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Subcommittee on Intellectual Property

Hearing on the Patent Eligibility Restoration Act (PERA)
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Mr. Chairman, Ranking Member, and Members of the Senate Judiciary Committee:

It is a great honor for me to testify before you again today.

In my testimony before this Subcommittee on May 14, 2025 at its hearing on "Foreign Threats to American Innovation and Economic Leadership", I also discussed the uncertainty in our law of patent-eligible subject matter and the risks it poses to innovation and competition with China.[1] I continue to believe that issues involving patent-eligible subject matter are one aspect of the competitive challenges that the Chinese IP system poses to US industry. Moreover, resolving these issues can serve as an important legal accelerant to increasing US technological competitiveness.

I am pleased to return to that theme today in the company of such individuals as former USPTO Directors Iancu and Kappos, two people who I deeply respect for their knowledge and experience of US intellectual property law. I will add a comparative perspective on Chinese patent law and how it differs from the current state of U.S. law on patent eligibility issues, leaving the detailed discussion on the US system to my two distinguished colleagues. The views expressed here are my own.

I commend this Subcommittee and its staff for including comparative perspectives on patent eligibility issues in its consideration of PERA. I will use two comparative approaches of (a) focusing on how the United States and China have changed in their

[1] See Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary, 119th Cong. (May 14, 2025) on "Foreign Threats to American Innovation and Economic Leadership", https://www.judiciary.senate.gov/committee-activity/hearings/foreign-threats-to-american-innovation-and-economic-leadership (all links last visited Sept. 20, 2025).

approach to eligibility both over time, and (b) how the United States and China have changed in comparison to each other.

It is critical that our IP system remains a leader in the world. To succeed in that endeavour, the United States needs to become more knowledgeable of the efforts by our competitors to surpass our IP regime and, where necessary, take appropriate self-strengthening steps to ensure that our system addresses any newly arising challenges in a timely fashion.

The challenges that the United States faces in maintaining the world's leading IP system while competing with Chinese are substantial. China today has the largest patent office in the world by volume of patent applications. It also has the largest and likely the fastest patent litigation court docket in the world. The overwhelming majority of patent applications in China are from Chinese companies and individuals. China also has an extensive national and local IP bureaucracy, including a system of specialized IP courts and tribunals. The Chinese government allocates significant resources to creating and implementing multi-year plans that affect, incorporate and/or manage intellectual property. China has also begun to challenge the United States as a significant exporter of technology in both high tech and biotech. Since the 1980's, China has also shown an ability to adjust its laws, regulations and rules in light of newly emerging technological or economic developments.

The results of these efforts can be found in numerous studies detailing how China has equaled or exceeded the United States in its technological capacities. For example, according to one important project of the Australian Strategic Policy Institute, China now leads the world in research in approximately 90% of critical technologies.[2] The ability of the United States to effectively measure technological competition with China is additionally the subject of a forthcoming workshop that I am organizing here on Capitol Hill with the support of the Asia Society of Northern California, the office of Senator Schiff and others on November 5, 2025 on Data Driven Approaches to Understanding Chinese Tech Competitiveness.[3]

I. The Problem: The US has Created Unclear Rules Which Narrow the Scope of Patent Eligible Subject Matter While China has Broadened its Rules.

A. The US Approach

[2] Australian Strategic Policy Institute, *Critical Technology Tracker*, https://techtracker.aspi.org.au/tech/all/?c1=us&c2=cn.
[3] Asia Society of Northern California, *Workshop: Data-Driven Approaches to Understanding Chinese Tech Competitiveness*, https://asiasociety.org/northern-california/events/workshop-data-driven-approaches-understanding-chinese-tech-competitiveness.

The United States has long prided itself on a patent system that is stable and predictable. But in one critical area—judicially crafted eligibility standards under Section 101 of the Patent Act,[4] that reputation has been lost. Section 101 itself provides for a broad scope of patent eligible subject matter, covering "any new and useful process, machine, manufacture, or composition of matter." This is the basic standard that the United States has used for over 200 years. In recent years, the Supreme Court has decided such cases as *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) ("*Mayo*"), *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) ("*Myriad*"), and *Alice Corp. v. CLS Bank Int'l,* 573 U.S. 208 (2014) ("*Alice*"), which have created a vague two-step test that is applied inconsistently by courts, the Patent Trial and Appeal Board, and the USPTO.

As articulated in *Alice*, the first step by the courts to determine patent eligibility is to ascertain whether a patent claim is directed to a "patent-ineligible concept[]," namely, abstract ideas, laws of nature or natural phenomena. If this inquiry is affirmative, the court inquiries whether there are "additional elements" that "transform" the claim into a patent-eligible application. This second step can involve a search for an "inventive concept," i.e., whether there is an element or elements that are "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."[5] The 2019 Patent Examination Guidelines (the "PEG") of the USPTO explain that the additional items amount to significantly more if "the additional elements were unconventional in combination." If the additional elements amount to significantly more, the claim is patent-eligible.

