

STATEMENT OF

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BEFORE THE

**COMMITTEE ON THE JUDICIARY**  
Subcommittee on Intellectual Property

United States Senate

**“The State of Patent Eligibility in America: Part 1”**

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**I. Introduction**

Chairman Graham, Chairman Tillis, Ranking Member Feinstein, Ranking Member Coons, and Members of the Subcommittee:

Thank you for this opportunity to speak with you today about the Supreme Court’s recent patent eligibility jurisprudence and its negative impact on the U.S. innovation economy.<sup>1</sup>

Over the past decade, the U.S. patent system has been under an extensive amount of stress from all branches of the federal government. For its part, the Supreme Court is now deciding patent cases at a rate not seen for almost a hundred years,<sup>2</sup> changing the law in all aspects of the patent system. Among these numerous changes were four decisions between 2010 and 2014 on patent eligibility doctrine under § 101.<sup>3</sup> These decisions severely restricted the inventions and discoveries that have long been considered patentable for over two centuries in the U.S. patent system.

These four decisions culminated in the “*Alice-Mayo* framework”—a two-factor inquiry that courts and the U.S. Patent & Trademark Office (USPTO) have applied since 2014 in assessing whether

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<sup>1</sup> Professor Mossoff is speaking on his own behalf, and his testimony does not reflect the views of his employer or of any institution or organization with which he is affiliated.

<sup>2</sup> See John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 6 SUP. CT. REV. 273, 288 (2002).

<sup>3</sup> See *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014); *Association for Molecular Pathology v. Myriad Genetics*, 133 U.S. 2107 (2013); *Mayo Collaborative Services LLC v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010).

an invention or discovery is patentable subject matter under § 101.<sup>4</sup> The *Alice-Mayo* framework has created a tremendous amount of uncertainty for innovators and severely restricted the patent eligibility of high-tech and biopharmaceutical innovations. It has had a negative impact on both inventors and the companies working in the innovation industries that invest millions of dollars in creating the new products and services that drive economic growth, job creation and higher standards of living. Thus, it is undermining the longstanding comparative advantage by the U.S. in the world in securing reliable and effective patent rights for all innovators.

The *Alice-Mayo* framework is one of many recent changes to the U.S. patent system that has called into question the longstanding U.S. claim to a “gold standard” patent system as compared to the rest of the world.<sup>5</sup> As a result of the *Alice-Mayo* framework, the U.S. is now denying patent applications or invalidating issued patents in cutting-edge discoveries in medical care, such as treatments for breast cancer, diabetes, and strokes, among others.<sup>6</sup> This is an alarming shift from the historical approach of the U.S. in securing reliable and effective patent rights in new innovations, which has been a key driver of economic growth in the U.S.<sup>7</sup>

It is even more concerning in a global economy in which R&D investments and the venture capital financing that are the lifeblood of innovation can easily move from one country to another in search of more reliable legal security in the fruits of inventive labors. Historically, it was the U.S. that became the home to innovators and R&D financing. Even with period upheavals in U.S. patent policy over the past two centuries, the U.S. often forged ahead when other countries hesitated in securing patents in cutting-edge discoveries and inventions, such as in biotechnology and computer software.<sup>8</sup> China and European countries are now the ones forging ahead and securing reliable and

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<sup>4</sup> The two-factor inquiry is (1) determine whether the patent claim is directed to an abstract idea, natural phenomenon, or law of nature that are ineligible for patent protection, and, if it is, then (2) determine if the claim adds something more that transforms it into a patent-eligible application (an “inventive concept”) of one of these ineligible categories or is this additional activity in the claim merely well-understood, routine, and conventional activity in the art. *See Alice*, 573 U.S. at 217-18; *Mayo*, 573 U.S. at 75-80.

<sup>5</sup> *See* Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

<sup>6</sup> *See id.* at 955-959 (identifying patent applications for significant biomedical tests rejected by USPTO). For a few examples of the many patents invalidated by courts, *see* *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed. Appx. 1013 (Fed. Cir. 2019) (nonprecedential) (invalidating a patent on a biotech-based medical test for detecting heart disease as covering a patent-ineligible law of nature); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019) (invalidating a patent on a biotech-based medical test for identifying neurological disorders as covering a patent-ineligible law of nature); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (invalidating a patent on non-invasive prenatal test using fetal DNA found the blood of the mother as covering a patent-ineligible law of nature and natural phenomenon);

<sup>7</sup> *See* Stephen Haber, *Patents and the Wealth of Nations*, 23 Geo. Mason L. Rev. 811 (2016) (surveying historical evidence and economic studies confirming that patents are a key factor in successful innovation economies); B. ZORINA KHAN, *THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790-1920* (2005) (detailing the key role that reliable and effective property rights in patents have served in spurring markets and economic growth in the U.S.). A recent economic study proves that patents more than double a startup’s chances of obtaining venture capital financing, and thus significantly increases a startup’s chances in growing into a small business in the marketplace. *See* Joan Farre-Mensa et al., *What is a Patent Worth? Evidence from the U.S. Patent “Lottery”* (Nat’l Bureau of Econ. Research) (March 14, 2017), at <https://ssrn.com/abstract=2704028>. Notably, small businesses create 65.9% of net new jobs in the country. *See* SMALL BUSINESS ADMINISTRATION, OFFICE OF ADVOCACY, FREQUENTLY ASKED QUESTIONS (June 2018), <https://www.sba.gov/sites/default/files/advocacy/Frequently-Asked-Questions-Small-Business-2018.pdf>.

