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Protecting Intellectual Property for National Security

A Transition Report for the New Administration

AUTHORS
Kirti Gupta
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Walter G. Copan
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A Report of CSIS LeadershIP and Renewing American Innovation

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First Solar Exhibit 2014, Page 3 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

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First Solar Exhibit 2014, Page 4 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Contents

Executive Summary VI

Introduction 1

1 | IP Rights and National Security 3

Economic Security Is National Security 3

How Technology and Innovation Advance National Security 4

The Global Competition for Technology Leadership 5

How IP Rights Promote Innovation 7

Protecting IP for National Security 14

2 | IP Rights and National Security: Industry Spotlight 16

Advanced Communications 16

Biopharmaceuticals 19

Agriculture 21

3 | Challenges in U.S. IP Policy 23

Uncertainty and Instability in IP Rights 24

Challenges Enforcing IP Rights 27

Misguided Attempts to Weaken IP Rights to Control End Product Prices 29

Erosion of the International IP System 32

Artificial Intelligence 37

4 | The Path Forward 42

Incorporate IP Policy into U.S. Economic and National Security Strategy 43

Bolster the U.S. Patent and Trademark Office 44

Uphold, Strengthen, and Lead the International IP System 45

Reduce Uncertainty in the U.S. IP System 46

About the Authors 49

Appendix A: Proposed IP Legislation 51

Appendix B: U.S. IP Regulation 53

Endnotes 61

First Solar Exhibit 2014, Page 6 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Executive Summary

The United States is undergoing a generational shift in how economic policy intersects with national security. Decades of globalization have exposed critical vulnerabilities in the U.S. economy, as dependence on foreign competitors for essential goods and the offshoring of manufacturing have weakened industrial capacity, eroded economic resilience, and threatened national security. These challenges are further compounded by geopolitical shifts, disruptive technologies like artificial intelligence (AI), and the rise of China as a strategic competitor that exploits its control over vital value chains and engages in economic coercion.

While these circumstances present the new administration with enormous challenges, they also offer a rare opportunity. The administration is in a unique position to define a consistent and coherent economic strategy that not only addresses the numerous challenges presented by current global circumstances, but also secures U.S. economic and technological leadership for decades to come.

To effectively achieve these goals and bolster U.S. economic and national security, this strategy must incorporate intellectual property (IP) rights—a fundamental yet often overlooked component of innovation and national security policy. A strong and predictable system of IP rights, where the rights of IP owners are well-defined and enforced, will enable investment in innovation, empower small businesses, and ultimately drive technological leadership. Secure IP rights will likewise encourage and enable U.S. workers and businesses to innovate and take risks, harnessing the U.S. entrepreneurial spirit to develop new technologies, establish new businesses, and create new jobs.

First Solar Exhibit 2014, Page 7 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

However, decades of inconsistent policies and weakened protections have eroded the U.S. IP framework, allowing adversaries to exploit these gaps and challenge U.S. leadership. A myopic view of IP rights by U.S. policymakers, who view IP rights as separate from the broader U.S. economic and national security toolkit, has further weakened the U.S. IP environment. By reestablishing robust IP protections and integrating them into the broader economic and national security strategy, the administration can strengthen U.S. innovation, secure economic prosperity, and ensure long-term national security.

IP Policy: A Cornerstone of Innovation and Security

The U.S. Constitution enshrines IP rights into the foundation of the United States, granting Congress the power to "promote the progress of science and useful arts" by securing exclusive rights for creators and inventors for defined periods of time. These exclusive rights laid the foundation for an economy driven by creativity and ingenuity, fostering a unique culture of innovation that the United States retains to this day. Secure, stable, and predictable IP rights encourage risk-taking and investment in innovation, protect small businesses, promote downstream innovation, and ultimately ensure that the United States retains its competitive edge in critical technologies. Conversely, weak and unpredictable protections stifle investment, hinder small innovators, and allow adversaries to gain unfair advantages through IP theft and coercion.

Despite the critical importance of secure, stable, and predictable IP rights for innovation and U.S. economic and national security, over the past several years U.S. IP policy has devolved into a state of incoherence, characterized by weakened protections, inconsistent enforcement, and legal uncertainty. These shifts threaten to erode the innovation ecosystem that has long been a pillar of U.S. economic strength and global leadership. At a time when the nation is striving to reinvigorate its technological base amid fierce global competition, particularly with China, an unstable IP environment risks undermining this effort.

The Challenge: Erosion of IP Protections

Innovators face several primary challenges in the U.S. IP system, which ultimately undermine U.S. innovation, economic security, and national security:

- **Legal uncertainty.** Certain elements of the U.S. patent system, such as statutory authority and case law around patent eligibility, are currently plagued by high levels of uncertainty and instability, disincentivizing the risk-taking and investment required to innovate in many critical technology fields and undercutting the market position of startups and other small enterprises.
- **Enforcement gaps.** Mechanisms to invalidate patents, such as the Patent Trial and Appeal Board (PTAB), are prone to abuse that disproportionately harms small innovators, while the reduced availability of injunctions has greatly diminished the ability to enforce patent rights and, therefore, the value of patents.

First Solar Exhibit 2014, Page 8 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

- **Domestic missteps.** The last administration abandoned several long-held U.S. IP policy positions at home and abroad that underpinned U.S. leadership. For instance, proposals like an expansive view of march-in authority, reinterpretations of Title 28, Section 1498, of the U.S. Code ("Section 1498"), and the Trade Related Aspects of Intellectual Property Rights (TRIPS) waiver threaten to destabilize the patent system while being unlikely to meet their stated goals, thereby undermining the security, stability, and predictability of IP rights.
- **Foreign exploitation.** Nations such as China are leveraging state-sponsored IP theft, forced technology transfers, and legal maneuvers such as anti-suit injunctions to undermine U.S. innovation and manipulate global IP standards. All the while, the United States has shrunk from its leadership position in the global IP system, not only by failing to push back on abuse, but through advancing ideas that weaken global IP protections.

The Path Forward: A Strategic IP Agenda

To reclaim global innovation leadership, the United States must adopt a comprehensive IP strategy aligned with its economic and national security goals. Key recommendations include:

1. **Integrate IP policy into the national security strategy.**
   - **Publicly reaffirm the importance of strong and secure IP rights.** The president should make a public statement emphasizing robust IP rights as essential to U.S. innovation, economic security, and global leadership, setting a strategic tone for domestic reforms and international collaboration.
   - **Strengthen the position of IP enforcement coordinator and appoint a pro-IP leader to champion IP rights and innovation.** The administration should appoint a pro-IP leader to the position of IP Enforcement Coordinator (IPEC) to champion secure, stable, and predictable IP rights in the United States and to defend U.S. IP from theft and coercive transfer abroad. Further, it should strengthen the position of and empower the IPEC to ensure coherence, coordination, and strategic foresight across the U.S. IP policy landscape, with the explicit objective of strengthening and stabilizing IP rights and promoting innovation.
2. **Bolster the U.S. Patent and Trademark Office (USPTO).**
   - **End the practice of fee-diversion at the USPTO.** Despite being a fully fee-funded agency that does not receive any tax-payer money, the USPTO faces chronic underfunding issues due to the practice of fee diversion—the diversion of funding received from patent application and maintenance fees away from the USPTO. The administration should end fee diversion at the USPTO so that the office can utilize the money it generates to modernize its resources to enhance efficiency, support innovation, and maintain global competitiveness.
   - **Empower the USPTO to hire patent examiners.** As the USPTO is fully fee-funded, the administration should, at a minimum, exempt the USPTO from government-wide hiring

First Solar Exhibit 2014, Page 9 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

freezes and efforts to reduce workforce headcount. In fact, the administration should consider expanding the USPTO workforce, as such efforts will be essential to reduce the patent backlog, expedite decisions, and provide inventors with greater certainty to advance their innovations.

- **Implement patent examination reform.** Instead of overly prioritizing reduction of erroneous patent approvals, the USPTO should adopt a balanced approach to reduce both erroneous approvals *and* erroneous denials, thereby enhancing the reliability and predictability of the patent system.

3. **Uphold, strengthen, and lead the international IP system.**

- **Remain engaged in international IP bodies and commit to robust and reliable IP protections globally.** The United States should remain a global champion of secure, stable, and predictable IP rights through international institutions. The new administration can lead by reaffirming U.S. commitment to fair and nondiscriminatory global IP protections and addressing concerns in multilateral forums.
- **Push back on demands to erode IP rights in the name of access to innovation.** The administration should oppose measures that weaken IP rights in the name of access to innovation, recognizing that a high-functioning global system of IP rights is essential to bringing more developing countries into the innovation ecosystem as effective partners.
- **Call out China and other bad actors in the international IP system.** The United States should strengthen its stance against IP abuses, support World Trade Organization (WTO) actions against unfair practices, and restore robust reporting of global IP violations to uphold international standards.

4. **Reduce uncertainty in the U.S. IP system.**

- **Revisit USPTO guidelines on patentability of AI-assisted inventions.** The USPTO should revisit the guidelines for AI-assisted inventions to reduce the potential for legal uncertainty and ensure that the United States remains competitive in AI-driven innovation.
- **Update U.S. Code guidelines to provide clarity for innovators.** Clearer standards for patent eligibility under Title 35, Section 101 of the U.S. Code will reduce ambiguity, encourage investment, and promote innovation in emerging technologies (More on Section 101 later in this report).
- **Reject government overreach on patent rights.** The administration should reinforce the seminal role of government in the U.S. innovation ecosystem by affirming mechanisms such as the Bayh-Dole framework that promote commercialization of new technologies from advances in scientific knowledge.
- **Advocate for reinstating the historical presumption of injunctive relief.** Restoring the expectation of injunctive relief will empower innovators, deter infringement, and align the United States with international best practices in patent enforcement.

First Solar Exhibit 2014, Page 10 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

- **Empower the Patent Trial and Appeal Board (PTAB) to employ discretionary denial of petitions to reduce duplicative litigation.** Limiting duplicative challenges by aligning PTAB processes with district court litigation will streamline patent disputes and reduce resource waste.

In the face of global competition and technological disruption, IP policy is not just a legal matter—it is a strategic priority. A revitalized IP system will drive U.S. innovation, protect national security, and secure economic resilience. By implementing bold reforms and reaffirming its commitment to strong IP protections, the United States can maintain its leadership in the technologies shaping the future while also ensuring the security and prosperity of its people.

First Solar Exhibit 2014, Page 11 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Introduction

"[The Congress shall have Power . . .] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

- Article I, Section 8, Clause 8, U.S. Constitution

The United States is undergoing a generational shift in how economic policy intersects with national security. Americans now recognize that decades of rapid globalization have created critical vulnerabilities. The integration of global supply chains has left the United States dependent on foreign competitors for essential goods, threatening both economic stability and national security. The offshoring of manufacturing has weakened U.S. industrial capacity and innovation, eroding communities and economic resilience. Nonmarket practices and policies in other nations have distorted global markets at the expense of U.S. workers and businesses.

These challenges are compounded by emerging geopolitical and technological threats. Global disruptions such as pandemics, natural disasters, and foreign military conflicts reveal the fragility of supply chains and the need for greater economic sovereignty. New, disruptive technologies such as AI are reshaping the global balance of power, creating new arenas for competition. Meanwhile, China is increasingly using its scale and prowess to flout fair competition, exercise control over vital value chains, and engage in economic coercion.

While these circumstances present the new administration with enormous challenges, they also offer a rare opportunity. The administration is in a unique position to define a consistent and

First Solar Exhibit 2014, Page 12 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

coherent economic strategy that not only addresses the numerous challenges presented by current global circumstances head on, but also secures U.S. economic, technological, and innovation leadership for decades to come. Policymakers across the political spectrum agree that the economic policies and global institutions fostered since World War II are no longer adequate. Nations across the globe are reevaluating the relationship between economics, technology, and national security.