The PEG were subsequently adopted into the Manual of Patent Examining Procedure (MPEP) to "provide more clarity and predictability."[6] These guidelines constitute a laudable effort to bring greater clarity to a confusing area. Their impact is, however, constrained by prior judicial decisions, and they also cannot bind the courts. See, e.g., *In re Rudy*, 956 F.3d. 1379, 1382 (2020). The result is that they can also contribute to a system where it is often difficult to determine whether a given claim constitutes patent-eligible subject matter upon which a valid patent may be granted or validated, which also has attendant economic consequences.

The effect of this approach to eligibility in biotechnology has been that patents appear to be less likely to be invalidated if they involved a new process or the making of a new thing, as opposed to the isolation or detection of a naturally occurring chemical. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) ("*Sequenom*"), for example, the Federal Circuit invalidated a patent on methods of

[4] 35 U.S.C. § 101.
[5] Paul R. Gugliuzza, *The Procedure of Patent Eligibility*, 97 TEX. L. REV. 571, 584 (2019).
[6] Notice, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019); U.S. PAT. & TRADEMARK OFF., "October 2019 Update: Subject Matter Eligibility" (Oct. 2019).

detecting fetal DNA that floats freely in the mother's body, notwithstanding the invention providing safer and cheaper fetal testing. The decision to invalidate the patent rested in part on the fact that fetal DNA appears naturally in the mother's blood and techniques used to detect it were already well-known.

In 2024, in response to concerns regarding patent eligibility and AI, the USPTO issued updated guidance on AI-related inventions.[7] The guidance is intended to provide greater clarity on such confounding issues as whether a patent claim contains an "abstract idea", and whether the abstract idea is integrated into a "practical application". USPTO also included concrete examples. A 2025 Congressional Research Service (CRS) report notes that while some organizations found the new AI rules to be an improvement, others believed that USPTO needed to do more to bring clarity and predictability to this key area.[8]

Professors. Renjun Bian at Peking University Law School and Robert S. Merges at Berkeley Law are critical of the "abstractness test" in determining US patent subject matter eligibility which has been a barrier since *Alice* held that computerized abstract ideas are patent ineligible. In their own comparison of US and Chinese practices, they have viewed abstractness as less practical, and difficult to define for software, diagnostics, and fintech inventions than China's more wholistic approaches.[9]

The CRS has noted that, as a general matter, the judicially created doctrine of patent eligible subject matter, "has waxed and waned over time, depending on the trends in judicial decisions."[10] Some supporters of the Supreme Court's approach believe that the US has simply adjusted its doctrinal approaches to pre-*Alice* doctrine, particularly with respect to software patents,[11] or that its impact has been limited.[12] The close timing of the Supreme Court cases suggests to me that the Supreme Court had intended to effect durable changes in patent practice. Some judges have also expressed their concerns in opinions regarding the "uncertainty", "unpredictab[ility]", and "inconsisten[cy]" arising from these Supreme Court decisions.[13] Moreover, the available data, some of which are

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[7] US PAT. & TRADEMARK OFF., "2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence", 89 Fed. Reg. 58,128 (July 17, 2024).
[8] CONG. RSCH. SERV., *Patent-Eligible Subject Matter Reform: Background and Issues for Congress*, CRS Report No. R45918 (March 31, 2025), https://www.congress.gov/crs_external_products/R/PDF/R45918/R45918.6.pdf ("CRS Report").
[9] Renjun Bian and Robert S. Merges, *Software Patents after CLS Bank: US–China Comparison*, UC Berkeley Pub. L. Rsch. Paper (2014, 2025), https://papers.ssrn.com/sol3/Delivery.cfm?abstractid=5196640/.
[10] CRS Report, supra, note 8, at 12.
[11] Charles Duan, *Examining Patent Eligibility*, 97 ST. JOHNS L. REV. 47 (2023).
[12] Robert Sachs, *Alice, The Illusory Death of Software Patents*, www.IPwatchdog.com (June 27, 2014), https://ipwatchdog.com/2014/06/27/alice-the-illusory-death-of-software-patents/id=50194/.
[13] See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs*., 827 F.3d 1333, 1352 (Fed Cir. 2019) (O'Malley, J. concurring); id. at 1363 (Newman, J., concurring); and *American Axle & Mfg. Inc. v Neapco Holdings LLC*, 966 F.3d 1347, 1365 (Fed. Cir. 2020) (Moore, J. dissenting from denial of reh'g en banc).

discussed below, confirms that concerns over increased invalidity on patent eligibility grounds and the economic impacts of such determinations have been warranted.