<sup>8</sup> *See* Madigan & Mossoff, *supra* note 5, at 942-946 (detailing this historical approach in biotech and software).

effective patents in innovation that the U.S. no longer protects due to the closing of its patent system under the *Alice-Mayo* framework.<sup>9</sup>

Congress should reform § 101 to reclaim the “gold standard” title for the U.S. patent system in securing reliable and effective property rights in the fruits of inventive labors. Article III courts created this problem with their judicial gloss on § 101 in fashioning the *Alice-Mayo* framework. The USPTO is unable to fix this problem given that it is only an administrative agency in the Executive Branch that is legally bound to obey the decisions of the Supreme Court and Court of Appeals for the Federal Circuit. Thus, it falls on Congress to achieve the necessary reform of § 101 to return the U.S. patent system back to its original constitutional function in “promoting the Progress . . . of the useful Arts.”<sup>10</sup>

In my comments, I will address several reasons that justify congressional action in reforming § 101 today. First, the high rates of invalidation of patents by courts and of rejection of patent applications by the USPTO under the *Alice-Mayo* framework is striking. There is widespread use of § 101 today. This is outside of historical norms for a doctrine this was understood to be “only a threshold test” among the more substantive and searching patentability requirements of novelty, nonobviousness, and disclosure.<sup>11</sup> Second, recent reforms at the USPTO in examination guidelines in applying the *Alice-Mayo* framework, while positive, are insufficient to solve the problem. Third, Congress has had to abrogate Supreme Court decisions and correct doctrinal requirements in the patent statutes many times in the past two hundred years,<sup>12</sup> and its enactment of § 103 in the 1952 Patent Act is a model for Congress to reform § 101.<sup>13</sup> In fact, § 103 was enacted in response to the exact same problems in nonobviousness doctrine that innovators face today under patent eligibility doctrine: a 1941 Supreme Court decision created a highly restrictive test for nonobviousness resulting in extensive invalidation of patents. In 1949, Justice Robert Jackson observed that in its zeal to address a concern about improperly granted patents, the Court had gone too far such “that the only patent that is valid is one which this Court has not been able to get its hands on.”<sup>14</sup>

Justice Jackson’s lament in 1949 could just as easily have been written today about the Supreme Court’s interpretation and application of § 101 under the *Alice-Mayo* framework. As with the

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<sup>9</sup> See *id.* See also Elizabeth Chien-Hale, *A New Era for Software Patents in China*, LAW360 (May 25, 2017), <https://www.law360.com/articles/924934/a-new-era-for-software-patents-in-china> (“China’s opening up [of its patent system to new high-tech innovation] contrasts with the United States’ move to cut back on business method patents and software patents.”); Preetika Rana, *Your Cancer Drugs May Soon Be Discovered in China*, WALL STREET JOURNAL (Apr. 11, 2017), <https://www.wsj.com/articles/china-emerges-as-powerhouse-for-biotech-drugs-1491816607> (reporting on R&D investment shifting to China given the inability of U.S. companies to obtain patents for their biotech drugs); Jack Ellis, *China Relaxes Rules on Software Patentability – and the United States Loses More Ground*, IAM (Mar. 3, 2017), <https://www.iam-media.com/law-policy/china-relaxes-rules-software-patentability-and-united-states-loses-more-ground>. (“China’s apparent embrace of software patents stands in stark contrast to the situation in the United States, which many would see as the traditional home of the software industry.”).

<sup>10</sup> U.S. Const. art. I, § 8, cl. 8.

<sup>11</sup> *Bilski*, 561 U.S. at 602.

<sup>12</sup> See Adam Mossoff, *Statutes, Common-Law Rights, and the Mistaken Classification of Patents as Public Rights*, 104 IOWA L. REV. (2019) (forthcoming), available at <https://ssrn.com/abstract=3289338>, at 24 (identifying past examples of Congress abrogating judicially-created patent doctrines, including the prohibition on functional claiming, the prohibition on “new use” patents, and the “flash of creative genius” test).

<sup>13</sup> See Patent Act of 1952, Pub. L. No. 82-593, § 103, 66 Stat. 792, 798.

<sup>14</sup> *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

enactment of § 103 in 1952, it is time for Congress to reform § 101. Congress should abrogate the *Alice-Mayo* framework and reestablish patent eligibility doctrine as only a threshold inquiry among the several statutory patentability requirements. Section 101 is not meant to be applied in an overly restrictive manner in invalidating all types of innovation long secured by the U.S. patent system, as is happening today under the *Alice-Mayo* framework.

## II. The Closing of the U.S. Patent System to Innovation

The empirical data on the rates of invalidation of patents by courts and of rejection of patent applications by the USPTO is striking. Between 2014 and 2018, there has been widespread application of *Alice-Mayo* framework under § 101, but patent eligibility doctrine was long understood to be “only a threshold test” among the more substantive and searching patentability requirements of novelty, nonobviousness, and disclosure.<sup>15</sup> The data also confirms extensive invalidations of patents and rejections of patent applications under the *Alice-Mayo* framework outside of historical norms. This is concerning given that it represents a significant break from the successful approach in the U.S. in promoting its own innovation economy. It also now places the U.S. at a relative disadvantage compared to other countries, such as China, who have a clear policy of promoting new inventions as a basis for growing their own innovation economies.

The U.S. has long been regarded as the world leader in securing property rights in technological innovation, securing the next wave of innovation with patent protection when the rest of the world hesitated. The U.S. patent system has been successful precisely because it consistently secured reliable and effective property rights in the fruits of inventors’ labors.<sup>16</sup> This pattern of U.S. leadership in patented innovation continued up through the two most recent technological revolutions of our modern era: the biotechnology<sup>17</sup> and high-tech revolutions.<sup>18</sup>

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<sup>15</sup> *Bilski*, 561 U.S. at 602.

<sup>16</sup> B. Zorina Kahn, *Trolls and Other Patent Inventions: Economic History and the Patent Controversy in the Twenty-First Century*, 21 GEO. MASON L. REV. 825, 855 (2014) (“Intellectual property institutions were successful in the United States largely because they ensured open access to creative individuals, decentralized decision making and extensive markets for technology, and strong legal enforcement of such rights.”); Adam Mossoff, *A Brief History of Software Patents (and Why They’re Valid)*, 56 ARIZ. L. REV. SYLLABUS 62, 79 (2014) (“The American patent system has succeeded because it has secured property rights in the new innovation that has come about with each new era—and it has secured the same property rights for all types of new inventions, whether in the Industrial Revolution or in the Digital Revolution.”).