As the new administration establishes and pursues its economic and national security policy agenda, it should take this once-in-a-generation opportunity to reshape a critical yet often overlooked policy domain connecting numerous U.S. security objectives: intellectual property rights. A strong and predictable system of IP rights, where the rights of IP owners are well-defined and enforced, is essential for U.S. innovation and technology leadership, and, in turn, for the country's economic and national security. Secure IP rights, such as patents and copyrights, encourage and enable workers and businesses to invest in innovation and take risks, harnessing the U.S. entrepreneurial spirit to develop new technologies, establish new businesses, and create new jobs.

A strong and predictable system of IP rights, where the rights of IP owners are well-defined and enforced, is essential for U.S. innovation and technology leadership, and, in turn, for the country's economic and national security.

Over the last several decades, the U.S. IP system has regressed, undercutting U.S. innovation to the detriment of small businesses and workers. Inconsistent and misguided government policies and priorities have undermined the stability and security of U.S. IP rights. Other nations are exploiting the United States' waning leadership to challenge international IP norms. Meanwhile, they are leveraging their domestic IP systems to lure investments in innovation that would otherwise accrue to the United States. Furthermore, U.S. policymakers continue to view IP rights in a silo, separate from the broader economic and national security toolkit developed and deployed by the U.S. government. This lack of cohesion undermines U.S. IP policy at home and effective economic statecraft abroad.

The new administration should reestablish a world-leading system of IP rights in the United States, boosting U.S. innovation and technological leadership and thereby delivering security and shared prosperity to the U.S. people. What follows is an examination of the connection between IP rights, innovation, and security, a deep dive into the current state of the U.S. IP regime, and a roadmap for ensuring future U.S. technological leadership, security, and prosperity through sound IP policy.

First Solar Exhibit 2014, Page 13 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

1

IP Rights and National Security

Intellectual property's role in promoting innovation is embedded in the U.S. Constitution. Article I, Section 8, Clause 8—commonly known as the "Intellectual Property Clause"—expressly states that "the Progress of Science and useful Arts" will be promoted "by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[1] Put differently, the U.S. Constitution recognizes that IP rights promote innovation.[2] Innovation, in turn, is essential for economic growth, technological leadership, and, ultimately, economic and national security.[3] Thus, IP policy must be considered as an essential component of the United States' economic and national security strategy.

This section explores the connection between secure IP rights, innovation, and security, and highlights the specific ways in which IP rights promote innovation.

Economic Security Is National Security

For much of U.S. history, policymakers viewed "economic security" as primarily concerning the economic stability of individuals, rather than nation as a whole or the benefits a strong U.S. economy affords to its citizens.[4] As recently as the Obama administration, economic security was mostly discussed in relation to labor issues.[5] However, over the past decade, shifting global dynamics—such as growing geopolitical tensions and the increasing use of coercive economic tactics by foreign actors—have prompted a reevaluation of this concept. Economic shocks from natural disasters and the Covid-19 pandemic have further underscored the need for a broader understanding of economic security.

First Solar Exhibit 2014, Page 14 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Today, economic security encompasses the economic vitality and resilience of nation states. This expanded definition reflects the growing recognition that economic abundance, strength, and stability are critical to maintaining national power.[6] Or, as stated in the Trump administration's 2017 National Security Strategy, "Economic security is national security."[7] Economic security includes a nation's ability to safeguard its economic interests, protect its industries from foreign threats, and maintain resilience to external economic, social, and environmental shocks. It also reflects a more comprehensive view of national security, where economic abundance and economic tools—such as trade policy, industrial strategy, and investments in innovation—are essential to securing a nation's long-term interests.

The G7 and other nations have begun to articulate frameworks for economic security at the state level. In May 2023, G7 leaders defined economic security through seven key dimensions: building resilient supply chains, protecting critical infrastructure, countering nonmarket economic practices, addressing economic coercion, enhancing digital security, setting international standards, and preventing the leakage of critical technologies.[8] Nations such as Japan, the European Union, and the United Kingdom have separately developed strategies aimed at reducing economic vulnerabilities and strengthening strategic advantages.[9]

These strategies share common themes, most notably increasing domestic technological innovation and industrial capacity, reducing foreign dependencies, and collaborating with international partners. At the core of these efforts is the idea that the health and resilience of a nation's economy are directly tied to its national security. A robust, secure, and bountiful economy underpins defense capabilities, technological advancement, and global competitiveness, making it a foundational element of national security.

How Technology and Innovation Advance National Security

While a focus on state-level economic security may be relatively new, technological leadership and innovation have long been identified as essential to national security. The first society to create bronze weapons had a tremendous advantage over adversaries armed with stone tools. Rapid defense-driven innovation was likewise crucial to the United States and its allies' victory in World War II.[10] The same dynamic persists to this day. Drones, AI, and cyberspace are transforming warfare, granting tremendous security advantages to those nations leading in these technologies.[11] Today, as in the past, the United States must continue to innovate to maintain its battlefield advantage.

Modern national security, however, extends far beyond the battlefield and requires a comprehensive strategy that actively facilitates technological innovation in a manner far surpassing what might have been traditionally demanded. New AI and cyber capabilities now empower U.S. intelligence agencies to detect and monitor emerging threats, including from terrorist organizations. Agricultural innovations help U.S farmers adapt to changing environmental conditions and ensure the country's people have safe, nutritious, and affordable food on the table.[12] A robust biopharmaceutical innovation ecosystem enabled the United States and its partners to design a novel Covid-19 vaccine in just two days, producing billions of doses within a few years.[13] In

First Solar Exhibit 2014, Page 15 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

short, in an increasingly complex global environment, defense innovation must be defined broadly to ensure the United States' ability to anticipate, adapt to, and counter evolving national security threats, which no longer reveal themselves in traditional military manifestations.

U.S. economic security likewise flows from a comprehensive technology and innovation strategy, which complements direct efforts to enhance U.S. national security. The development of advanced industries and critical and emerging technologies, particularly in manufacturing, reduces dependency on foreign actors and mitigates exposure to economic coercion and external economic shocks. Cultivating homegrown innovations and industries creates high-quality jobs and strengthens the U.S. workforce's knowledge base in a self-reinforcing cycle. Innovations in information technology and cybersecurity bolster the resilience of critical infrastructure, securing both economic stability and national defense. Furthermore, innovation across the U.S. economy promotes economic growth, delivering prosperity to the U.S. people.[14]

In short, the nations that can harness the transformative potential of innovation will gain numerous advantages. The United States should be at the forefront in seizing such advantages to ensure that it retains its strategically competitive leadership position and secures the nation in all respects.

The Global Competition for Technology Leadership

Given the stakes, the competition for innovation and technology leadership is fierce. Governments worldwide are deploying ambitious national strategies coupled with massive investments to secure technological dominance.[15] Global funding of research and development (R&D)—activities aimed at generating new knowledge and creating new technology—has more than tripled in the last 30 years to over $2.2 trillion annually, with countries prioritizing technologies critical to future economic strength and geopolitical influence, such as AI, quantum computing, biotechnology, semiconductors, and advanced manufacturing.[16]

These developments are increasingly contesting, and in some instances reportedly surpassing, the United States' global technological leadership, a position the United States has held since World War II.[17] A 2023 Australian Strategic Policy Institute study analyzing academic research and human capital warns that China has overtaken the United States in 37 of 44 critical technologies, including advanced robotics and autonomous systems.[18] Similarly, in 2024, the Information Technology and Innovation Foundation highlighted China's rapid advancements in nuclear energy, electric vehicles, robotics, quantum computing, and AI, concluding that Chinese firms in these industries are poised to match or surpass their Western counterparts within a decade.[19]

Relative R&D investment reflects this shifting dynamic as well. Between 2000 and 2020, China's share of global R&D spending grew from under 5 percent to over 24 percent, making they country the second-largest R&D spender worldwide.[20] This significant investment underscores China's determination to compete for technology and innovation leadership for the foreseeable future, a strategy directly tied to its geopolitical ambitions. In comparison, the United States' share of global R&D declined from nearly 40 percent in 2000 to just under 31 percent in 2020, highlighting the urgency for actions to address the current competitive global landscape.[21]

First Solar Exhibit 2014, Page 16 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

The administration can and should leverage one clear advantage the United States has over its global competitors: a robust and dynamic private sector that takes risks and invests heavily in innovation. Indeed, while the public sector used to lead U.S. R&D funding, over time, funding has shifted significantly to the private sector. During the 1960s Space Race, federal funding accounted for 67 percent of total R&D investment in the United States, but by the 1980s, public and private contributions were nearly equal, and by the 2020s, private sector investment had grown to more than three times that of the public sector.[22] While total U.S. R&D spending nearly doubled from 2010–2020, this growth was overwhelmingly driven by the private sector, which, as of 2025, represents approximately 75 percent of total U.S. R&D investment.[23] This is a major advantage for the United States: The U.S. private sector invests more in R&D than firms in any other nation, investing $655 billion in 2022.[24]

The administration can and should leverage one clear advantage the United States has over its global competitors: a robust and dynamic private sector that takes risks and invests heavily in innovation.

Innovation in technologies vital to U.S. national security, such as AI, biotechnology, and advanced communications, therefore, should be led by the private sector and be market driven. Powered by private sector investment and entrepreneurial ingenuity, such an innovation system is one of the United States' greatest strengths, and an inherent advantage that can be leveraged in fostering U.S. technological and innovation leadership. Unlike China's centralized, top-down model, the U.S. innovation ecosystem allows for market-driven flexibility and thrives on the creativity of all market participants, from large established firms to newly founded startups. This decentralized approach has consistently delivered groundbreaking advancements that underpin both national security and economic prosperity.

To sustain this success, the U.S. government must support and strengthen the private sector's leadership in innovation. This means continuing to align private sector efforts with clearly defined economic and national security priorities, promoting market-based solutions in collaboration with global partners, and countering unfair practices by adversaries. At the core of this system must be a carefully balanced framework of incentives, protections, and connections. Secure IP rights are the foundation of this framework, providing the necessary legal structure and certainty. Without strong IP protections, the capital investments that fuel the U.S. innovation ecosystem would be significantly diminished, jeopardizing the nation's technological leadership and economic security.

A consistent, whole-of-government approach to innovation and IP policy will ensure cohesive and coherent strategy across federal agencies and create the legal and regulatory certainty needed to attract investment, enable risk-taking, and support the development of transformative technologies. This, in turn, will facilitate the dissemination of critical innovations throughout the

First Solar Exhibit 2014, Page 17 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

economy through licensing and other mechanisms that appropriately value critical discoveries. Such a strategy will also stimulate follow-on innovation, empowering startups, small businesses, and individual inventors to build upon existing breakthroughs, develop new products and services, and unlock fresh use cases. This dynamic ecosystem will expand economic opportunities while bolstering U.S. competitiveness and supporting the nation's workforce.

How IP Rights Promote Innovation

IP rights—e.g., patents, copyrights, and trade secrets—are more than legal instruments; they are vital drivers of innovation and critical components of U.S. economic and national security strategies. This connection was evident to the nation's founders, who enshrined IP protections in the U.S. Constitution to promote ingenuity. A century later, President Abraham Lincoln recognized that the patent system "added the fuel of interest to the fire of genius."[25] However, in a time where technological progress is expected and innovation taken for granted, the critical role of IP in fostering that innovation and maintaining a technological edge is often overlooked. Many policymakers do not even realize that IP policy is missing from their economic statecraft toolkit.

To fully grasp the importance of IP rights in advancing national security, it is necessary to explore their direct impact on innovation. By understanding the mechanisms through which IP rights stimulate creativity, protect investments, and support small businesses, one can appreciate how they underpin a robust innovation ecosystem that safeguards America's economic and strategic interests.

Intellectual Property Basics

There are several categories of IP protections in the United States highlighted in this report: patents, copyrights, and trade secrets.

