also adds the sole exception to patent eligibility.

[136] *Re: Request for Comments Related to Patent Subject Matter Eligibility*, ABA (Mar. 28, 2017), https://www.americanbar.org/content/dam/aba/administrative/intellectual_property_law/advocacy/advocacy-20170328-comments.authcheckdam.pdf. The proposed 101 section by the ABA provides that subject matter is not patent eligible if the "scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea."

[137] THE FEDERALIST NO. 51, at 322 (James Madison) (Clinton Rossiter ed., 1999).