<sup>17</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (affirming the patentability of a genetically modified organism given the expansive approach in U.S. patent law in securing new innovations); see also ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY* 77 (4th ed. 2007) (noting how the Supreme Court’s decision *Diamond v. Chakrabarty* was “extremely important for the then nascent biotechnology industry because it established that the fruits of the industry’s research . . . would be eligible for patenting”); LIFE SCIENCES AND BIOTECHNOLOGY: A STRATEGY FOR EUROPE, EUROPEAN COMMISSION (2002) (discussing Europe’s “fragile” biotechnology sector and noting that “the US biotechnology industry started earlier, produces more than three times the revenues of the European industry, employs many more people (162,000 against around 60,000), is much more strongly capitalized and, in particular, has more products in the pipeline.”).

<sup>18</sup> See *Diamond v. Diehr*, 450 U.S. 175 (1981) (affirming the patentability of a rubbing curing process whose only novel element was the use of a computer software program to operate the 150-year-old process); see also Mossoff, *supra* note 17 (explaining how courts secured computer software within the patent system in an incremental process from the 1980s through 1990s and why they did so given the value of computer software as a product for consumers and businesses in the marketplace).

Courts are now relying on § 101 and applying the *Alice-Mayo* inquiry in many more decisions than what they have historically done in the past, and the invalidation rates are similarly high compared to historical practices. Between July 2014 and June 2018, courts issued 692 decisions in which judges applied the *Alice-Mayo* framework to assess the validity of a patent.<sup>19</sup> The overall invalidation rate was 65.8%. The Federal Circuit’s invalidation rate was 87.5%. At the Patent Trial & Appeal Board (PTAB), the invalidation rate under the *Alice-Mayo* framework for business method patents is even higher—an astounding 97.9% of patents invalidated in final decisions.

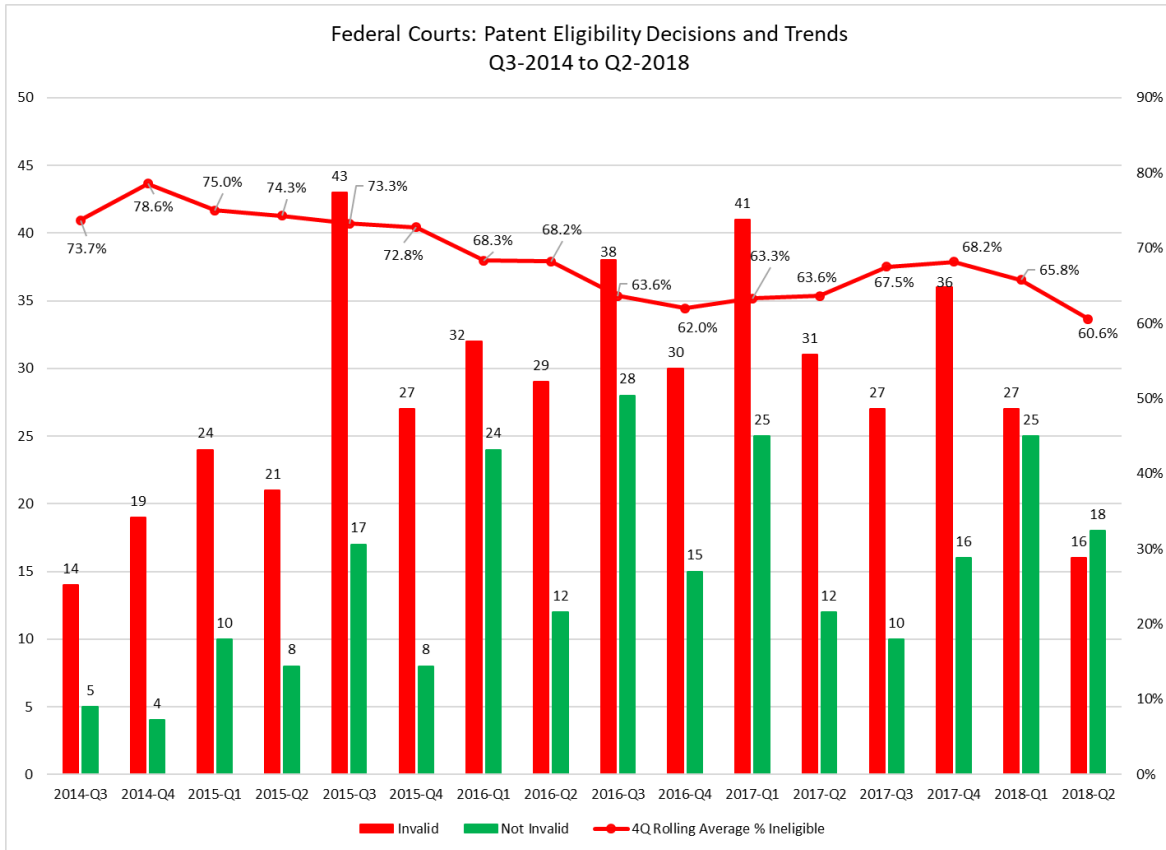
	Total	Valid	Invalid	% Invalid
Fed. Ct. Decisions	692	237	455	65.8%
Federal Circuit	128	16	112	87.5%
District Courts	564	221	343	60.8%
Patents	1114*	494	675	60.6%
Motions on Pleadings	382	147	235	61.5%
PTAB CBM Petitions	182	26	156	85.7%
PTAB CBM Final Decisions	97	2	95	97.9%
PTAB PGR Petition	7	4	3	42.9%
ITC (Initial Determination, Summary Determination, & Comm. Review)	19	12	7	36.8%

As of 6/30/18

While there has been a slight downward trend in the rate of invalidations of patents by courts over these four years, the average invalidation rate appears to have stabilized at a significantly high percentage, fluctuating within a range of 60% to 70% in the past couple years.<sup>20</sup>

<sup>19</sup> For questions about his dataset, Robert R. Sachs may be reached at [rsachs@patentevaluations.com](mailto:rsachs@patentevaluations.com).