B. The Chinese Approach

China's Patent Law has undergone five major enactments. The law was first enacted after considerable internal debate in 1984. Revisions followed in 1992, 2000, 2008 and most recently 2020. The 2000 amendments were made largely in anticipation of China's joining the WTO the following year. Later amendments were typically made to advance China's own interests in becoming a self-reliant, innovation-oriented economy. China's multiple progressive efforts to amend its patent law are not unusual in China's IP regime, its legal system, or in light of China's rapid economic advancement and changing technologies. China has often pursued an experimental approach by passing legislation for "trial" implementation, and/or of limited geographic scope (such as confining legislation to special economic zones), and/or with the possibility of near-term revision based on monitoring of its social effects. China's 2019 PEG similarly had a goal of "serving the needs of fast-developing new technology, [and] responding to new requests from innovation entities on patent examination rules and methods."[14] I view this experimental approach, used judiciously, as a strength of the Chinese legal system. In some cases, such as in civil procedure, experiments have also been undertaken in intellectual property before being adopted more broadly by the Chinese judicial system. Of course, AI and other emerging technologies have also brought new challenges to patent eligibility in China much as they have also done so in the West.

Chinese Patent Law provides more statutory exceptions to eligible subject matter than the United States. In addition to a morality/public order exclusion in its Article 5.1, there are also exclusions for scientific discoveries and rules and methods for intellectual activities, which are similar to the judicially created exceptions in the United States. China also statutorily excludes methods for the diagnosis or for the treatment of disease, animal or plant varieties, methods of nuclear transformation and substances obtained by means of nuclear transformation, and certain designs (Patent Law, Art. 25).[15]

Changes in patent eligible subject matter began early in the evolution of China's patent system. In its original 1984 patent law, pharmaceuticals were excluded from patent protection entirely. Patent protection for pharmaceuticals was first included in the 1992

[14] Mark A. Cohen, *Crossing the River by Feeling the IP Stones: How China's Civil Procedure System Benefits from Reforms Made in IP Civil Litigation*, www.chinaipr.com (Nov. 8, 2012), https://chinaipr.com/2012/11/08/crossing-the-river-by-feeling-the-ip-stones-how-chinas-civil-procedure-system-benefits-from-reforms-made-in-ip-civil-litigation/ (Nov. 8, 2012).

[15] Liaoteng Wang, et al., *A Comparative Look at Patent Subject Matter Eligibility Standards: China Versus the United States*, UC Berkeley School of Law, Berkeley Center for Law & Technology (May 2021), reprinted in IP Watchdog (June 12, 2020), https://www.law.berkeley.edu/wp-content/uploads/2021/05/Comparative-Look.pdf.

revision, with subsequent improvements in patent protection occurring with WTO accession and as recently as the Phase 1 Trade Agreement signed by President Trump during his first term.[16]

Regardless of statutory exception for diagnostic methods, it has long been possible to redraft surgical or diagnostic method claims into product claims and/or Swiss-type claims and enjoy patent protection. An example of a claim describing a method as a product might be: "Use of [substance or composition] for the manufacture of a medicament for a [new medical use]."

China also offers less expensive 10-year utility model patents (UMPs) for mechanical inventions which are typically granted in a shorter period than China's 20-year invention patents. UMPs are also subject to more limited examination procedures but nonetheless provide robust protection. UMPs can be the basis for an earlier overseas priority filing by a Chinese applicant. Although SMEs are major users of UMPs, they have also been strategically used by companies such as Huawei and Foxconn that require more continuous or earlier protection in conjunction with an invention patent application. They can sometimes provide alternative or additional protection to invention patents rather than a direct substitute. UMPs are subject to the same statutory subject matter ineligibility rules as invention patents, although their role is limited as they do not protect methods or chemical compositions. They are, however, subject to a lowered inventiveness requirement and may be used for an apparatus, device or physical structures that incorporate minor improvements in a product, which may enable them to capture these developments in physical products that are not otherwise protectable under invention patents.[17]

If a patent application is not completely in areas that are completely prohibited, such as computer software, business methods, AI, etc., an invention must pass a technicity (technical solution) test. This requires showing that the invention uses technical means (involving natural laws or forces of nature), to solve a technical problem, and achieve a technical effect. After this test is satisfied the China National Intellectual Property Administration ("CNIPA") (China's patent authority), proceeds to examine the application for novelty, inventiveness, and practical applicability.

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[16] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, Chapter 1 (Intellectual Property), https://ustr.gov/countries-regions/china-mongolia-taiwan/peoples-republic-china/phase-one-trade-agreement/text.

[17] Siwei Cao et al, *Utility Models vs. Invention Patents: Why File Utility Models for Good Inventions in China?* (Univ. of California, Berkeley working paper, c. 2011–2014); see also Aaron Wininger and Jingyuan Nan, *Utility Model Patents: An Overlooked Chinese IP Right,* (Nov. 28, 2019), https://www.chinaiplawupdate.com/2019/11/utility-model-patents-an-overlooked-chinese-ip-right/.