A **patent** is an official document granting the owner exclusive rights to an invention. Patents granted by the U.S. Patent and Trademark Office confer the patent holder the right to exclude others from making, using, selling, or importing the invention throughout the United States.[26] U.S. patents typically provide these rights for a period of 20 years from the application date. Patents are territorial, meaning U.S. patents only apply in the United States. Almost every country has its own patent system that applies to its territory, with its own requirements and application process.[27]

To qualify for a U.S. patent, an invention must meet several criteria: subject matter eligibility, utility, novelty, and nonobviousness.[28] In other words, the invention must be new, useful, and related to a field that is eligible for patent protection. The applicant must also disclose the technical nature of their invention, thus making this information available to the public. This is a key function of patents: In exchange for patent rights, the inventor describes the invention in clear terms, thereby accelerating innovation by allowing others to learn from this information.

First Solar Exhibit 2014, Page 18 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

A **copyright** is an IP right that protects original works of authorship and artistic expression.[29] Unlike patents, which protect inventions and new processes, a copyright is directly tied to a tangible form of artistic, literary, or intellectually created work, such as paintings, photographs, musical compositions, books, and movies. In contrast to patents, which typically last for 20 years, copyright protections can last for many decades. Works created after 1978 are under copyright protection for up to 70 years after the death of the author, while pseudonymous works are protected for as long as 120 years. Works created for hire are under copyright protection for 95 years from the date of publication or 120 years from the date of creation, whichever comes first.[30] Also unlike patents, copyright does not need to be applied for—it is a right that automatically protects a work as soon as the work itself is created.

While copyright law is typically associated with art and entertainment, it nonetheless carries significant implications for innovation. Computer code, for instance, falls under copyright law, not patents, meaning a copyright protects the source code underlying the $1.9 trillion U.S. software and information technology industry.[31] The emergence of large language model (LLM) artificial intelligence algorithms has raised several major questions around the intersection of copyright and innovation, such as if training an AI algorithm on copyright-protected works constitutes copyright infringement and if AI-generated works are protected by copyright.

A **trade secret** protects commercially valuable information that is not generally known, has value to those who cannot legitimately obtain it, and has been subject to reasonable efforts to keep it secret.[32] Trade secrets can cover, but are not limited to, manufacturing processes, distribution methods, marketing strategies, financial information, formulas, recipes, and lists of suppliers and clients.

Trade secrets complement patent protection and have both advantages and disadvantages. Unlike patents, there is no time limit to trade secret protection, and trade secrets do not need to be publicly disclosed. Trade secrets can also be licensed to others without losing trade secret protection, and with the obligation that the licensee protect the trade secret. However, trade secrets do not protect against independent discovery as patents do. Patents also do not require efforts to maintain secrecy which can be costly and subject to errors, whereas trade secret protection is lost following disclosure.

THE INNOVATION ECOSYSTEM

Innovation is the process of transforming new ideas into practical applications that result in new or improved goods and services. It bridges the gap between conceptual breakthroughs and real-world impact, delivering tangible benefits to society and strengthening economic and technological capabilities. Understanding this process is key to recognizing the value of IP rights in facilitating and protecting the investments that make innovation possible.

First Solar Exhibit 2014, Page 19 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Following World War II, when the foundations of modern innovation policy began to emerge, U.S. innovation strategy relied on a relatively simple linear model.[33] This model concentrated on publicly funding basic research at the front end of the innovation process, after which private actors would take the lead in applying that research to new products and bringing them to market.

Through the years, however, our understanding of innovation has advanced considerably.[34] Today, we recognize the process of innovation as occurring in an "ecosystem" in which various networks each play a role in developing new technologies and bringing them to market. For instance, research networks composed of universities, research institutes, and national labs generate new knowledge and ideas; financial networks comprised of banks, venture capital funds, and other investors fund these innovative ideas; and entrepreneurial networks of startups and other firms drive new innovations to the marketplace. For innovation to reach its full potential, each of these networks needs to operate individually while also connecting with each other throughout the innovation ecosystem through partnerships, collaborations, and complementary joint activities.

IP rights are a foundational pillar of this broader innovation ecosystem. They provide the connective infrastructure that enables funding and information to move within and across networks, supporting the innovation ecosystem and enabling stakeholders to efficiently connect and collaborate while also motivating them to operate at full capacity.

IP RIGHTS ARE PROPERTY RIGHTS

At the most fundamental level, secure IP rights provide a stable and predictable framework and market that actors in the innovation ecosystem can utilize to make decisions. Property rights for physical goods and spaces are widely considered as essential to the functioning of market economies.[35] Buyers and sellers cannot transact if rights over the property in question are unclear. Would you buy a house if the seller could not also hand over the deed?

IP rights similarly transform inventions, artistic works, and other ideas into discrete economic assets that enable commercial transactions. This greatly increases market efficiency by providing economic actors with the security they need to collaborate and appropriately value their innovation. Indeed, a 2021 estimate placed the value of all U.S. patents at just under $3 trillion.[36] By allowing the market to value innovation as an economic good, IP rights incentivize further innovation.

Further, numerous U.S. businesses rely on IP as their primary assets and depend on secure IP rights to survive. Though these firms do not necessarily produce consumer-facing end products, they are nonetheless vital components of critical and emerging technology value chains. Several U.S. advanced communications firms, for instance, invest heavily in R&D to develop new interoperable technologies such as 5G, Wi-Fi, and Bluetooth, then leverage the IP system to license their innovations to other firms who integrate them into their products for commercialization. Without secure IP rights, these upstream R&D-focused firms could not safely license their innovations, undermining their viability as businesses, as well as their vital contributions to the sophisticated technologies many have come to rely on.

First Solar Exhibit 2014, Page 20 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Critically, given the fundamental nature of IP rights to many industries and markets today, the predictability and stability of these rights are essential for economic activity. This is a well-substantiated economic concept. Uncertainty—situations where the range and probability of outcomes cannot be predicted—hampers economic activity.[37] Similarly, uncertainty in IP rights can disrupt the many connections across networks that make up our comprehensive innovation system as actors lose the ability to make informed decisions. In the absence of a high degree of legal certainty surrounding IP rights, it is simply impossible for parties to appropriately value IP assets, thereby impeding their ability to make deals.

THE BENEFITS OF SECURE IP RIGHTS

In addition to their underlying function of creating a secure marketplace in which the various networks the United States' innovation ecosystem can interconnect, IP rights promote innovation in three distinct ways:

1. **IP rights enable risk-taking and investment.** Innovation is inherently risky, time-consuming, and capital-intensive. Developing new ideas and bringing them to market requires significant investment, particularly in critical and emerging technology fields. Bringing a new drug to market can cost several billion dollars, while the cost of training a frontier AI model doubles every year.[38] The top 100 firms invested over $720 billion in R&D in 2022, a 15 percent increase from 2021.[39] Yet success is far from guaranteed—more than 75 percent of startups fail, while less than 14 percent of drugs pass clinical trials and are approved for use.[40]

   Strong and secure IP rights play a pivotal role in enabling inventors, entrepreneurs, and investors to take on these massive and risky undertakings by providing clear ownership rights to their work. Absent such rights, it would be extremely rare for investors and firms to allocate large amounts of capital to fund projects with a high risk of failure, as success would inevitably be met with free riding by competitors. Why take the risks if someone else can simply steal your success? Secure IP rights are essential for promoting investment in innovation, as they enable innovators to recoup their investments should they succeed and, ideally, fund further innovation.

   The role of IP rights in driving investment is compounded today as the center of gravity of U.S. R&D funding continues to move away from government. While public funding once played a central role in R&D, the private sector has now become the primary investor in innovation. In the early 1980s, public and private contributions to U.S. R&D were roughly equal, but by 2021, private sector investment accounted for 75 percent of total U.S. R&D spending.[41] Meanwhile, federal R&D funding continues to decline, with a 2.7 percent cut in FY 2024, including an 11.3 percent reduction in non-defense R&D spending.[42]

   Put simply, in the twenty-first century, the vast majority of R&D in the United States that drives innovation in critical and emerging technologies is funded by the private sector. Secure IP rights are the foundation that keeps these investments flowing.

2. **IP rights empower small economic actors.** A fundamental component of any healthy innovation ecosystem are small actors such as startups, small- and medium-sized

First Solar Exhibit 2014, Page 21 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

enterprises, and individual inventors. These actors account for over 40 percent of U.S. economic activity and create two-thirds of new jobs.[43] They take risks that established companies cannot, driving innovation, technological change, and economic growth.[44] Indeed, many of the most impactful companies today were once startups.

Strong and secure IP rights are essential for small economic actors to continue flourishing.[45] Large firms often have several ways to secure competitive advantages in technology, including market access, rapid development cycles, and consumer goodwill. Smaller firms, in contrast, typically lack the resources necessary to quickly develop their ideas into large-scale marketable products, nor the means to monetize them in adjacent markets. Small firms often require external financing to support cost-intensive R&D and must engage other developers to manufacture and market their ideas. By transforming their ideas into property that can be assigned and protected, IP rights allow small businesses to both attract investment and form commercial partnerships with other firms with the assurance that their ideas will not be stolen.[46] For this reason, inventors, entrepreneurs, and startups repeatedly emphasize the importance of secure IP rights as a critical path for providing them market entry, growth, and fair participation.[47] Research bears this out: The approval of a startup's first patent can increase its employment growth over the next five years by 36 percent, bringing quality jobs to U.S. workers.[48]

U.S. history further underscores the importance of strong IP rights for small economic actors. The late 1930s through the 1970s, for instance, was marked by relatively weak IP protections in the United States, as U.S. courts were reluctant to enforce patents in a period of strict antitrust enforcement.[49] During this span, both small innovators and the U.S. innovation ecosystem overall suffered. R&D activity became concentrated in the research labs of large corporations, and was principally supported by large amounts of government funding.[50] Though innovation did not come to a complete halt, this era of weak patent protection coincided with a noticeable decline in U.S. innovation performance.

It was only when patent protections were strengthened in the 1980s through reforms like the Bayh-Dole Act and the establishment of the U.S. Court of Appeals for the Federal Circuit that U.S. innovation rebounded.[51] Rather than protecting incumbents, strong IP rights spurred the entry of new R&D-focused firms into high-tech industries like biopharmaceuticals and semiconductors. With IP protections providing a secure foundation, private capital flowed into startups, fueling competition, fostering partnerships with larger firms, and reinvigorating the U.S. innovation ecosystem. Indeed, one scholar of economic history described the patent system as the "democratization of invention" because it empowers inventors from all backgrounds—not just the wealthy and powerful—to invent and protect their ideas.[52]

Conversely, weakened IP rights disproportionately hurt small economic actors. They increase to attracting investment and make small firms more susceptible to attacks and theft by larger, better-resourced firms who can quickly scale up production and afford scores of

First Solar Exhibit 2014, Page 22 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

lawyers. Without a strong ecosystem of small economic actors, the entire U.S. innovation ecosystem suffers, undermining U.S. economic and national security.

3. **IP rights facilitate downstream innovation.** Downstream innovation refers to the process by which new inventions or technologies serve as the foundation for subsequent innovations, often leading to the development of entirely new industries, markets, and applications. GPS technology, for example, spurred the creation of navigation systems, ride-sharing platforms, and precision agriculture, among other new technologies, while the invention of the transistor in the mid-twentieth century laid the groundwork for the semiconductor industry, which, in turn, made modern computing possible.

   Secure IP rights are an essential catalyst for downstream innovation, as they promote the open exchange of technical information. To receive a patent, for instance, an applicant must disclose the technical nature of their invention, thus making this information available to the public.[53] This is a key function of patents: In exchange for patent rights, the inventor describes the invention in clear terms, thereby accelerating innovation by allowing others to learn from this information and build on it. Without secure IP protections, inventors might resort to secrecy, which would hinder the diffusion of ideas and slow technological progress.

   Critically, however, IP rights also play a key role in facilitating the collaborative and non-linear nature of innovation. Bringing new ideas to market often requires partnerships between diverse actors, each contributing expertise, resources, or complementary innovations. Secure IP rights empower these firms to confidently engage in such collaborations without fear that their novel and original creations will be taken away.[54] They can safely license their inventions and creative works to other firms, who help bring their innovations to market.