<sup>20</sup> Data from Robert R. Sachs. For questions, Mr. Sachs may be reached at [rsachs@patentevaluations.com](mailto:rsachs@patentevaluations.com).



These are only the invalidation rates of existing patents by courts and by the PTAB. Patent applicants in many areas of innovation in the twenty-first-century economy have faced a stringent gauntlet at the USPTO under the *Alice-Mayo* framework. There are examination units at the USPTO for inventions in e-commerce, business cryptology, and healthcare who were rejecting applications on the basis of the *Alice-Mayo* framework at rates well over 80% or over 90% in 2017 and in the first quarter of 2018.<sup>21</sup>

<sup>21</sup> Data from Robert R. Sachs. For questions, Mr. Sachs may be reached at [rsachs@patentevaluations.com](mailto:rsachs@patentevaluations.com).

**Percent of Office Actions with Section 101 Rejections  
2017 vs. 2018 Q1**

Tech Center	Art Unit Technology	2017	2018 Q1
1600	Agriculture	21%	17%
	Chemical Engineering	4%	3%
	Immunology	13%	12%
	Medicine	3%	2%
	Microbiology	16%	15%
	Molecular Biology	24%	21%
1700	Chemical Engineering	1%	1%
2100	Computer Engineering	22%	29%
	Computer Science & Applications	39%	54%
2400	Communications & Networking	20%	25%
	Computer Science & Applications	19%	26%
	Cryptography	34%	45%
2600	Communications & Networking	11%	14%
	Computer Engineering	3%	3%
	Computer Science & Applications	20%	23%
	Signal Processing	20%	24%
2800	Electrical Components, Devices & Sys.	10%	12%
	Physics	3%	4%
	Semiconductors	5%	9%
3600	Civil Engineering	3%	3%
	Manufacturing	2%	1%
	Transportation	14%	14%
3600BM	Business Crypto	80%	78%
	Business Processing	91%	91%
	Cost/Price, Reservations	88%	89%
	E-Shopping	85%	86%
	Finance & Banking	93%	92%
	Health Care	94%	93%
	Incentive Programs	90%	87%
	Operations Research	92%	91%
	POS, Inventory, Accounting	73%	68%
3700	Amusement & Education	35%	38%
	Apparel	0%	0%
	Energy & Power	2%	2%
	Manufacturing	1%	0%
	Medicine	10%	11%
<b>Overall Average</b>		<b>15%</b>	<b>17%</b>

These high rates of rejections of patent applications are not merely a departure from historical U.S. practices. They also signal that the U.S. has closed its patent system as compared to China and Europe. A recent study of patent applications between August 2014 and September 2017 found that 1,694 patent applications that were abandoned after receiving initial or final rejections by the USPTO for lack of patent eligibility under the *Mayo-Alice* inquiry. What makes these 1,694 patent applications important is that, in contrast to the U.S., the patents applications for the same inventions and discoveries were *granted* by China, the European Patent Office, or both.<sup>22</sup>

<sup>22</sup> See Madigan & Mossoff, *supra* note 5, at 956. For a description and link to the complete database of 48,586 total patent applications that received either an initial or final rejection based on the *Mayo-Alice* inquiry and then were subsequently abandoned, see *id.*, at 941 n.10.

Given past U.S. leadership relative to other world economies, this data represents a disturbing trend for the future of the U.S. innovation economy, especially compared to countries like China. Since 2014, patent applications at the USPTO for important inventions in the diagnosis and treatment of breast cancer, lung cancer, gynecological cancer, liver disease, diabetes, ultrasound imaging (used in neonatal care and in other medical treatments), and others, were rejected under the *Alice-Mayo* framework. These same inventions and discoveries were secured with patent protection by China, the European Patent Office, or both.<sup>23</sup> The signal this sends to inventors and companies is not just that the U.S. has changed course from its own past innovation policy, but that it is diverging from other countries that already have or are developing patent systems securing reliable and effective property rights in cutting-edge innovations.

The high rates of invalidations and rejections is also revealing because the *Alice-Mayo* framework is often accused of being indeterminate and providing little predictability for inventors or lawyers in how a judge or examiner at the USPTO may choose to apply it. Yet, it does appear to offer some predictability: the odds of receiving or keeping a patent under § 101 are not in your favor if you are innovating new products and services in computer software, internet technologies, cryptology, medical diagnostics, medical devices, and other inventions driving the U.S. innovation economy.

This invalidation contagion is spreading, too, and is not limited to cutting-edge inventions in the twenty-first-century innovation economy. Patents covering classic technologies from the Industrial Revolution are now being invalidated as ineligible subject matter under the *Alice-Mayo* framework. Some recent examples include patents on methods covering automobile engines and oil drilling rigs.<sup>24</sup> Patent applications on methods of operating combustion engines are also being rejected for claiming an abstract idea or law of nature.<sup>25</sup>

Despite numerous certiorari petitions seeking both clarification on the *Alice-Mayo* framework and development of limiting principles to cabin in the excessive invalidations of patents on breakthrough inventions and discoveries, the Supreme Court has denied every certiorari petition since its 2014 decision in *Alice*. The Supreme Court appears to be uninterested, unwilling, or unable to fix this problem, and thus it rightly falls on Congress. The *Alice-Mayo* framework represents only a judicial gloss on a statute that was first enacted by Congress in 1790 and subsequently re-enacted in varying forms up through 1952.<sup>26</sup> Thus, Congress should act in amending this statute, and the proposed draft amendments for § 101 address the key doctrinal concerns plaguing innovators and causing the excessive invalidation of patents since 2014.