During the past several years, China has expanded patent eligibility in a range of areas. As a result of changes in China's own 2019 PEG issued by the CNIPA, one of the areas where China has recently expanded patent eligible subject matter is stem cell research from human embryos. If the stem cells are obtained within fourteen days of fertilization, and have not gone through in vivo development, the stem cells may be used as part of an invention patent claim. In practical terms, this means that this relaxation of Chinese prohibitions has made it easier to obtain stem cell patents in China, while in the United States there have been concerns about narrowed claim construction or invalidity of such patents.[18]

China also generally takes a broad view of patent eligible subject matter in areas such as human mental activities or principles of nature. For example, when claims covering algorithm features, business rules or method features belong to technical solutions, the examiner is required to consider the features recorded in the claims as a whole. For software, the Article 25 ban in China's patent law on "rules and methods for mental activities" uses this holistic approach. According to the PEG, Part II, Chapter 9, 2.2, "if all the contents of a claim include not only rules and methods for mental activities but also technical features, [...] the claim as a whole is not rules and methods for mental activities, and the claim shall not be excluded from patentability in accordance with Article 25."

Certain leading academics and practitioners have praised China's approach to patent-eligible subject matter. Professors Bian and Merges have observed that, in practice, a Chinese claim must include at least one technical feature that distinguishes it from the prior art to overcome the "rules and methods for mental activities" exclusion. Moreover, it is generally believed that the "rules and methods for mental activities" standard is less stringent than the broader "technical solution" requirement. According to the Examination Guidelines, Part I, Chapter 2, Section 6.3, "[t]echnical means is usually embodied by technical features." As a result, a patent application can often overcome the "rules and methods for mental activities" hurdle with relative ease.[19]

At a UC Berkeley webinar in 2020 discussing patent developments in China which included as speakers Professor Cui Guobin of Tsinghua Law School, Judge Paul Michel (ret.), Dr. Liaoteng Wang (who has authored articles on comparative patent eligibility),[20] and former USPTO Director Kappos, Mr. Kappos noted that some of the examples given in the AI PEG may be unpatentable in the US, even if they are patentable in China. Mr. Kappos noted that the CNIPA PEG urged examiners to review a proposed invention as a whole and to focus on the technical solution, which "leads you down a much more

[18] See Liaoteng Wang et al, *Comparative Look*, supra note 15; see also Nov. 1, 2019 Amendments to PEG.
[19] Bian & Merges, *Software Patents After CLS Bank*, supra note 9.
[20] Mark A. Cohen, *China Patent and Licensing Developments – Week of June 14th,* (June 14, 2020), https://chinaipr.com/2020/06/14/china-patent-and-licensing-discussions-week-of-june-14th/.

constructive path." One of the benefits of China's approach is that the technical-solution test tends to focus on the concrete features of the invention, whereas in the US considerable time is spent arguing whether the actual claim in the case is abstract or not. These observations of Mr. Kappos were also subsequently published in English in the China Daily, an official Chinese newspaper.[21]

On January 20, 2024, China subsequently revised its PEGs for AI-related inventions, particularly computer implemented inventions and big data algorithms. While diagnostic methods are generally considered ineligible subject matter, these new guidelines also limit their application to diagnostic devices by providing that "information processing methods where all steps are executed by devices such as computers" are not considered ineligible patent subject matter. To be patentable, the claimed technology should solve technical problems, using technical means that follow natural laws and thereby achieve technical effects. This means that claims in patent applications can include algorithms, provided that they include technical features paired with the algorithm features. Furthermore, when examining inventiveness, both technical features and algorithmic features should be considered as a whole. This approach is intended to recognize the interconnected nature of AI inventions, where algorithms and technical implementations work in tandem. The AI guidelines are similar to the CNIPA 2019 and 2020 PEGs, which also apply to software, and business methods. Examiners are told to evaluate claims "as a whole," reducing the risk that an invention is dismissed as an "abstract idea." A crucial aspect of the inventiveness assessment is the consideration of how algorithmic features functionally support and interact with technical features.

In the examples provided in their respective amendments to their respective PEGs, CNIPA and USPTO reveal the challenges they face in evaluating patent-eligible subject matter. For example, the USPTO examples generally point to outcomes that depend on careful claim drafting. Examples are highly fact specific. Often, minor changes will make a patent ineligible. This is due in part to their caselaw orientation. By contrast, CNIPA guidelines focus on bright line differences which are more like checklists tied to China's statutory "technical solution" requirement. Part of these differences may be related to the determinative legal role played by US judges, particularly the US Supreme Court and its case law. However, the US approach necessarily reflects the lack of clarity behind these judicial decisions, the risk that a given claim may be subject to a differing judicial interpretation, and laudable efforts by the USPTO to improve patent application quality in order to overcome ineligible subject matter issues. By contrast, the Chinese

[21] Lia Zhu, *Experts: China Outpacing US on Patent Eligibility*, CHINA DAILY (June 23, 2020); see also Mark A. Cohen, *Berkeley Webinar Recap*, www.chinaipr.com (June 23, 2020), https://chinaipr.com/2020/06/23/berkeley-webinar-recap/.

approach tends to emphasize relatively straightforward drafting pathways which also appear more welcoming to well-drafted patent claims.