   Standards development is an important example of how a collaborative innovation ecosystem based on IP rights has succeeded in driving the development and commercialization of new technologies at a breakneck speed. Technical standards are sets of technical specifications, guidelines, or protocols that are widely accepted within a particular industry or field of technology.[55] These standards are rarely made by a single firm. Instead, they are typically developed by industry consensus and can include contributions from hundreds of firms. The 5G standard, for instance, is not owned by any individual company, but rather is the result of industry consensus—it encompasses over 25,000 distinct patents contributed by a range of participants in the standards development process.[56] For a standard like this to succeed, the owners of the patents necessary to implement the standard—standard essential patents (SEPs)—must have sufficient confidence in their rights to their own inventions to contribute those inventions to the standard. For the most complex standards, such as 5G, this confidence is achieved through IP policies that balance the rights of IP owners to realize a proper return on their innovations, while also affording implementers of standards the opportunity to access SEPs on fair, reasonable, and nondiscriminatory terms.

First Solar Exhibit 2014, Page 23 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

In other words, secure, stable, and predictable IP rights lay the foundation necessary for the development of sophisticated technical standards. This secure foundation affords IP owners the assurances needed to cooperate in the development and implementation of standardized technologies and provides the incentives to make those technologies broadly available through licensing. Without secure IP rights, IP owners would be less likely to cooperate for fear of having their innovation stolen or dramatically devalued, greatly undercutting innovation and harming consumers everywhere. Think about how different life would be if phones from different manufacturers could not call each other, and each device required a different power outlet.

Secure, stable, and predictable IP rights lay the foundation necessary for the development of sophisticated technical standards.

University technology transfers are another example of how IP rights foster collaboration and benefit the U.S. economy. In many ways, universities are a central hub of the U.S. innovation ecosystem, working with federal government agencies to advance national research priorities, spinning off startups, and licensing discoveries to firms with the capabilities to commercialize resulting products. In the 1960s and 1970s, however, while federally funded U.S. research universities generated huge numbers of new discoveries and technologies, these were rarely translated into commercial products.[57] At the time, the U.S. government had taken the position that inventions created from federally funded research would belong strictly to the government and would be solely non-exclusively licensed. In essence, the universities and researchers who invented new products were required to forfeit their rights over them. This not only hampered economic incentives for commercial development, but also inhibited would-be university inventors from pursuing inventions since the government would own the rights to whatever they created.[58]

It was not until Congress enacted the Bayh-Dole Act in 1980 that this research began to be converted into useful products.[59] Bayh-Dole empowered universities and other grant recipients to own patents on inventions stemming from government-funded research, and therefore to be able to license these inventions to private sector partners who were then able to commercialize them. In this way, Bayh-Dole decentralized and privatized technology management to the universities and businesses that invented the technologies with government support, creating a mechanism and incentive for universities and the private sector to commercialize federally funded R&D.[60] Since its enactment, Bayh-Dole has led to over $1.3 trillion in U.S. economic growth, created more than 4.2 million jobs across the country, and contributed to the success of over 11,000 new startup companies from universities throughout the United States.[61] Without this collaboration—enabled by

First Solar Exhibit 2014, Page 24 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

the efficient allocation of secure IP rights—thousands of inventions in industries including advanced communications, AI, biotech, renewable energy, food, and many others would not have been brought to market, where they have benefitted everyday lives.[62]

Protecting IP for National Security

As discussed above, secure and stable IP rights promote private sector, market-driven investment, protect startups and small businesses driving disruptive innovation, and ensure that downstream innovators can build on protected ideas with confidence. IP policy is, therefore, a critical tool for ensuring that the United States remains competitive in the global technology race, which the administration can employ as a tool of economic statecraft to promote the United States' domestic innovation agenda.

Moreover, as innovation becomes increasingly central to global competition, the impetus for protecting IP should rise. State-sanctioned IP theft and cyber espionage, particularly from China, remain a critical security issue.[63] For example, Operation CuckooBees—a multiyear cyber espionage campaign targeting multinational companies—may have stolen hundreds of gigabytes of IP linked to China's stated technology goals before being exposed in 2022.[64] Furthermore, forced technology transfer is an increasingly popular policy option for foreign governments, including China obliging foreign firms to transfer technology in exchange for market access and growing demands in international fora for compulsory licensing and IP waivers—mechanisms that permit third parties to use patented products or processes without the patent owner's consent.[65] When foreign entities steal U.S. IP or coerce its transfer, they gain access to critical technologies without bearing the costs of innovation. This erodes the competitive advantage of U.S. innovators, weakens domestic U.S. industries, and diminishes the nation's overall economic security.

When foreign entities steal U.S. IP or coerce its transfer, they gain access to critical technologies without bearing the costs of innovation.

Indeed, compelled technology transfer and IP leakage are deeply intertwined with the decline of U.S. manufacturing, creating a self-reinforcing cycle that undermines economic and national security. A sizeable portion of IP transferred to foreign nations, particularly to China, occurs through joint ventures established to support overseas manufacturing operations.[66] This not only results in U.S. firms losing control of valuable critical and emerging technologies, but also erodes the competitive edge of U.S. firms, as manufacturing operations are a key driver of commercial innovation.[67] The transferred IP is then used to compete against U.S. firms in these technologies, further undermining U.S. manufacturing and depriving the U.S. workforce of high-quality jobs and expertise. By protecting U.S. IP and halting its compelled transfer to foreign adversaries, the United States can break this cycle, bolster its manufacturing base, and champion U.S. workers.

First Solar Exhibit 2014, Page 25 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

To reestablish the United States' unquestioned technology and innovation leadership and to meet U.S. economic and national security objectives, the administration must act decisively to protect and leverage the U.S. IP system and pursue an unequivocal and persistent position supporting strong and robust IP protections and enforcement worldwide. This includes supporting R&D and downstream innovation through stronger IP protections, promoting international cooperation on IP standards, and ensuring that U.S. innovators, manufacturers, and workers can compete on a level global playing field. The importance of the administration prioritizing such efforts is not just economic—it is strategic, and it will determine whether the United States will continue to lead the shaping of technologies in the future.

First Solar Exhibit 2014, Page 26 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

2

IP Rights and National Security

Industry Spotlight

Modern technology industries are highly specialized. Building a next-generation wireless network is different from creating a new pharmaceutical, which is different from developing a cutting-edge AI algorithm. These industries have different innovation networks, market structures, and supply chains.

However, while distinct, many modern technology industries also share key similarities. They are critical for economic and national security. They require tremendous amounts of R&D to develop next-generation products. And, to be effective and efficient, they rely on high-functioning markets underpinned by a balance of incentives, protections, and connections. Secure, stable, and predictable IP rights are essential for maintaining that balance while enabling the massive R&D investments required for innovation and technology leadership.

To highlight the role of IP rights in promoting innovation, along with their breadth of impact on U.S. economic and national security, this section examines three distinct technology industries: advanced communications, biopharmaceuticals, and agriculture.

Advanced Communications

Advanced communications technologies—e.g., AI, semiconductors, cellular and wireless networks, satellites, and drones—play a critical role in maintaining national security by enabling secure, efficient, and reliable communication across military, economic, and public safety sectors. For the military, secure and high-speed communication networks are essential for coordinating operations, sharing real-time intelligence, and supporting other advanced technologies like

First Solar Exhibit 2014, Page 27 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

autonomous weapons systems. Similarly, communications networks are deeply integrated into critical infrastructure, including energy, transportation, and financial systems. Disruptions to these networks, particularly in times of crisis, could cause cascading effects that disrupt economic stability and compromise national defense.

Accordingly, leadership in next-generation communications technologies offers a decisive edge in both security and economic domains. Enhanced wireless connectivity can transform industries like autonomous vehicles, advanced robotics, and smart agriculture while improving military capabilities in command, control, intelligence, surveillance, and reconnaissance, among other domains. By securing this leadership, the United States can strengthen its defense posture, safeguard its critical infrastructure, and maintain its competitive advantage in the global arena.

Historically, the United States has led in communications technology thanks to the combination of massive private investment, robust free-market competition, and a flexible, pro-innovation regulatory framework. This has benefitted both U.S. national security and the U.S. economy tremendously. The U.S. cellular and wireless industry, for example, contributed over $825 billion in GDP and nearly 4.5 million jobs to the U.S. economy in 2020.[68] This is to say nothing of the multi-trillion-dollar U.S. digital economy supported by advanced communications technologies.

However, other nations, particularly China, are intensely focused on closing the technology gap in pursuit of their own geopolitical ambitions.[69] Chinese advanced communications firms, such as Huawei, have benefited significantly from state subsidies. For instance, through guaranteed domestic markets and credits, the Chinese government was responsible for helping Huawei secure 10 percent of global mobile wireless infrastructure sales by the mid 2000s.[70] Furthermore, China is handing out massive amounts of export financing for its firms' mobile wireless infrastructure, helping these Chinese firms gain significant market share worldwide.[71] Such subsidies create an uneven playing field that advantages Chinese firms, allowing them to undercut competitors on price, distort global markets, and gain a competitive edge.

Although it may seem counterintuitive, innovation in advanced communications—where interoperability and openness are essential—is supported by secure IP rights that grant owners the right to exclude unauthorized use. As in other critical technology industries, R&D in advanced communications technologies requires billions of dollars in investments.[72] By providing innovators with secure, stable, and predictable ownership rights over the products of their labor, robust and reliable IP rights enable these massive, risky, and long-term investments.

Secure, stable, and predictable IP rights are also critical to innovation in advanced communications because they are fundamental to the creation of technology standards. When properly developed, standards are created by market participants in a voluntary and consensus-driven manner, creating a robust process that is difficult for individual actors to manipulate. No single faction can force their vision on others, and firms cannot be forced to use a particular standard. Instead, firms collaborate and ultimately adopt standards developed through a coordinated effort that reflect market-driven consensus solutions with broad applications.

First Solar Exhibit 2014, Page 28 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

As highlighted above, however, without secure, stable, and predictable IP rights, successful standards development would be greatly undermined. Without such rights, innovators risk losing ownership of their technical contributions to the standard and not receiving fair compensation. The incentives encouraging IP owners to share their breakthroughs within the standards development process would, consequently, be destroyed. And without this collaboration, the strength and appeal of the overall standard would be greatly diminished: The 5G cellular telecommunications standard, for instance, which encompasses over 25,000 patents developed by numerous companies, could not have been developed without secure IP rights.[73] Without reliable IP protections, firms would be less inclined to prioritize standardized innovations or to contribute them to the global commons, potentially stalling advancements in fields ranging from telecommunications to smart devices and autonomous systems, or ceding advancements to other nations.

Standards and Standard Essential Patents

To interoperate, advanced communications rely on technology standards—sets of established technical specifications, guidelines, or protocols that are widely accepted within a particular industry or field of technology. Standards create a common language for communication about technology and innovation, thereby allowing firms to collaborate and develop interoperable products, reduce costs, and improve quality.[74] Communications technologies used daily by billions of people, such as 5G, Wi-Fi, and Bluetooth, are based on standards that any wireless device maker can utilize. In addition to advanced communications, industries and technologies including semiconductors, microelectronics, biotech, quantum computing, clean energy, and distributed ledgers heavily employ standards.

A standard essential patent (SEP) is a patent on a technology used within an industry standard. The patent is considered "essential" because any product that conforms to that standard must use the patented technology. For instance, if a company holds a patent over a component necessary in USB ports, no smartphone manufacturer could add a USB port to their device without licensing that patent from the relevant SEP owner.

Standards are typically set by standards development organizations (SDOs), also known as standards setting organizations (SSOs). SDOs are composed of market participants and driven by consensus to establish voluntary standards. This combination of elements creates a robust standards development process that is difficult for individual actors to manipulate. No single party can force their vision on others, nor can a specific standard be forced upon any party. Instead, firms collaborate through SDOs and ultimately adopt standards developed through a coordinated technical effort.