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<sup>23</sup> See *id.* at 957-958.

<sup>24</sup> See, e.g., *TDE Petroleum Data Solutions v. AKM Enterprise Inc.*, 657 Fed. Appx. 991 (Fed. Cir. 2016) (nonprecedential) (applying *Alice-Mayo* framework to invalidate a patent on a method of operating an oil drilling rig despite exact parallels in claims to those affirmed as patent eligible in *Diamond v. Diehr*, 450 U.S. 175 (1981)); *American Axle & Mfg., Inc. v. NEAPCO Holdings LLC*, 309 F. Supp. 3d 218 (D. Del. 2018) (applying *Alice-Mayo* framework to invalidate a patent on a method of constructing and operating a driveshaft in an automobile engine as claiming a unpatentable law of nature).

<sup>25</sup> See Madigan & Mossoff, *supra* note 5, at 958.

<sup>26</sup> See *Bilski*, 561 U.S. at 601-02 (noting that the judicially-created exclusionary rule prohibiting patents for “laws of nature, physical phenomena, and abstract ideas” is “not required by the statutory text” in § 101); *Bilski*, 561 U.S. at 637 (Stevens, J., concurring) (“[A]lthough the Patent Act was amended, revised or codified some 50 times between 1790 and 1950, Congress steered clear of adding statutory requirements of patentability.”) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 10 (1966)).



### III. Regulatory Reforms in Examination Guidelines at the USPTO are Not Enough

In early January 2019, USPTO Director Andrei Iancu, who was recently appointed and confirmed by the Senate in early 2018, issued new examination guidelines under the *Alice-Mayo* framework. Director Iancu announced the reforms with the intent to “improve certainty and reliability” in how examiners would use § 101 in reviewing patent applications.<sup>27</sup> Anecdotal reports in recent months indicate that patent applications may now be faring a bit better under the *Alice-Mayo* framework than they were in the years between 2014 and 2018.

However, Director Iancu is limited in how much he can achieve. First and foremost, he has authority only over the USPTO, not the courts. Thus, even if the USPTO scales back its high rates of rejections under the *Alice-Mayo* framework, courts and the PTAB will continue to invalidate these patents in alarmingly high numbers in their own application of the *Alice-Mayo* framework. This is not merely a law professor’s hypothetical scenario. On April 1, 2019, the Federal Circuit applied the *Alice-Mayo* framework to invalidate another patent under § 101 on a breakthrough diagnostic method for detecting heart disease; the court held that the patent claimed a “law of nature.”<sup>28</sup> In this case, the patent owner argued that the Federal Circuit should defer to the USPTO’s examination guidelines in finding this invention to be patent eligible. The court expressly *rejected* this contention, stating that “we are not bound by [the USPTO’s] guidance.”<sup>29</sup>

Second, and related to the first point, Director Iancu lacks the legal authority to change the fundamental cause of the problem: the *Alice-Mayo* framework created by the U.S. Supreme Court. While Director Iancu has some discretion to act within this generalized legal inquiry to lessen its arbitrariness and negative impact in examining patent applications, he must ultimately follow the law set by Congress and the Supreme Court. In fact, his reforms in the examination guidelines have been criticized by policy organizations for failing to do just this; the Electronic Frontier Foundation (EFF), for example, started a “Save Alice” campaign, arguing that “Under its new Director, Andre [sic] Iancu, the Patent Office is trying get around *Alice*.”<sup>30</sup> In its official comments on the new guidance for examiners, EFF argued that it is “contrary to law.”<sup>31</sup>

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<sup>27</sup> U.S. Patent and Trademark Office announces revised guidance for determining subject matter eligibility (Jan. 4, 2019), <https://www.uspto.gov/about-us/news-updates/us-patent-and-trademark-office-announces-revised-guidance-determining-subject>.

<sup>28</sup> See *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed. Appx. 1013 (Fed. Cir. 2019) (nonprecedential).

<sup>29</sup> See *id.* at 1020 (“While we greatly respect the PTO’s expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.”).

<sup>30</sup> See <https://act.eff.org/action/save-alice-tell-the-patent-office-to-apply-supreme-court-law> (last visited May 30, 2019).

<sup>31</sup> See Stuart P. Meyer, *No Shortage of Viewpoints on New USPTO Patent Eligibility Guidelines*, BilskiBlog (Mar. 26, 2019), <https://www.bilskiblog.com/2019/03/no-shortage-of-viewpoints-on-new-uspto-patent-eligibility-guidelines/> (quoting from EFF’s comment filed with the USPTO). Another EFF attorney, Daniel Nazer, referred to Director Iancu’s regulatory reforms as “the agency’s most radical move yet” in permitting “a renewed flood of bogus patents.” Daniel Nazer, *Call to Action: Tell the Patent Office Not to Reopen the Software Patent Floodgates* (Feb. 6, 2019), <https://www.eff.org/deeplinks/2019/02/call-action-tell-patent-office-not-reopen-software-patent-floodgates> (last visited May 30, 2019).

Lastly, Director Iancu’s regulatory reforms can just as easily be undone, whether by a legal challenge in court for allegedly exceeding his authority or by repeal by administrative fiat by a future Director of the USPTO. While Director Iancu’s reforms may constrain some of the excessive use of the *Alice-Mayo* framework in rejecting patent applications, these regulatory measures cannot offer the promise of long-term permanence and stability. Inventors and companies making long-term R&D investment decisions need to rely on a stable set of legal rules in order to create innovative medical treatments and other new technologies. They need Congress to amend § 101 and permanently reestablish the longstanding historical approach of a restrained and limited application of this threshold test.