III. Analyses of the Impact of US Patent Eligibility Doctrine

Although there are a number of statistical studies (discussed below) of the impact of US eligibility doctrine, there are limited detailed analyses comparing specific eligible subject matter invalidations or grants in the United States with China. Additional research on specific patent applications and their fate in key markets such as China and Europe would be helpful in assessing the extent and manner by which other jurisdictions impose restrictive (or differing) patent eligibility requirements, their economic impacts and the impact of efforts to navigate around eligibility requirements. As one example, a counterpart patent to the *Sequenon* patent was not applied for in China, making it impossible to use this patent as a basis for distinguishing US and Chinese approaches.[22] However, Europe, which often has a similar approach to China on patent eligibility issues, granted the counterpart patent, EP0994963 and it expired at term.

One area where data would be helpful but is not readily available involves U.S.–Chinese scientific cooperation. The U.S. government may currently be funding international scientific collaborations where inventions arising from that work are not patentable in the United States and, as a result, may not be pursued globally.[23] Differences in patent-eligibility doctrine can also discourage applicants from filing at all: if protection cannot be obtained in the U.S., there is often reduced incentive to seek approval and protection overseas. This dynamic may deprive U.S. innovators of the ability to exploit patents in their home market, while creating opportunities for potential infringers to manufacture in China or other jurisdictions and export to the United States and elsewhere. Unfortunately, there is little hard data on how many U.S. government funded inventions are lost in this way. Improved oversight of patenting strategies should therefore be an integral part of U.S. management of scientific collaborations with China and other major markets.[24]

The academic literature describes the broader systemic impact of more restrictive US rules on patent-eligible subject matter. The leading academic article comparing US and Chinese patent eligibility is Kevin Madigan and Adam Mossoff's, "Turning Gold to Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation." Their 2017 article was revised in 2018 to update and correct some errors in their database.[25] Their dataset was based on 17,743 patent applications recently filed in the

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[22] Liaoteng Wang et al, *Comparative Look*, supra note 15.
[23] 37 C.F.R. Part 401.
[24] Mark A. Cohen, *Renewing the US-China STA is Not the Question*, www.chinaipr.com (Aug 13, 2023), https://chinaipr.com/2023/08/13/renewing-the-us-china-sta-is-not-the-question/.
[25] 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), revised (2018). Kevin Madigan & Adam Mossoff, *The Value of Public Data: Update to Turning Gold to Lead*, (June 28,

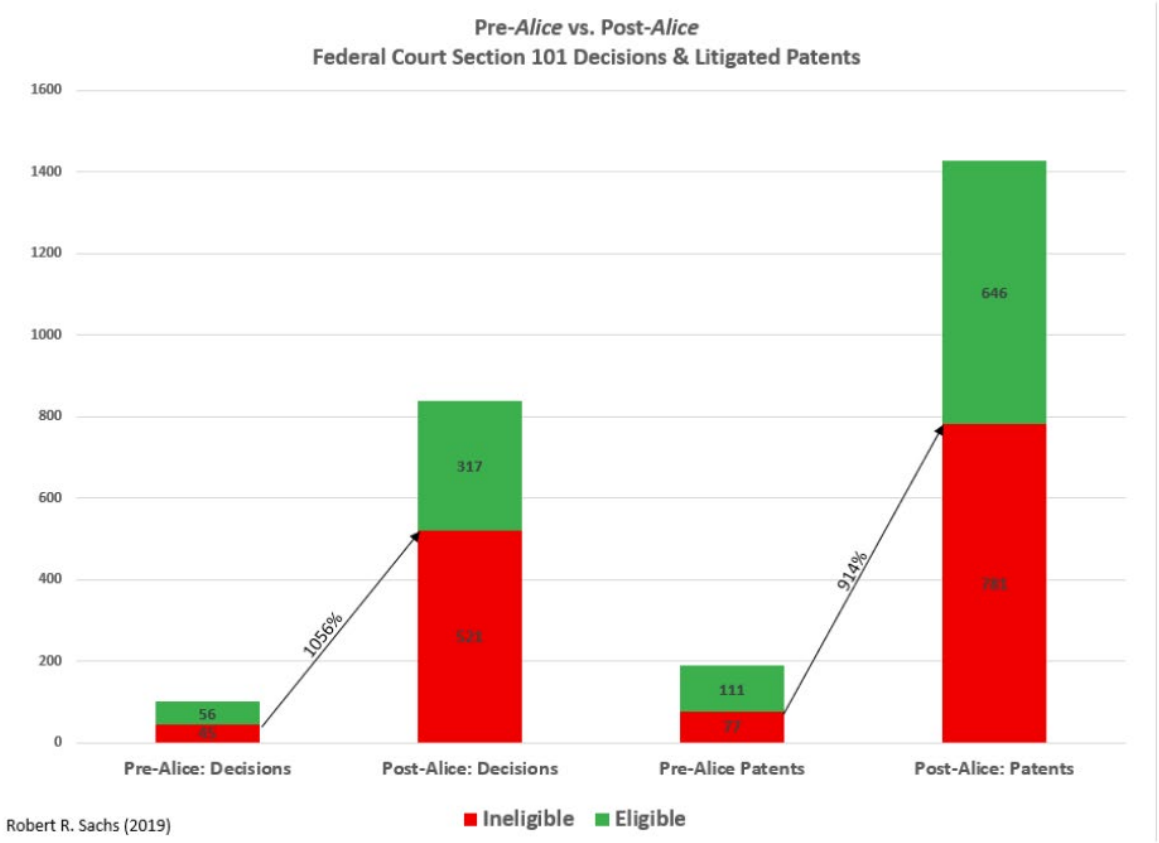
U.S., China, and Europe, of which 1,694 had originally been identified as falling victim to *Alice-Mayo* eligibility standards. Their revised dataset corrects for subsequent developments in patent validity following the original publication of their article, as well as certain false positives where there were Section 101 rejections based on issues other than *Alice* rejections. Their revised article determined that 1,310 applications were abandoned following rejections under the *Alice-Mayo* framework for lack of patent eligible subject matter and had issued patent family members in either China or Europe. Even accounting for the correction in cases, the number of patent applications that fell victim to the *Alice-Mayo* framework while being granted in foreign jurisdictions remained significant both in number and content. The authors also note that many of the technologies that are being abandoned in the United States—and at the same time being issued as patents by the European Patent Office (EPO), China, or both—covered innovations in medical treatments and the life sciences.