First Solar Exhibit 2014, Page 29 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

SEPs and National Security

Technology standards are a critical domain of international cooperation and competition in advanced technologies.[75] As technology standards are foundational to many critical technologies, influence over global standards-setting processes may grant nations notable geopolitical advantages. Nations can guide standards development in directions that favor their own domestic industries, thereby bestowing them with a technical edge.[76]

Moreover, as technology becomes increasingly ubiquitous in everyday life, standards development carries considerable political considerations. In communications, for instance, the same standards that ensure all mobile devices are interoperable can dictate requirements around data retention, encryption, and location tracking, among other privacy considerations. Thus, influence over communications standards could allow nations to advance their own human rights and security agendas.

Accordingly, SEPs are important for national security. Should a company successfully create an SEP, the revenue generated from licenses allows them to recoup their investment and generate profit that they can invest in creating next-generation technologies and new standards. In other words, the R&D required to develop the technology used in standards draws on revenue generated from SEP licensing. In some key fields such as advanced communications, SEPs account for billions of dollars in annual licensing revenue.[77] If companies did not receive sufficient licensing revenue from their SEPs, they would be less able to invest in developing new technologies used in standards, and less willing to contribute that technology to standards. This will cause their home nations to lose influence over the global standards-setting process.

Biopharmaceuticals

The U.S. biopharmaceutical innovation system—which translates groundbreaking research into life-saving treatments—is an essential pillar of U.S. national security. In addition to the long-standing threat of bioterrorism, the landscape of biological risks has expanded dramatically in recent years. Russia and North Korea possess active offensive bioweapons programs, while China has accelerated its plans to integrate civilian biological research programs into its military.[78] New technologies expand the risks of bioweapons exponentially: In a single 2022 experiment, U.S. and European scientists generated 40,000 potential biological weapons using AI.[79] Meanwhile, rapidly proliferating under-regulated biolabs increase the likelihood of an accidental leak, and global trends such as climate change, increasing urbanization, and rising meat consumption make future pandemics more likely.[80]

In this increasingly complex threat environment, maintaining a dynamic and innovative U.S. biopharmaceutical industry is crucial. The benefits of such an industry were clearly demonstrated during the Covid-19 pandemic, when the robust U.S. biopharmaceutical industry led the way

First Solar Exhibit 2014, Page 30 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

for the United States and its partners to design a novel Covid-19 vaccine within days, saving countless lives.[81] This effort illustrates the ability of the United States, through reliance on its biopharmaceutical sector, to preempt and respond to biological threats, safeguarding both public health and national security.

The U.S. biopharmaceutical industry is also a major engine of job creation and economic growth. In 2022, the sector directly employed over 1.1 million Americans, including more than 350,000 in high-value manufacturing roles, while contributing over $800 billion, or 1.6 percent, to U.S. GDP. Its broader economic impact is even more significant, indirectly supporting an estimated 3.8 million jobs and generating $850 billion in output, equivalent to 3.6 percent of the U.S. economy.[82]

These economic contributions are fueled by innovation, which ensures that U.S. patients benefit from an expanding arsenal of life-saving treatments. To date, the Food and Drug Administration (FDA) has approved over 20,000 prescription drugs for marketing in the United States.[83] The number of new drug approvals has increased over time as well. New FDA drug approvals surged from 209 between 2000 and 2008 to 302 between 2009 and 2017—a 44.5 percent boost.[84] Furthermore, 68 percent of novel drug approvals in 2024 were first approved for use in the United States, giving Americans first access to breakthrough treatments.[85]

Secure, stable, and predictable IP rights support and encourage this innovation and growth in several key ways. First and foremost, they enable the enormous and high-risk investments required to develop new drugs, complete the clinical trials process, and bring them to market for use by the medical community. The drug development process is incredibly expensive, with estimates for the average cost to develop a new drug ranging from $300 million to $2.8 billion per drug.[86] Furthermore, the entire drug development process—from target identification to FDA approval—can take 10-15 years, which eats considerably into the period of market exclusivity provided by certain IP protections.[87] Yet, despite these considerable investments of money and time, most drugs never make it to market: Only 13.8 percent of drugs that enter clinical trials are approved for use.[88]

In other words, the biopharmaceutical innovation process is expensive, lengthy, and risky. Many initially promising products fail in trials, and many fail late in the process, thereby incurring significant losses. Given that only a few novel compositions become approved treatments and that the investment cost of those that do is high, biopharmaceutical companies must be able to sell their products at prices that reflect the overall cost and value structure in which they operate, not the cost of a single product's development. Without IP rights, it would be impossible for biopharmaceutical companies to commit enormous sums of capital again and again in inherently uncertain ventures.

Second, secure, stable, and predictable IP rights ensure that key actors in the biopharmaceutical innovation ecosystem are able to safely and efficiently collaborate. For instance, basic research, which explores the underlying biological pathways and the pathophysiology behind a disease, frequently identifies potential targets for treatments and searches for new molecular entities that can modulate such targets.[89] This research is largely carried out by universities, federal agencies, and nonprofits, who then partner with private biopharmaceutical companies to continue the

First Solar Exhibit 2014, Page 31 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

research process, enter clinical trials, and ultimately commercialize the discovery. This partnership is facilitated by the Bayh-Dole Act, which created the uniform framework that facilitates orderly and efficient technology transfers from universities and other institutions receiving government research funding to the private sector. While exact estimates are difficult to find, the Association of University Technology Managers reports that between 1996 and 2020, over 200 new drugs and vaccines were developed as a result of the Bayh-Dole Act.[90] Secure IP rights provide these actors with a secure framework for collaboration and licensing between academia and the private sector, which is essential for innovation in the complex biopharmaceutical innovation ecosystem.

Promoting collaboration is particularly important for startups and small firms, which leads to the third critical role of IP rights in the biopharmaceutical industry: protecting small economic actors. These actors are a powerful driver of innovation. Recent research estimates that startups and small pharmaceutical companies were responsible for the introduction of 64 percent of new molecular entities in 2018. In terms of R&D expenditures, small biopharmaceutical firms invested $637,735 per employee in 2021, compared with $82,515 per employee in large biopharmaceutical firms. This is especially true in the United States—of the 260 small biopharmaceutical companies worldwide that invested the most in R&D in 2021, 193 were U.S.-based. These firms work at the cutting edge of biopharmaceutical research, often taking a chance on novel products that are too risky for the larger, more established players in the market. This may include pursuing abandoned projects, investing in areas of pharmaceutical research known for higher-than-normal failure rates, or pursuing "orphan drugs" that treat conditions with small patient populations.[91]

However, while startups and other small economic actors conduct significant amounts of R&D and identify many promising candidates for new drugs, they often lack the resources and expertise needed to navigate clinical trials, scale up operations, develop supply chains, and successfully market newly approved drugs. Thus, smaller companies frequently partner with larger ones via licensing or through mergers and acquisitions to obtain the resources needed to scale their activities.[92] Strong and enforceable IP rights enable small and large firms to partner with each other and with research institutions and the government to develop new medications, benefiting the U.S. people, the U.S. economy, and U.S. national security.

Agriculture

Food security is inseparable from national security. All aspects of society require reliable access to food in order to function. In times of food insecurity, societies begin to fracture, and political instability often follows.[93] Consequently, the practice of denying food to adversaries remains in practice in 2025, as the pressure of food insecurity undermines both militaries and civilian populations.[94] For these same reasons, dependence on another nation for food creates significant vulnerabilities. Nations that control food access and supply can leverage that control as a tool of influence or coercion.

Moreover, though our ability to feed the global population has improved over time, new challenges are on the horizon. The global population is skyrocketing—the United Nations projects an approximate increase of two billion people by 2050—causing the demand for food to surge, just

First Solar Exhibit 2014, Page 32 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

as intensifying and expanding pest, disease, and climate pressures are making food more difficult to grow.[95] Meanwhile, geopolitical events continue to shock the global food supply. To give one example, the UN Food and Agriculture Organization predicts that millions will still be chronically undernourished in 2030 because of Russia's war in Ukraine, a major agricultural exporter.[96] Indeed, these shocks have contributed to global food price inflation over the last several years. Between December 2019 and February 2022, the Producer Price Index for grains rose by 73.5 percent, driven primarily by the impact of the Covid-19 pandemic on corn and wheat prices. Russia's invasion of Ukraine caused a further shock to grain availability, as wheat and corn were heavily supplied by Ukraine, resulting in a 24.1 percent increase in prices in just the first four months of the conflict.[97]

Much of the success and resilience of the U.S. agriculture industry stems from patentable innovation in agricultural technology. New seed varieties enable farmers to plant crops that are resistant to pests, disease, and drought, dramatically boosting efficiency and crop yields.[98] Novel herbicides, fungicides, and pesticides, along with new innovative tools such laser scarecrows, drones, and automated sound and motion systems, allow farmers to protect their crops from the persistent threats that can damage up to 50 percent of output.[99] Indeed, despite the increasing challenges of pests, disease, and climate, the United States is likely to produce a record crop of both corn and soybeans in 2025, nearly doubling the per-acre productivity of the rest of the world.[100] This productivity allows U.S. farmers to feed not only the 330 million who call this country home, but many millions more around the world.

Secure, stable, and predictable IP rights support and encourage food-related innovation and growth by incentivizing the massive and high-risk investments required to develop new agricultural technologies, complete the regulatory approval process, and bring those technologies to market for use by U.S. farmers. Bringing a new transgenic seed trait to market costs an average of over $100 million and takes more than 16 years, and bringing a new pesticide to market costs an average of $301 million over 12 years.[101] Not only is the cost to develop these innovative new products enormous, but the lengthy time needed to complete the regulatory approval process means that half of a patent's term has typically elapsed before a product has entered the market. Secure IP rights provide innovators with an opportunity to recoup their investments and fund R&D into the next generation of products.

Ensuring that U.S. businesses are able to invest and innovate securely is critical in today's globalized agriculture industry. As of 2023, China and the European Union significantly outspent the United States in public agricultural R&D investments, while Brazil and India were quickly gaining ground.[102] The strength of the U.S. agriculture industry largely stems from the private sector, which drives much of the industry's innovation and growth: Over 70 percent of U.S. agricultural R&D spending is privately funded.[103] Strong and secure IP rights enable private enterprises to invest and innovate, securing the U.S. food supply during a time of growing challenges.

First Solar Exhibit 2014, Page 33 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

3

Challenges in U.S. IP Policy

For much of its history, the United States has been a global leader in fostering innovation through strong and secure IP rights. The U.S. Constitution itself underscores the importance of IP protections, granting Congress the power to "promote the progress of science and useful arts" by securing for defined periods exclusive rights for creators and inventors.[104] These exclusive rights laid the foundation for an economy driven by creativity and ingenuity, fostering a unique culture of innovation that the United States retains to this day.

However, the path of U.S. IP policy has not always been steady. The federal government's commitment to ensuring stability and security in IP rights has fluctuated over time. In the 1930s, for instance, the patent system was weakened amid efforts to dismantle monopolies, which were perceived as contributing to the Great Depression.[105] This skepticism towards patents persisted through World War II, resurging during the economic challenges of the 1970s.[106] During this 40-year period, courts were reluctant to enforce patents, and antitrust agencies widely issued compulsory licensing orders against some of the largest tech firms.[107] This era of weak patent protection coincided with a noticeable decline in U.S. innovation performance.

Nevertheless, these stretches of weak IP protections gave way to periods of reform. In the 1980s, amid growing global technological competition—particularly from a rapidly advancing Japan—the United States recommitted to strengthening its IP system with the aim of reinvigorating innovation. This pro-IP resurgence included the passage of the Bayh-Dole Act and the establishment of the U.S. Court of Appeals for the Federal Circuit, a specialized court with exclusive jurisdiction over patent appeals instituted to ensure greater consistency in patent rulings.[108] U.S. innovation rebounded,

First Solar Exhibit 2014, Page 34 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

and these reforms helped fuel the wave of technological advancements that defined the late twentieth century.[109]

In 2025, the United States finds itself at a crossroads. Over the past several years, U.S. IP policy has devolved into a state of incoherence, characterized by weakened protections, inconsistent enforcement, and legal uncertainty. These shifts threaten to erode the innovation ecosystem that has long been a pillar of U.S. economic strength and global leadership. At a time when the nation is striving to reinvigorate its technological base amid fierce global competition, particularly with China, an unstable IP environment risks undermining this effort. This section explores how the erosion of U.S. IP policy threatens innovation, thereby creating vulnerabilities in critical industries, and weakening the United States' position in the global technology race.[110] It also illustrates the opportunity this administration has to reestablish the United States as the leading proponent of secure, stable, and predictable IP rights.