#### **IV. The Enactment of § 103 in the 1952 Patent Act is a Guide for Reform of § 101 Today**

Congress should reform § 101 today. It should do so to reset U.S. innovation policy back on its original path, which has been a wellspring for two centuries of growth in the U.S. innovation economy. The problems faced by innovators today under the *Alice-Mayo* framework are entirely doctrinal—they are the result of a judicial decision based in a statute enacted by Congress. These problems can be addressed through legislative reform.

In reforming § 101, Congress will not tread on new ground. Its enactment of § 103 in the 1952 Patent Act<sup>32</sup> is a model for how Congress can (and should) reform § 101 today. Congress enacted § 103 into law to address the same doctrinal and policy problems that innovators face today with the *Alice-Mayo* framework. In both form and substance, the draft legislative language achieves two key functions that were achieved by the enactment of § 103.

##### **A. Section 103 Successfully Abrogated a Supreme Court Decision That Undermined the Function of the U.S. Patent System in Promoting Innovation**

Similar to the pressing need today to abrogate the *Alice-Mayo* framework, Congress enacted § 103 in 1952 to abrogate the Supreme Court’s 1941 decision in *Cuno Engineering v. Automatic Devices*.<sup>33</sup> In this case, the Supreme Court applied a longstanding legal requirement in U.S. patent law that an invention or discovery must be more than new, useful, and fully disclosed to justify patent protection—it must also be a true invention, as opposed to a minor and obvious step forward in a field of art.<sup>34</sup> In *Cuno Engineering*, the Supreme Court ruled that an invention must arise from a “flash of creative genius” to justify patent protection.<sup>35</sup>

Just as today with the *Alice-Mayo* framework, the “flash of creative genius” test was an insuperable hurdle for inventors to overcome. Courts dissected patent claims into their individual elements, found each element to be lacking a “flash of creative genius,” and thus invalidated many patents.

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<sup>32</sup> See Patent Act of 1952, Pub. L. No. 82-593, § 103, 66 Stat. 792, 798.

<sup>33</sup> *Cuno Eng’g Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941).

<sup>34</sup> This hoary patentability requirement was renamed in §103 as the requirement that an invention must be “nonobvious.” This was necessary to distinguish it clearly from the separate novelty requirement, which had created some confusion among some courts and some indeterminacy in the doctrine. See *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966) (“The major distinction [between § 103 and the older case law] is that Congress has emphasized ‘nonobviousness’ as the operative test of the section, rather than the less definite ‘invention’ language . . . that Congress thought had led to ‘a large variety’ of expressions in decisions and writings.”).

<sup>35</sup> *Id.* at 91.

The Supreme Court did just this in *Cuno Engineering*: the Court invalidated a patent on a new electric-powered cigarette lighter in automobiles (we use these sockets today in our automobiles to power our smartphones). The *Cuno Engineering* Court assessed each separate element in the claim, identifying how each part was old, such as an electrical circuit, a heating element, and temperature control by a thermostat, among others. Despite the novel, useful, and inventive combination of these old elements into an innovative device that was widely successful in the marketplace and became a ubiquitous feature in all automobiles, the Court concluded the invention was not the result of a “flash of creative genius” and thus invalidated the patent.

After *Cuno Engineering*, the Supreme Court was invalidating patents so frequently under the “flash of creative genius” test that Justice Jackson lamented in 1949 that “the only patent that is valid is one which this Court has not been able to get its hands on.”<sup>36</sup>

Justice Jackson’s complaint could just as easily be said today about patent eligibility doctrine and the *Alice-Mayo* framework. As confirmed in Part I, courts are extensively invalidating patents and the USPTO has been rejecting patent applications at very high rates as well. In fact, just as in *Cuno Engineering* decision itself, the Supreme Court invalidated the contested patent claims in its four patent eligibility cases in creating the *Alice-Mayo* framework.<sup>37</sup>

Congress responded in 1952 by enacting § 103, and part of its purpose was to abrogate the “flash of creative genius” test created eleven years earlier by the Supreme Court in *Cuno Engineering*. The second sentence in § 103 achieves this goal: “Patentability shall not be negated by the manner in which the invention was made.”<sup>38</sup> Having performed this function in relegating the “flash of creative genius” test to the historical dustbin of mistaken legal doctrines, this sentence in § 103 has served no role in patent law since 1952. Congress should do this again with the *Alice-Mayo* framework, as the draft legislative language proposes to do.

## **B. Section 103 is a Model for Congress to Reform § 101 Because It Expressly Mandates Considering Only the “Claimed Invention as a Whole” in Assessing Patentability**

Section 103 is also a model for § 101 reform today given its simplicity in both form and substance, as reflected in the proposed draft legislative language for § 101. Section 103 is two sentences in length with all of the doctrinal work falling within the first sentence. Here, it sets forth several doctrinal requirements to ensure that the restyled “nonobviousness” inquiry would be more predictable and bounded in its application.<sup>39</sup> One requirement expressly brought to an end the judicial practice of dissecting claims into their individual elements and then assessing each basic element as being ordinary, routine, or obvious, just as the Supreme Court did in *Cuno Engineering*.<sup>40</sup> Thus, § 103 mandates that the obviousness of an invention can be determined only

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<sup>36</sup> *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

<sup>37</sup> See *supra* note 3.

<sup>38</sup> 35 U.S.C. § 103; see also *Graham*, 383 U.S. at 15 (“Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase ‘flash of creative genius’ . . .”).

<sup>39</sup> See *supra* note 34.

<sup>40</sup> Another requirement eliminated the subjective and arbitrary nature of an inquiry into what counts as “creative genius” by establishing an objective standard of legal evaluation: the person having ordinary skill in the art (known in patent law by the acronym, PHOSITA).

by assessing the “invention as a whole” (reframed as the “claimed invention as a whole” in the America Invents Act of 2011).