The study included an analysis of the 618 healthcare-related patents. The analysis showed cancer treatments to be the most prominent category of abandoned or rejected applications, making up 150 (or about 24%) of the total healthcare-related technologies. The authors suggest that healthcare-related technologies are "bearing the brunt" of the "invalidation contagion" precipitated by the "*Alice-Mayo* framework." Consequently, potential patents for innovations to diagnose or cure diseases are being abandoned in the United States. Additionally, the overlap of Sections 101 and 103 (non-obvious) rejections suggests that the *Alice-Mayo* test appears to be inconsistently applied, and conflates importantly different legal and policy concerns in patentability requirements

Another significant report on the impact of court decisions applying the *Alice-Mayo* framework was compiled by Robert Sachs. Mr. Sachs showed that court decisions under Section 101 jumped 730% during the five-year period since *Alice*, with a 659% increase in the number of litigated patents. This is in stark contrast to the longstanding, historical role of Section 101 as a limited "threshold test". Sachs also noted that over 1,000 patents have been invalidated by the federal courts and the PTAB, while over 60,000 patent applications have been abandoned before the USPTO following rejections for patent ineligible subject matter. [26] Here is one graph detailing the impact of *Alice* on post-*Alice* federal court Section 101 adjudications and litigated patents:

2018), Center for Intellectual Property x Innovation Policy, https://cip2.gmu.edu/2018/06/28/the-value-of-public-data-update-to-turning-gold-to-lead/; Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System Is Still Turning Gold to Lead,* www.ipwatchdog.com (Dec. 15, 2019), https://ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id%3D116984/ .

[26] Robert R. Sachs, *Alice: Benevolent Despot or Tyrant? Analyzing Five years of Case Law Since Alice v CLS Bank*, www.ipwatchdog.com (Aug 29, 2019), https://ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrant-analyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/.



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Relative ease in obtaining AI-related patents may also have contributed to a patenting surge in China. During the five years from 2019 to 2024, China's AI patent filings climbed from 59,054 in 2019 to a peak of 188,757 in 2024, nearly tripling in volume. This rapid growth may reflect national and local government efforts to dominate AI technologies in a range of sectors. By comparison, during this same period, the United States' filings numbers varied little, ranging between 31,000 and 35,000 annually. According to WIPO data, GenAI patenting has been especially focused on software/other applications followed by patents in life sciences. These are both areas where US patent eligibility doctrine could be a handicap.[27] While U.S. AI patents may attract more citations per grant, the volume difference underscores a role of predictable eligibility standards in driving filing behavior.

[27] WIPO, "Patent Landscape Report – Generative Artificial Intelligence (GenAI)", (2024) https://www.wipo.int/web-publications/patent-landscape-report-generative-artificial-intelligence-genai/en/key-findings-and-insights.html. See also "Artificial Intelligence AI Patent Landscape: USA and China", https://insights.greyb.com/artificial-intelligence-ai-patent-landscape-usa. -china/.

IV. The U.S. Retroactively Invalidating Patents Contributes to Instability Concerns

One comparative aspect of US and Chinese approaches to patent eligible subject matter that is hardly discussed in the academic/comparative legal literature involves different approaches to retroactivity decisions and their impact on the stability of patent validity determinations. In the United States, patents obtained in good faith under one validity standard may be later invalidated under subsequent judicial decisions. In *Sequenom,* for example, a pioneering non-invasive prenatal diagnostic test was invalidated in the U.S. under Section 101. In another Federal Circuit decision, *CareDx, Inc. v. Natera*, *Inc.*, *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371 (Fed. Cir. 2022), organ transplant diagnostic patents were struck down years after issuance.

Retroactive invalidation risks and the attendant legal uncertainty after *Alice-Mayo* can undermine confidence in the very purpose of the patent system: to provide reliable, enforceable rights that encourage investment and innovation over the life cycle of the patent, which is typically 20 years but may be extended in the United States for certain pharmaceutical patents based on regulatory delays.