Uncertainty and Instability in IP Rights

As highlighted previously, predictability and stability are essential conditions for an efficient and productive market and are especially critical to innovative industries with high levels of inherent risk, large financial commitments, and long-term horizons. Unfortunately, certain elements of the U.S. patent system are currently plagued by high levels of uncertainty and instability, disincentivizing the risk-taking and investment required to innovate in many critical technology fields and undercutting the market position of startups and other small enterprises.

UNCERTAINTY IN PATENT ELIGIBLE SUBJECT MATTER

Among the most fundamental questions within any patent regime is what subject matter and which fields of invention will be eligible for patent protection. In the United States, this is codified in Title 35, Section 10, of the U.S. Code—often referred to as Section 101—as "any new and useful [1] process, [2] machine, [3] manufacture, or [4] composition of matter."[111] However, despite the tremendous technological change the United States has experienced since its founding, this definition of patent-eligible subject matter has remained essentially unchanged for over two centuries. Instead, courts have attempted to reconcile the critical and emerging technologies of today with a centuries-old statute, often with confounding results.

Most recently, a series of Supreme Court decisions between 2010 and 2014 significantly decreased the scope of Section 101, denying patent protection to entire fields of invention.[112] These decisions established a two-step test for determining patent-eligible subject matter known as the Alice/Mayo Test, which restricts patents related to laws of nature, natural phenomena, and abstract ideas.[113] Eliminating fields of inventions from the patent system has had clear downstream consequences on U.S. innovation and international competitiveness. One 2017 study, for instance, identified over 1,400 inventions, including treatments for cancer and diabetes, that were granted patent protection in Europe and China but not the United States.[114] This heavily incentivized firms to develop and commercialize those technologies abroad, where they could protect their investments, instead of in the United States.

First Solar Exhibit 2014, Page 35 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Moreover, Alice/Mayo rendered it unclear if additional fields of invention are eligible for patent protection, such as medical diagnostics, personalized medicine, methods of treatment, computer software, and artificial intelligence.[115] For instance, numerous judges for the Federal Circuit have expressed dismay at the current state of patent eligibility law, calling it "incoherent" and "indeterminate."[116] Kimberly A. Moore, chief judge of the Federal Circuit, expressed that the court's judges were "at a loss" in how to apply the current patent eligibility provisions in light of the Supreme Court decisions.[117] Furthermore, some IP legal professionals claim that they are unable to provide clear guidance to businesses due to Alice/Mayo, while the U.S. Chamber of Commerce identified "continued uncertainty over patentability for high-tech sectors" as a key weakness in U.S. IP protections in its 2023 International IP Index.[118]

This uncertainty in patent eligibility has had, and threatens to continue to have, negative downstream consequences for innovation, particularly in industries strongly impacted by Alice/Mayo such as life sciences and advanced communications technologies. First, it deters risk-taking and investment. Investors may avoid companies with patents in affected fields as they cannot accurately assess the risk of patent invalidity. It is safer to eschew the field altogether and invest elsewhere. Indeed, one 2022 study estimated that medical diagnostic technologies, which are highly impacted by Alice/Mayo, lost out on $9 billion in investment in the four years following the test's implementation.[119] Moreover, stakeholders in both the biotechnology and information technology industries contend that Alice/Mayo constrains their capacity to secure patents for novel inventions, ultimately reducing the economic viability of developing these new technologies.[120]

Alice/Mayo may have already disproportionately hurt small economic actors as well. A 2020 study found that individual inventors and inventor-founded businesses lost their patent eligibility cases far more often than other actors under Alice/Mayo.[121] By creating legal uncertainty and confusion, Alice/Mayo may reward large companies that, with the resources to engage scores of lawyers, opportunistically challenge patents of smaller companies lacking comparable resources. Indeed, several large technology firms are known to infringe on patents and rely on large and well-compensated legal teams to drag out litigation and avoid penalties, or simply swallow damage payments as a cost of doing business.[122]

In short, the uncertainty surrounding patent-eligible subject matter under the Alice/Mayo framework has already posed, and will continue to pose, a barrier to innovation in the United States. By limiting the scope of patent protection and thereby creating ambiguity in key high-tech and life sciences sectors, the current legal landscape discourages investment, stifles the development of new technologies, and disproportionately harms smaller innovators who lack the resources necessary to navigate complex legal challenges. Without clear and predictable guidelines for patent eligibility, the United States risks ceding its position as a global leader in innovation, as companies and investors increasingly turn to jurisdictions with more consistent and supportive IP regimes.[123] To restore confidence in the U.S. patent system and foster robust innovation, a legislative or judicial resolution to the uncertainties of patent eligibility is urgently needed.

First Solar Exhibit 2014, Page 36 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

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UNCERTAINTY OF PATENT VALIDITY

When the USPTO grants a patent, that patent becomes property that its owner can use to attract investment, form commercial relationships, and otherwise integrate into the market and develop their business. Significant and costly decisions are often made on the basis of a patent, not only by the patent owner, but also by investors, partners, and potential competitors. Conversely, the rejection of a patent application can inhibit a business' ability to attract investment and form commercial relationships, making the patent application process particularly crucial for many small businesses.

Occasionally, the USPTO grants a patent that should not have been granted, so there are mechanisms in place to invalidate patents if, for example, it is found that the claimed invention is not sufficiently distinct from previous inventions. Given the potential disruption to economic activity caused by a patent invalidity decision, however, invalidating a patent is not taken lightly and U.S. patents are presumed to be valid by federal courts.[124]

Nevertheless, over the last decade, changes to the U.S. patent system have dramatically increased the rate at which patents are invalidated. Through 2020, 60 percent of patents challenged under the new Alice/Mayo framework has claims invalidated, resulting in hundreds of invalidated patents.[125] As a result, businesses with patents related to the affected subject areas have seen their patents devalued, as the chance of their patent being invalidated has increased. This can lead to decreased investment and challenges in establishing new commercial partnerships.

Further, while the Supreme Court was establishing the Alice/Mayo framework in the early 2010s, Congress enacted a second major reform to the patent system: the America Invents Act (AIA) of 2011, which created the Patent Trial and Appeal Board (PTAB).[126] The PTAB was established as a faster and cheaper alternative to district court for reevaluating patent validity and was granted the power to invalidate patents and render them unenforceable.

However, lawmakers included several design flaws in the PTAB that have undermined patent rights and injected significant uncertainty into the overall system. For instance, the PTAB uses a lower standard of evidence for invalidating a patent than used in district courts, leading to a patent invalidation rate of approximately 70 percent at the PTAB compared to roughly 30 percent at district court.[127] This high invalidation rate led former Federal Circuit Chief Judge Randall Rader to describe the PTAB as "death squads killing property rights."[128] Even the increased risk of a successful retrospective patent eligibility challenge at the PTAB introduces significant uncertainty for startups and other small actors who rely on IP to attract financing.[129]

First Solar Exhibit 2014, Page 37 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

While it is imperative to preserve a mechanism for invalidating erroneously granted patents, the PTAB has shifted the balance of power excessively in favor of patent challengers. This has created new pathways for abuse, particularly by larger entities. For instance, large tech companies, including Chinese companies Huawei and ZTE, are the leading users of the PTAB, and appear to be leveraging the system to clear out patents owned by smaller companies who may challenge them in the future.[130] Furthermore, evidence suggests that such intense scrutiny on erroneously granted patents is likely misplaced. A 2024 study from the Sunwater Institute concluded that the USPTO (1) improperly grants patents at a lower rate than its counterparts around the world and (2) improperly rejects patents at a far greater rate than it improperly approves patents.[131]

Uncertainty surrounding patent validity, exacerbated by the high invalidation rates under the PTAB and the Alice/Mayo framework, has created a chilling effect on innovation and investment in the United States. Startups and small firms—key drivers of technological progress—are particularly vulnerable to these risks, as they often lack the resources to defend their patents against well-funded challengers. Moreover, the systemic imbalance favoring patent challengers risks enabling strategic abuse by dominant firms, including foreign competitors, thereby undermining U.S. technological leadership and economic security. Addressing these challenges requires recalibrating the system to ensure that mechanisms like the PTAB serve their purpose without eroding the stability and reliability of U.S. patent rights.

Challenges Enforcing IP Rights

A patent provides its owner with the right to exclude others from making, using, selling, or importing an invention throughout the United States. In practice, however, the patent owner cannot forcibly prevent another entity from making use of its protected IP. Secure patent rights rely on a legal system that defends and enforces those rights. Without the ability to enforce patent rights, the value of a patent greatly diminishes as infringement becomes more common and commercial transactions become protracted and difficult.

Over the last decade, enforcing patent rights in the United States has become increasingly difficult, which has profoundly disrupted the U.S. innovation ecosystem. The security and predictability of the IP rights underlying effective collaborations, licensing, and other complementary activities that make patented technologies broadly available throughout innovation networks has been weakened. Rather than affording patent owners the ability to realize fair and reasonable compensation for their inventions based on their value, firms instead strategically free ride, taking the chance they will never be called to task. While this may be beneficial for those opportunistic firms, it is detrimental to the overall health of the United States' innovation ecosystem and presents a particularly negative environment for small innovators who do not have the resources to challenge such conduct.

LACK OF INJUNCTIVE RELIEF

If an entity is infringing on a patent—that is, using that protected IP without the patent owner's authorization—the patent owner must go to court to receive a remedy. The court's authority and actions are the source of the patent's practical value: A patent is a right to exclude, and courts are the entity that enforces that right. In the case of patent infringement, courts can issue

First Solar Exhibit 2014, Page 38 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

injunctions, which are court orders that instruct the infringing party to end all alleged breaching activities immediately.

An injunction is the legal backstop for commercial negotiations; it is the protection that secures actors the freedom to say "no" to an offer to purchase or access one's property. As just one example of their critical importance, injunctions provide patent owners with leverage to get a fair market price for their IP. Injunctions allow them to walk away from the table, which is fundamental to a fair negotiation, and therefore the patent's value. Furthermore, injunctions protect the value of IP by forcing infringers to immediately halt the production or sale of infringing products, a crucial defense for patent owners in situations where the infringement could cause significant harm to the patent owner's market share or reputation.

For much of U.S. history, injunctions were common. By some measures, injunctions were granted in approximately 95 percent of cases where infringement was found, meaning that courts almost always enforced a patent owner's right to exclude.[132] Economic actors, in turn, recognized that courts would defend a patent owner's right to exclude via an injunction, and acted accordingly. Patent owners were empowered to negotiate from a fair position.

This equilibrium was ruptured by the 2006 Supreme Court case *eBay v. MercExchange*. In a ruling that has been the subject of fierce legal debate ever since, the Supreme Court weakened patent owners' ability to receive legal injunctions by creating a four-factor test for deciding whether to grant an injunction.[133] As a result, while injunctions are still available for patent owners, they are now sought and granted significantly less often.[134] Indeed, a June 2024 study found as much as a 91 percent decrease in the granting of permanent injunctions to patent owners after a finding of infringement post-*eBay v. MercExchange*.[135]

The decreased rate of injunctions in the aftermath of *eBay v. MercExchange* changed market dynamics and undermined the balance of rights among various actors in the U.S. innovation ecosystem, creating perverse incentives that cash-rich firms have been able to exploit.[136] Without any serious risk of an injunction that would require withdrawing a product from the market, a well-resourced infringer is free to profit from an innovator's technology during a protracted litigation process that can take years and consume millions of dollars in legal fees.[137] Even if the infringer loses, in some cases it can simply pay a reasonable royalty award that may undervalue the infringed patent. Alternatively, a resource-constrained patent owner may agree to settle on below-market terms to avoid the costs and delays of litigation. In this way, the rarity of injunctive relief today has distorted the relative bargaining power between patent-owners and patent-licensees, greatly favoring licensees over innovators.