Congress adopted the “claimed invention as a whole” requirement in § 103, because this is a basic legal requirement that is fundamental to many provisions of the Patent Act in ensuring proper protection of the rights of inventors and the predictable application of the law.<sup>41</sup> As the Supreme Court recognized almost four decades ago in a significant patent eligibility case that has been ignored since 2014, it is “inappropriate to dissect the claims” down into their component elements, because an unpatentable abstract idea or law of nature may be used in part of a claim on a process, such as “a mathematical formula,” but “the process *as a whole* does not thereby become unpatentable subject matter” simply because of this single element.<sup>42</sup>

This is supposed to be settled patent law, and courts even state this legal rule in patent eligibility decisions today, at least in the abstract before deciding otherwise.<sup>43</sup> Even in the Supreme Court’s 2012 decision in *Mayo Collaborative Services v. Prometheus Laboratories*, it cautioned that “too broad an interpretation of this exclusionary principle [under § 101] could eviscerate patent law,” because “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”<sup>44</sup> This is true of combustion engines that rely on the laws of thermodynamics, as well as drugs that rely on the natural phenomena of how molecules are processed by and affect the human body, and of the software programs performing valuable functions in modern computers that rely on abstract ideas of mathematical algorithms. Each of these innovations—engines, drugs, and software programs—have long been recognized by the courts as representing real-world innovations deserving of patent protection as long as they are novel, useful, and fully disclosed. At least, this was the law before the *Mayo-Alice* framework was developed by the Supreme Court and applied by lower courts since 2014.

A significant reason for the high rates of invalidation of issued patents and of rejection of patent applications is that courts and examiners are dissecting claims down into their component elements and invalidating them under the *Mayo-Alice* framework as covering unpatentable subject matter with no nonobvious, inventive contributions in these specific elements. Courts and the USPTO were expressly authorized to do this by the Supreme Court in its 2014 decision in *Alice Corporation v. CLS Bank International*. Contradicting longstanding and settled patent law in assessing or applying a claim as a whole, the Court in *Alice* said that “we consider the elements of each claim both *individually* and ‘as an ordered combination.’”<sup>45</sup> Who could blame courts and

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<sup>41</sup> For example, it is a basic requirement in assessing the novelty of an invention under § 102, where it is called the “identity” requirement. When an examiner at the USPTO or a court assesses the novelty of a patent claim, it must match “each and every element as set forth in the claim . . . in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In sum, there must be a one-to-one symmetry between a claimed invention as a whole and a single pre-existing example of the alleged invention in the prior art. It is impermissible to focus on a single element in a claim or to ignore other elements in the claim.

<sup>42</sup> *Diehr*, 450 U.S. at 187.

<sup>43</sup> See *Parker v. Flook*, 437 U.S. 584, 594 (1978) (“[A] patent claim must be considered as a whole.”); *Athena Diagnostics*, 915 F.3d at 750 (“The step one ‘directed to’ inquiry [of the *Alice-Mayo* framework] focuses on the claim as a whole.”); *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) (describing “the first-stage inquiry as looking at the ‘focus’ of the claims, their ‘character as a whole’”).

<sup>44</sup> *Mayo Collaborative Services*, 566 U.S. at 71.

<sup>45</sup> *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 79) (emphasis added).

examiners for feeling justified in considering elements “individually” when the Supreme Court instructed them to do so in the *Alice-Mayo* framework?

There are too many examples to review here, and thus one illustrative court opinion must suffice. In a recent patent eligibility decision in *TDE Petroleum Data Solutions v. AKM Enterprises*, the district court and the Federal Circuit both concluded that a patent on a process for operating an oil drilling rig was invalid for allegedly claiming only an “abstract idea.”<sup>46</sup> In this case, the Federal Circuit and the district court dissected the patent claim into separate elements and ignored other express elements that comprised the claimed invention as a whole. In its opinion, the Federal Circuit focused solely on a single element in the claim, and then asserted that the invention as a whole performed only the “generic computer functions” of this single element.<sup>47</sup> Thus, the Federal Circuit disintegrated the claimed invention into a single element—reducing it to the single abstract idea of generic and abstract data analysis—and ignored other claim elements, such as the express terms “well operation” in the claim and other language in the patent that made it clear the claimed invention as a whole was for an industrial process in running an oil-drilling operation on an oil rig.

Even worse, the *TDE Petroleum* decision directly contradicted the Supreme Court’s own ruling in *Diamond v. Diehr* in 1981 that affirmed the patent eligibility under §101 of an almost identically structured patent claim covering a computer-operated industrial rubber curing process.<sup>48</sup> In *Diehr*, the data processing element in the claim referred to a well-known equation that had long been used for many years in the even older 150-year-old process of curing rubber. For this reason, the Supreme Court recognized this data processing element in the claim was not patentable *by itself*.<sup>49</sup> Yet, the Supreme Court concluded that the invention was patent eligible under § 101 precisely because the *claimed invention as a whole* was an industrial process.<sup>50</sup> Unfortunately, such contradictions in the § 101 case law have become all too common given the practice of courts under the *Alice-Mayo* framework in deciding how and in what ways they will dissect claims into their component parts in determining if the claims fall within the judicially-created exclusionary principle prohibiting the patenting of abstract ideas or laws of nature.

It bears emphasizing that the proposed congressional reform of § 101 in abrogating the *Alice-Mayo* framework merely returns the U.S. patent system back to its original constitutional function in securing to “Inventors the exclusive Right to their . . . Discoveries.”<sup>51</sup> In aggressively using § 101 in applying the *Alice-Mayo* framework today, courts are misapplying what was historically understood to be merely a threshold test. They are also now dissecting claims into their component parts and then focusing on one or two elements that are deemed to represent the “focus” of the entire claim as a whole.<sup>52</sup> Courts thus easily conclude that this single element, or two elements, is an ineligible claim to an abstract ideas or laws of nature.

This new method of interpreting patents today under the *Alice-Mayo* framework would result in the invalidation of the very first patent that issued in the U.S. under the first Patent Act of 1790.