China's approach to retroactivity in legislation is based on a default prohibition, tempered by a narrow exception. Article 104 of the Law on Legislation (as amended in 2023) provides that: "Laws, administrative regulations, local regulations, autonomous regulations and separate regulations, and rules are not retroactive, except for special provisions that are made to better protect the rights and interests of citizens, legal persons, and other organizations." This framework can be described as a non-retroactivity rule with exceptions: laws will not be applied retroactively unless the legislature or regulator specifically authorizes retroactivity, and only in certain limited circumstances where retroactive application is considered manageable and rights-enhancing.[28]

Non-retroactivity of more restrictive patent validity determinations has occasionally featured in U.S.–China trade and intellectual property engagements. A key example arose during then-Vice President Biden's 2013 visit to China, where the two sides issued an outcome statement regarding post-filing supplementary experimental data in pharmaceutical patent examinations. The outcome sheet affirmed that:

> China affirms that the Chinese Patent Examination Guidelines permit patent applicants to file additional data after filing their patent applications, and that the Guidelines are subject to Article 84 [now Article 104] of the Law on Legislation,

[28] Legislation Law of the PRC (2023), https://www.chinalawtranslate.com/en/legislation-law-2023/ .

> to ensure that pharmaceutical inventions receive patent protection. China affirms that this interpretation is currently in effect.[29]

Later that year, at the bilateral 2013 U.S.–China Joint Commission on Commerce and Trade, China made a similar commitment, extending the principle beyond examinations to re-examinations and judicial proceedings:

> Data Disclosure Requirements for Pharmaceutical Patents
>
> China re-affirms that the Chinese Patent Examination Guidelines permit patent applicants to file additional data after filing their patent applications, and that the Guidelines are subject to Article 84 of the Law on Legislation [now Article 104] to ensure that pharmaceutical inventions receive patent protection. China affirms that this interpretation is currently in effect for patent examinations, re-examinations, and representations before the Courts. Relevant Chinese and U.S. agencies will continue to engage on specific cases.[30]

These outcomes were largely proposed and negotiated by me during my government service, based on my understanding of China's legal approach to retroactivity in civil legislation. At that time, I was advised by Chinese patent office officials that they had convened a conference on the application of the retroactivity provisions of the Legislation Law to patent matters prior to agreeing to these outcomes.

While the retroactive application of Chinese law remains a complex subject, the prohibition against retroactivity—together with the possibility of less restrictive standards being introduced by CNIPA or by law—can provide additional stability to China's patent system. This stability, in turn, helps support long-term investment in technology-intensive fields.

V. Economic and Innovation Impacts

The costs of patent eligibility instability (or "PEI") have also been well documented. Several consequences may flow from this instability.

[29] Mark A. Cohen, *Vice President Biden and Pharmaceutical Innovation*, www.chinaipr.com (Dec. 6, 2013), https://chinaipr.com/2013/12/06/vice-president-biden-and-pharmaceutical-innovation/.
[30] USTR, "24th U.S. –China Joint Commission on Commerce and Trade Fact Sheet" (Dec. 2013), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2013/December/JCCT-outcomes.

First, when patent applications are ill-advised or patents are unavailable, companies may turn to trade secrets in lieu of patent protection. That may protect investments if proper safeguards are in place, and the underlying information is not publicly disclosed in the United States or elsewhere. However, such an approach undermines the disclosure function of the patent system which can help in developing improvements to patented technology. Trade secrets are also often more difficult to license as they lack any public market reference. If technology is easily reverse engineered, trade secrets may also provide insufficient protection. Moreover, use of trade secrets deprives innovators of other ancillary functions of the patent system. For example, in universities and other research institutions, patents are not just commercial assets; they are also markers of achievement, and may be used in tenure and promotion decisions. In the commercial world, patents are also basis for cross-licensing with other market players, or as a component of a trade secret license where certain aspects might otherwise be easily reverse engineered.

Second, PEI also undermines our ability to convince our trade partners to accord appropriate protection to the full scope of patent eligible subject matter. The U.S. Chamber of Commerce's *International Intellectual Property Index*, for example, has noted that "uncertainty surrounds what constitutes patent eligible subject matter in the United States." These uncertainties undermine our global ranking and investor confidence. The Chamber also has also praised the introduction in 2023 of PERA as addressing its PEI concerns.[31]

Third, and most importantly, innovative companies incur economic losses. In a survey of 475 venture capital and private equity investors, Professor David O. Taylor found that Section 101 PEI significantly reduced willingness to invest in diagnostics, biotechnology, and software.[32] Prof. Taylor noted that 74% of the investors agreed that patent eligibility is an important consideration in firm decisions whether to invest in companies developing technology. Overall, 62% of the investors agreed that their firms were less likely to invest in a company developing technology if patent eligibility makes patents unavailable, while only 20% disagreed. Investors also overwhelmingly indicated that the elimination of patents would either somewhat or strongly decrease their firms' investments in such industries as biotechnology (77%), medical devices (79%), and pharmaceuticals (73%). Taylor also noted that almost 40% of the investors who knew about at least one of the Court's eligibility cases indicated that the Court's decisions had somewhat negative or very negative effects on their firms' existing investments, while only about 15% of these investors reported somewhat positive or very positive effects.