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The significant decrease in injunctions is particularly troubling in an international context. Courts in many advanced economies, such as China, France, Germany, Japan, and the United Kingdom, are much more likely than U.S. courts to grant permanent injunctions, making these jurisdictions more attractive for businesses with global patent portfolios.[138] Ultimately, the United States could lose out on investment and innovation as firms focus their patenting activity, and related R&D and innovation, in jurisdictions that are better prepared to defend their rights.

DUPLICATIVE LITIGATION

A core benefit of the U.S. IP system is that it empowers smaller actors by giving them the legal protections needed to negotiate fairly with larger competitors. This is essential for them to fully participate in the market. Without strong IP rights, small innovators risk being marginalized by well-established technology incumbents, some of which are known to leverage their resources to infringe on patents with little consequence. [139] These large firms can deploy extensive legal teams to prolong litigation, minimize penalties, or simply absorb damages as a routine cost of business. Strong IP protections help mitigate this imbalance by providing smaller firms with the legal safeguards and recourse they need defend their innovations, compete effectively, and contribute to technological progress.

Loopholes in the AIA, however, have undermined the ability of small firms to counterbalance the leverage large firms can exert in litigation. Specifically, the PTAB allows 1) repeat challenges to the same patents and 2) for petitioners to challenge the same patent at both the PTAB and district court. Evidence suggests large tech firms exploit these loopholes: approximately 80 percent of patents challenged through the PTAB have been litigated in at least one district court, and large tech companies, including Chinese companies Huawei and ZTE, are the leading users of the PTAB.[140] Moreover, PTAB experts claim large companies often challenge the same patent repeatedly to drive up litigation costs and get more chances to invalidate the patent.[141] As PTAB cases cost patent owners $300,000-$450,000 on average to litigate, duplicative hearings are quite costly.[142]

The U.S. IP system functions best when it protects smaller actors and empowers them to fully engage in the market. Instead of protecting these actors, however, over the last two decades the IP system has begun working against them. Without a clear and effective means to enforce their patent rights, small economic actors suffer, undermining the U.S. innovation ecosystem that relies on them as a crucial source of new ideas.

Misguided Attempts to Weaken IP Rights to Control End Product Prices

Over the last several years, the costs of certain goods for consumers, particularly medications and therapeutics, have become a significant political issue. A January 2024 survey from the Pew Research Center found that 72 percent of Americans are “very concerned” about the price of food and consumer goods, while another recent survey found that 82 percent of U.S. adults believe that prescription drug prices are “unreasonable.”[143] Accordingly, lowering prices was a key priority for the Biden administration.

First Solar Exhibit 2014, Page 40 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Alarmingly, however, the Biden administration and other policymakers responded to these price concerns by attempting to weaken the patent system in an effort to control end product prices. While the cost to consumers of certain products may indeed be worth scrutiny, a broad assault on patents for such purposes is misguided. Such efforts directly risk damaging the security, stability, and predictability essential to incentivizing investment and forming the commercial partnerships needed to develop new and potentially lifesaving products. Indeed, many of these proposals to weaken IP rights are unlikely to reduce prices, causing significant harm without achieving their goals.

FAILURE TO REDUCE PRICES

The stated objective of several recent regulatory actions and proposed bills has been to reduce the price of certain goods for consumers. For instance, the Biden White House proposed a framework for the federal exercise of "march-in rights" to require firms to license certain patented inventions based on the price of the end-product, while the Federal Trade Commission (FTC) has challenged hundreds of patents in the FDA's Orange Book with the express intended purpose of lowering drug prices for consumers.[144] Meanwhile, some policymakers advocate relying on a reinterpretation of Section 1498 to freely infringe on patents, and others have introduced bills such as the Medication Affordability and Patent Integrity Act, the Affordable Prescriptions for Patients Act of 2023, and S.3583 to alter the patent system with the stated intent lowering drug costs.[145] As patents grant holders a limited period of market exclusivity that enables them to gain financially from their innovation, the reasoning for these actions is that weakening patent rights will increase competition and lower prices.

Such reasoning, however, has been shown to be suspect and dependent on questionable data. For instance, the sponsors of the Medication Affordability and Patent Integrity Act, the Affordable Prescriptions for Patients Act, and S.3583 explicitly state that the bills would address "abuses" of the patent system by innovative biopharmaceutical firms, specifically "patent thickets" and "evergreening"—two practices that some advocates for lower drug prices claim biopharmaceutical companies employ dishonestly to extend their period of market exclusivity and ward off generic competition.[146]

A 2022 USPTO study shows that these concerns are largely based on unreliable and unreproducible data that overstates a drug's period of market exclusivity and the number of patents protecting drugs.[147] In a multiyear study undertaken at the request of Senator Thom Tills (R-NC) and published in 2024, the USPTO concluded that claims around patent thickets and evergreening were misplaced.[148] The study found no correlation between the number of patents on a product and generic market entry, thus undermining the assertions about "thickets" of patents blocking competition. The study likewise found that follow-on innovations and patents do not block generic entry, contradicting claims of evergreening. In addition, according to the USPTO study, there are significantly fewer patents protecting drugs and significantly shorter periods of market exclusivities than external sources claim, further suggesting that these narratives are built on unreliable evidence.[149]

First Solar Exhibit 2014, Page 41 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Proposed regulatory efforts to lower drug prices are similarly based on misunderstandings of the pharmaceutical patent landscape. For example, the Biden administration's proposed framework for employing march-in rights—which empower the government to compel the owners of patents on federally funded research to allow others to use the patented technology under certain conditions—under the Bayh-Dole Act, is unlikely to lower drug prices in any meaningful way.[150] A 2023 study found that drugs developed solely with government support, and therefore subject to march-in, account for less than 2 percent of all new drugs approved by the FDA between 2011 and 2020, while another study found that 98 percent of new drugs approved by the FDA since 1985 were developed with privately funded IP.[151] Put simply, the proposed march-in rights framework will likely have little, if any, of its intended impact on lowering drug prices.

UNINTENDED IMPACT ON INNOVATION

Proposals to weaken IP rights with the supposed goal of lowering consumer prices are unlikely to achieve their objectives, and even proposing them—must less enacting such proposals—creates risks of inhibiting the discovery of new, potentially life-altering drugs. At its core, the patent system encourages companies to invest in R&D by enabling a return on that investment. Diluting these protections reduces potential returns on high-stakes investments, incentivizing firms to scale back or discontinue projects that could yield groundbreaking products. This threat is especially concerning in industries like pharmaceuticals and agriculture, where bringing a single product to market can require billions of dollars and over a decade of research—risks few would undertake without reliable patent safeguards.

Moreover, such policies erode the stability and predictability of the U.S. patent system—a critical factor in encouraging investors and companies to pursue cutting-edge research. Repeated attempts to weaken IP rights generate uncertainty, discouraging the partnerships and collaborations that transform nascent ideas into market-ready innovations. Universities and private sector firms, for instance, depend on secure IP rights to forge alliances that have resulted in hundreds of technological breakthroughs.[152] Without a stable patent framework, these partnerships risk being disrupted, stalling the development of lifesaving or life-improving products.

The risks of a weakened patent system under the guise of controlling end-product prices are not limited to the biopharmaceutical industry. The march-in rights proposal, for instance, would expand the federal government's march-in authority across all sectors of the economy, allowing federal agencies to challenge exclusive rights in patents across all market sectors on the basis of product price. An accompanying Request for Information (RFI) from the National Institute for Standards and Technology (NIST) outlines potential scenarios where march-in could be invoked involving patents ranging from 3D printing technology to communications technology, face masks, and water purification systems.[153]

There is no simple, one-size-fits-all solution to reducing consumer prices. However, dismantling the patent system in pursuit of short-term cost cuts for consumers risks significant collateral damage to the research and collaborations critical for ongoing innovation. Instead, policymakers should focus on addressing other aspects of supply chain—such as reforming pharmacy benefit managers, in the case of pharmaceuticals—to deliver lower prices without eroding the incentives that drive

First Solar Exhibit 2014, Page 42 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

technological advances.[154] Ultimately, a robust, resilient innovation system that provides effective, affordable, and accessible products and services depends on preserving the fundamental balance upheld by strong and secure IP rights.

Erosion of the International IP System

The U.S. IP regime does not exist in a vacuum. It operates within a global framework of multilateral treaties and international organizations that collectively make up a system of international IP protections. This system underpins the operations of multinational firms, investors, and the broader innovation ecosystem, making it essential for U.S. policymakers to consider its dynamics and impact.

Since the late twentieth century, the United States had been a leading advocate for strong IP protections both at home and abroad. This has provided the United States with significant economic and national security benefits. However, recent years have seen a troubling retreat from this leadership role, as well as policies and proposals that may undermine the entire international IP system. Meanwhile, foreign nations are increasingly leveraging their own IP laws and market powers to influence the global IP system and advance their industrial and national security goals.[155] Without renewed U.S. engagement and defense of strong and secure IP rights at home and abroad, the nation risks undermining its own innovators and losing critical ground to global competitors.

BENEFITS OF THE INTERNATIONAL IP SYSTEM

While IP protections such as patents and copyrights are territorial, meaning they are limited to the territory of the country where they have been granted, IP rights are nonetheless a topic of international concern. In a globalized economy, businesses rely on strong IP rights to capture a return on their investments, securely engage in international partnerships, and protect themselves from counterfeiting, piracy, and theft.

The United States and its partners have spent decades developing a system of multilateral treaties and international organizations focused on maintaining a strong and stable system of IP rights around the world.[156] This system includes the Patent Cooperation Treaty, which allows inventors to file a single "international" patent application rather than apply separately in each jurisdiction; the World Intellectual Property Organization, a United Nations agency tasked with promoting global IP protections and international cooperation in IP rights; and the Patent Law Treaty, which makes it easier for applicants to obtain and maintain patents throughout the world by simplifying and aligning formal requirements in global patent offices and jurisdictions.[157]

The TRIPS Agreement

The most prominent international IP treaty is the Trade Related Aspects of Intellectual Property Rights agreement, a binding pact that sets minimum standards for IP protections among the 166 members of the WTO.[158] Several countries, including the United States, provide intellectual property standards that exceed these minimum requirements, but

First Solar Exhibit 2014, Page 43 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

many countries do not meet the minimum standards required by the TRIPS Agreement. Signed in 1994, TRIPS provides mechanisms for enforcement and dispute resolution through the WTO.

Like other WTO agreements, TRIPS applies the fundamental principles of nondiscrimination, specifically through National Treatment and Most Favored Nation (MFN) Status. National Treatment requires that nations treat foreign companies the same as domestic firms within their own markets. In the case of IP, this means that nations cannot discriminate against foreigners in patent applications, copyright enforcement, or trade secret disputes. MFN Status ensures that all member countries receive equal treatment, meaning that any favorable trade or IP terms granted to one member must be extended to all other WTO members.[159] These principles made IP protections around the world available to foreign businesses and inventors, who have seized the opportunity: Growth in cross-border patenting has significantly outpaced domestic patenting since TRIPS was established.[160]

Overall, the United States benefits tremendously from this international system of IP protections. Foreign markets are critical for the competitiveness of U.S. firms—companies in the U.S. S&P 500 generate approximately 41 percent of their revenue abroad.[161] Secure IP protections abroad help safeguard U.S. companies operating in and exporting to foreign markets, reducing the risks of piracy and counterfeiting.[162] This can be particularly beneficial in industries like software, pharmaceuticals, and media, where unauthorized reproduction is common. Strong IP protections abroad also allow U.S. businesses to better capture the returns on their investments in R&D, creating powerful incentives for U.S. firms to engage in long-term, high-risk innovation. These benefits are reflected in the United States' IP balance of trade: The United States is a net exporter of IP, with IP licensing fees comprising 14 percent of U.S. services exports yet only 8 percent of U.S. services imports in 2022.[163] This is a major advantage relative to competitors such as China. In 2021, the United States experienced an IP trade surplus of $78 billion, while China had an IP trade deficit of $35.1 billion.[164] The administration should advocate aggressively to expand the conditions that result in such benefits for the United States and U.S. firms.