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<sup>46</sup> See *TDE Petroleum Data Solutions*, 657 Fed. Appx. at 993.

<sup>47</sup> *Id.*

<sup>48</sup> *Diamond v. Diehr*, 450 U.S. 175 (1981).

<sup>49</sup> See *Diehr*, 450 U.S. at 188. (observing that the “Arrhenius’ equation is not patentable in isolation . . .”).

<sup>50</sup> *Id.* at 192-93.

<sup>51</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>52</sup> *Electric Power Group*, 830 F.3d at 1353.

The first U.S. patent issued to Samuel Hopkins in 1790 for his discovery of a new method of making potash.<sup>53</sup> His novel method comprised well-known steps at the time such as burning and dissolving ash. Hopkins' sole discovery was improving the timing and specific order of the steps in the process.<sup>54</sup> If Hopkins' patent were challenged today and the courts applied their now-established methodology in construing it under the *Alice-Mayo* framework, they would first find that the elements of timing one's steps in a process and using heat are abstract ideas, laws of nature or natural phenomena and thus ineligible for patent protection. Under the second step of the *Alice-Mayo* framework, a court would find that Hopkins did not add anything "inventive" to the steps beyond timing and heating contributions, all of which were well-known and conventional at his time. Thus, it is an entirely logical application of the *Alice-Mayo* framework today to find the first U.S. patent for a process of making potash to be ineligible for patent protection.

This is significant because Hopkins's patent application was reviewed, approved, and signed by Thomas Jefferson as Secretary of State, who was a member of the three-person committee created under the 1790 Patent Act to review patent applications. Jefferson was both a drafter of some of the early patent laws and is known today for his belief that patents should be granted rarely and for only truly innovative inventions.<sup>55</sup> Moreover, Hopkins's patent was issued under the 1790 Patent Act, which was drafted by original Framers of the Constitution who were serving in the First Congress.<sup>56</sup> In fact, the other two members of the committee that reviewed Hopkins' application and approved his patent were President George Washington and Attorney General Edmund Randolph, both of whom also were members of the Constitutional Convention of 1787.

When a set of Supreme Court decisions between 2010 and 2014 creates a legal doctrine that, if applied to the first U.S. patent, would call into question its validity, this is cause to question if the Supreme Court has rightly followed the law that has existed since the first Patent Act of 1790. It is especially concerning when this first patent was reviewed and signed by two prominent members of the Constitutional Convention (Washington and Randolph) and a prominent Founder (Jefferson) who is largely known today for his skepticism about patents. Thus, Congress should return the patent system back to promoting and securing innovation, especially in the key biopharmaceutical and high-tech sectors of the U.S. innovation economy in the twenty-first century. It should abrogate the *Alice-Mayo* framework and reestablish the basic legal rules in § 101 that apply throughout the patent system, such as the requirement that in assessing the patentability of an invention, courts must always assess the claimed invention as a whole.

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<sup>53</sup> See U.S. Patent No. X00001 (granted July 31, 1790).

<sup>54</sup> See Henry M. Payntor, *The First Patent* (rev., 1998), at [http://www.me.utexas.edu/~longoria/paynter/hmp/The\\_First\\_Patent.html](http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html).

<sup>55</sup> See Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 93, 959–63 (2007).

<sup>56</sup> See Neal Katyal & Paul Clement, *On the Meaning of "Natural Born Citizen,"* 128 Harv. L. Rev. 161, 161 (2015) ("The Supreme Court has long recognized that two particularly useful sources in understanding constitutional terms are British common law and enactments of the First Congress."); cf. *Wisconsin v. Pelican Ins. Co.*, 127 U.S. 265, 297 (1888) (recognizing that actions of the first Congress are "contemporaneous and weighty evidence" of the Constitution's "true meaning").

## V. Conclusion

The Supreme Court is uninterested, unwilling or unable to address the serious problems that it has created with its *Alice-Mayo* framework in its interpretation of § 101. It has repeatedly denied certiorari petitions in follow-on cases in which valuable patents for groundbreaking innovations have been invalidated by courts using the *Alice-Mayo* framework. Given the high rates of invalidations of patents by courts and the high rates of rejections of patent applications in some fields of technology at the USPTO, it is Congress' job to perform its key constitutional role in amending the legislation that has been the fountainhead of the U.S. patent system since 1790.

The guidepost for Congress today is its enactment of § 103 in the 1952 Patent Act. Congress adopted § 103 to address a similar problem at the time of unpredictable judicial decision-making and extensive invalidations of patents by courts following a mistaken ruling by the Supreme Court in 1941 that created the “flash of creative genius” test—an insurmountable legal obstacle in proving patents were validly issued to innovators. As Justice Jackson noted in a patent case in 1949 in which the Supreme Court invalidated yet another patent: “the only patent that is valid is one which this Court has not been able to get its hands on.”<sup>57</sup> Not only did § 103 abrogate the “flash of creative genius” test created by the Supreme Court, it also mandated doctrinal limits on the judicial decision-making process in assessing the patentability of an invention, such as requiring assessment only of a claimed invention as a whole.

The innovation industries today are again facing a judicially-created doctrine that permits unbounded judicial decision-making in dissecting claims and results in high rates of invalidations of patents. Just as Congress successfully resolved the problems created by the Supreme Court by enacting § 103 in the 1952 Patent Act, it should act today to resolve the problems created by the Supreme Court in patent eligibility doctrine in § 101. It should reestablish § 101 back to its longstanding historical role as a threshold inquiry among the patentability requirements that allowed for more searching and stringent review for novelty, utility, nonobviousness, and disclosure. It is time for Congress to restore balance to a patent system that has historically secured the fruits of inventive labors with reliable and effective property rights in inventions and discoveries. The draft legislative language is an important step in achieving this goal.

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<sup>57</sup> *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).