[31] US CHAMBER OF COMMERCE, *International Intellectual Property Index*, pp. 389-390 (13th ed. 2025).
[32] David O. Taylor, *Patent Eligibility and Investment*, 20 CARDOZO L. REV. 2019 (2020).

After China joined the WTO, I frequently heard from Chinese officials that they viewed the availability of patent protection as a key factor in decisions by multinational companies to bring high value technology-oriented jobs and investments to China. Academics have also noted that foreign direct investment in technology has helped further stimulate disruptive innovation in China as measured by patent filings and citation data.[33] The Report on Foreign Investment in China (2024) (中国外商投资报告) of Chinas Ministry of Commerce correlated increases in valid pharma and medical device patents with other foreign investment trends in China. This report noted that foreign companies in China had been increasing their R&D efforts between 2021 and 2022 with 37,000 fulltime researchers in pharmaceutical manufacturing, an increase of 23.3%, and 24,000 fulltime researchers in medical equipment and instruments, an increase of 9.1%. Pharma R&D expenses also increased to 346.6 billion Chinese yuan, up 17.0%, while medical devices increased 8.3% to 12.5 billion yuan.[34] Accompanying these increases, whether as cause or effect, were increases in valid pharma patents held by these foreign-invested enterprises by 15.2% to 12,308, while medical devices increased to 13,025 valid patents, an increase of 16.3%.[35] China's rapid growth in the competitiveness of its biotech sector, including an upsurge in licensing to foreign companies, likely has benefited to some degree from restrictive patenting in the United States.

Another useful study is by A. Sasha Hoyt, who calculated a billion dollar decline in investment in diagnostics in the four-year period following *Alice* based on empirical data in the venture capital industry. The decrease in investment occurred in the four-year period following *Mayo* and noted likely additional impacts on precision medicine and underinvestment in medical treatments.[36] *Alice* also appears to have had a dramatic effect on the validity of software patents and business-method patents.[37]

Judge Michel (ret.) and Mr. Kappos, writing with other colleagues, have also warned repeatedly that U.S. unpredictability on eligibility has no parallel abroad and affects our national security, and that legislative reform is essential.[38]

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[33] Yongmin Chen et al, *The Impact of Foreign Direct Investment on Innovation: Evidence from Patent Filings and Citations in China*, 50 J. COMP. ECON. 917 (2022).
[34] 1 USD = 7.262 RMB on June 30, 2024, See Currency Exchange Rates Converter Tool, https://fiscaldata.treasury.gov/currency-exchange-rates-converter/.
[35] Ministry of Commerce of the People's Republic of China, *Report on Foreign Investment in China* (2024).
[36] A. Sasha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH & LEE L. REV. 397 (2022).
[37] Steven Callahan, *Alice: The Death of Software-Related Patents?,* www.NDTexblog.com, (May 1, 2015), https://www.ndtexblog.com/2015/05/01/alice-the-death-of-software-related-patents/.
[38] Paul Michel, David J. Kappos, Corey A. Salsberg & Matthew J. Dowd, *Presenting the Evidence for Patent Eligibility Reform: Part IV—Uncertainty Is Burdening Litigants and Courts, Threatening U.S. Competitiveness and National Security*, www.ipwatchdog.com (Oct. 26, 2022), https://ipwatchdog.com/2022/10/26/presenting-evidence-patent-eligibility-reform-part-iv-uncertainty-burdening-litigants-courts-threatening-u-s-competitiveness-national-security/id=152341/ .

VI. Why PERA Matters

PERA restores a clear statutory baseline for eligibility, while preserving exclusions for laws of nature and mental processes. It ensures that such applied technologies as diagnostics, biotechnology, artificial intelligence, and computer-implemented inventions, are unmistakably eligible for patent protection. In doing so, PERA eliminates uncertainty for previously granted patents and clarifies the path for new applications. Importantly, it does not compromise patent quality: the traditional requirements of novelty, non-obviousness, enablement, and written description remain in full force.

The evidence shows that instability in Section 101 jurisprudence has been costly and disruptive for innovators, investors, and researchers. It has had retroactive effects, reduced investment, and encouraged invalidity challenges. U.S. inventors have been placed at a disadvantage compared to counterparts in China and Europe, while judges and the USPTO alike have struggled to apply the standards consistently. These effects have varied across technological sectors, depending, in part, on the technology's reliance on patents or alternative forms of protection.

By enacting PERA and exercising robust oversight of its implementation, Congress would send a clear signal that the United States is fully committed to a predictable, reliable patent system. Congress would help ensure that this system attracts investment, facilitates commercialization, enhances legal certainty, and sustains America's global innovation leadership.

Thank you, and I look forward to your comments and questions.