In addition, granting foreigners secure IP protections benefits the domestic U.S. economy and innovation ecosystem. The positive relationship between secure IP rights and foreign direct investment is well documented.[165] Secure IP rights for foreign actors promote foreign investment in the United States and incentivize these foreign actors to innovate and conduct high value-added R&D activities in the United States. Furthermore, foreign-born inventors disproportionately contribute to U.S. innovation and patent filing, driving innovation and growth across the U.S. economy. While accounting for just 16 percent of all individual U.S.-based inventors, for instance, foreign-born inventors produce nearly a quarter of total innovation output as gauged by patent volume, patent citations, and patent value.[166] The United States also benefits from foreign firms filing for U.S. patents and disclosing their inventions in English, thereby enabling U.S. innovators and companies to learn from their discovery.[167] Put differently, the practice of nondiscrimination

First Solar Exhibit 2014, Page 44 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

against patent applicants benefits U.S. companies both abroad and domestically. This too should be part of the administration's IP policy.

WANING U.S. LEADERSHIP

Despite the United States' long-standing commitment to and the numerous benefits it receives from the international IP system, the actions of U.S. policymakers have undermined this system in three distinct ways.

First, the weakening of IP protections at home has undermined the international competitiveness of the U.S. IP system, thereby diminishing the United States' leadership in the international IP system. For instance, as injunctions have become less common in the United States, courts in other advanced economies—e.g., China, France, Germany, Japan, and the United Kingdom—are now much more likely than U.S. courts to grant permanent injunctions, making these jurisdictions more attractive for businesses with global patent portfolios.[168] Ultimately, the United States could lose out on investment and innovation as firms focus their patenting activity and related R&D and innovation in jurisdictions that are better prepared to defend their IP rights. Similarly, eliminating fields of inventions from the patent system has clear downstream consequences on U.S. competitiveness, as certain inventions ineligible for patent protection in the United States remain patent eligible in other nations.[169] This heavily incentivizes firms to develop and commercialize those technologies abroad where they can protect their investments, instead of in the United States.

The decline in domestic IP protections makes the United States a less attractive venue for settling patent disputes, ultimately reducing U.S. influence in the global IP system. As U.S. courts resolve fewer patent disputes, they produce fewer precedential decisions, diminishing their authority in shaping global IP jurisprudence. This creates a self-reinforcing cycle: The resulting lack of robust case law creates uncertainty and makes the United States a less attractive venue for firms seeking clarity and enforcement, leading to even fewer opportunities to produce precedential decisions.

Meanwhile, international competitors are actively enhancing their own IP systems to attract more cases and investment. In June 2023, Europe launched the Unified Patent Court (UPC), streamlining patent litigation across member states.[170] Early indications show that the UPC operates with greater speed and efficiency than U.S. courts, where patent disputes often take three to five years to resolve and cost an average of $3.5 million.[171] The UPC, in contrast, renders decisions in approximately one year, reducing litigation costs and making Europe a more appealing venue for resolving patent disputes.[172] This shift gives European courts greater influence in shaping global patent law and strengthens their standing in the international IP system, further challenging U.S. dominance.

Second, the United States has backed away from upholding the IP rights of U.S. firms in the international IP system. For instance, the TRIPS waiver for Covid-19 vaccines promoted by the Biden administration—which allows foreign governments to authorize local Covid-19 vaccine production without permission from U.S. patent holders—risks eroding the U.S. biopharmaceutical innovation ecosystem while failing to boost vaccine access.[173] These risks are exacerbated when viewed in a global context. A TRIPS waiver expansion might lead to an uneven global market in which U.S. firms are disadvantaged by an uneven playing field where foreign firms can free ride off of U.S. R&D

First Solar Exhibit 2014, Page 45 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

efforts. This would create a perverse incentive for the private sector to shift capital away from any pharmaceutical segment that is encumbered by a TRIPS waiver.

This retreat from defending the IP rights of U.S. firms abroad is reflected in more subtle ways as well. For example, the 2024 Special 301 Report from the United States Trade Representative (USTR), which reviews if U.S. trade partners are providing "adequate and effective" protection of IP rights, fails to address potential abuses in compulsory licensing, a mechanism that allows third parties to use patented products or processes without the patent owner's consent.[174] This failure, which marks a clear deviation from past Special 301 Reports, ultimately provides tacit approval for practices that misuse the TRIPS system, such as issuing compulsory licenses to boost medical tourism or achieve industrial policy goals.[175] In another example, there was no push back on the recent proposal by the African Group, comprised of the 54 member states of the African Union at the United Nations, that suggested weakening IP protections to create more "policy space" to "reindustrialize strategic sectors."[176]

These moves and missed opportunities by the Biden administration are magnified by the growing international movement to reform the TRIPS agreement, as they lend credence to mounting calls for additional IP waivers, less IP enforcement, and increased technology transfer. Indeed, the TRIPS waiver may have already emboldened certain actors in the global economy. Colombia, for example, recently issued its first compulsory license for an innovative medicine, while the European Union is finalizing legislation that would expand compulsory licensing beyond patents to patent applications, trade secrets, and tacit knowledge.[177] Colombia is further proposing a comprehensive review of TRIPS with the objective of renegotiating the agreement.[178]

The U.S. administration should push back. TRIPS flexibilities are meant to address extraordinary circumstances without prejudice to the underlying commitment to protect IP—broadening or normalizing these exceptions can undermine the same IP protections that facilitated rapid vaccine development in the first place.

Finally, several bills proposed by Congress, while perhaps well intentioned, similarly weaken the international IP system by restricting the IP rights of foreign-born inventors in the United States. The Prohibiting Adversarial Patents Act (PAPA), for instance, would bar persons and entities sanctioned by the United States from receiving new U.S. patents and invalidate their existing patents, while requiring the disclosure of an inventor's ties to China and other "foreign adversaries" such as Iran, North Korea, and Russia in their patent applications.[179]

Though perhaps not unreasonable at face value, PAPA would violate the principles of nondiscrimination in the TRIPS agreement, undermine the U.S. economy and innovation ecosystem, and ultimately fracture the international IP regime while also inviting retaliation against U.S. firms abroad. This could be a considerable loss for U.S. firms as foreign-born inventors drive significant amounts of innovation for U.S. firms and U.S. firms have led the world in foreign patent filings every year for the last decade.[180] PAPA would also weaken the United States vis-à-vis China: In 2023, U.S. firms filed over twice as many foreign patent applications as China.[181] Addressing

First Solar Exhibit 2014, Page 46 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

legitimate concerns about Chinese IP theft by rupturing the international IP system is likely to cause significant harm in the long run.[182]

Ultimately, these moves by policymakers undermine the strong and secure IP rights promoted by the international IP system that historically has greatly benefited the United States.[183] Not only does weakening this system, therefore, harm the United States and its innovation ecosystem, but it also creates significant space for the United States' competitors and adversaries to exploit the system for their own gains. As the United States retreats from the international IP system, other actors, such as China, may seek to fill the leadership void and promote policies against the United States' interest.

THE CHINA CHALLENGE

The connections between secure IP rights, innovation, and national security are well understood in China. Indeed, IP policy is an established component of China's industrial strategy. In 2021, China released its fourteenth Five-Year Plan, which includes ambitious goals such as doubling the number of patents it awards to foreign firms.[184] This was followed up with the 2024 Plan for Promoting the Construction of a Powerful Intellectual Property Country, a 110-point proposal outlining specific tasks China should complete to strengthen IP protections and improve its IP regime.[185]

China has followed these plans with concrete actions to develop a sophisticated and predictable IP legal regime, thereby promoting domestic innovation. For instance, in 2014, China opened its first court that specifically adjudicates IP cases, which has since grown into a network of IP courts.[186] Between 2017 and 2019, China further established 18 specialized IP tribunals in various provinces.[187] China is using this system to stake out its interests in critical and emerging technologies, including agriculture and artificial intelligence, and is funding it accordingly.[188] Since 2020, China has nearly quadrupled the funding for its patent office, known as China's National Intellectual Property Administration.[189]

In addition to employing IP policy to boost its innovation ecosystem, China also leverages IP to implement its broader industrial policy initiatives in subversive ways. This includes acquiring and replicating foreign IP through tactics including corporate espionage, forced technology transfer, and counterfeiting, along with strategically leveraging Chinese courts to influence international IP litigation and licensing negotiations, thereby promoting China's own interests in the global IP system.[190]

For example, one growing trend in Chinese courts is the use of "anti-suit injunctions." Anti-suit injunctions are legal measures that order a party engaged in a lawsuit in one jurisdiction to refrain from simultaneously pursuing the case in a foreign court.[191] In jurisdictions such as the United States and the United Kingdom, anti-suit injunctions are often issued by courts to stop the same legal dispute from proceeding in multiple legal venues simultaneously. In one prominent case, a federal-district court in Washington state issued an anti-suit injunction preventing Motorola from pursuing a parallel lawsuit against Microsoft in Germany.[192]

In China, however, courts are leveraging anti-suit injunctions in more aggressive ways. For instance, Chinese injunctions bar legal action globally rather than in specific jurisdictions. In recent years,

First Solar Exhibit 2014, Page 47 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Chinese courts have issued anti-suit injunctions in several cases in an attempt to dictate global licensing rates for inventions patented worldwide, anticipating that firms will adhere to their decisions rather than risk massive fines—if a patent owner subject to a Chinese anti-suit injunction continues to pursue a case in another jurisdiction such as the United States, China's courts have threatened to impose fines of as much as $150,000 per day.[193] Such proceedings have resulted in reducing the licensing fees Chinese companies pay to access non-Chinese patented inventions, including those of U.S. companies.

In addition, Chinese courts have asserted jurisdiction over patent licensing fees globally, issuing decisions that extend their jurisdictional reach and often favor Chinese firms. In November of 2023, in a landmark decision in Oppo vs. Nokia, a global dispute, a Chinese court set global royalty rates for a patent owned by Nokia, as well as a global aggregate royalty rate for 4G and 5G phones.[194] In other words, the Chinese court dictated the price Nokia could charge for its technology all over the world, setting a price that favored the Chinese firms who had to pay to license this technology. Soon afterwards, China's Supreme People's Court reinforced this position when it ruled that Chinese courts have jurisdiction over royalty rates involving foreign patents.[195]

Just as the United States is retreating from the international IP system, these moves by China represent an attempt to employ IP policy to promote and defend its economic and national security interests abroad. Absent strong U.S. opposition to these moves and leadership in the international IP system, China may continue to pursue its interests by aggressively probing the system for weaknesses, to the detriment of the United States and its allies.

Artificial Intelligence

AI is poised to reshape the geopolitical landscape, becoming a cornerstone of both economic growth and national security. As the National Security Commission on Artificial Intelligence observes, AI technologies will become "the foundation of the innovation economy," offering immense strategic advantages to nations that harness them.[196] The United States and its partners are only beginning to assess how deeply AI will affect societies, economies, and defense frameworks. Among the many policy domains influenced by AI, IP stands out as an area demanding thoughtful adaptation to preserve incentives for AI-driven innovation.

Traditionally, the U.S. patent system has incentivized creativity by granting protection to human inventors for inventions meeting established criteria for patentability—i.e., utility, novelty, and nonobviousness. With AI becoming integral to sectors such as biopharmaceutical research and semiconductor design, policymakers now must decide how AI-assisted inventions fit into these established frameworks.

Similarly, copyright law—long focused on human creativity—faces novel questions as AI-generated or AI-assisted works emerge across artistic and literary fields. Additionally, the widespread use of AI models trained on extensive datasets raises concerns about copyright infringement for both the data used (input) and the content produced (output). These AI models often rely on collections of internet-sourced material, which may include copyrighted works. The legality of such data usage

First Solar Exhibit 2014, Page 48 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

is a flashpoint for legal and creative communities, prompting discussions on potential licensing models. The U.S. Copyright Office, in response, is developing guidelines to clarify these issues, the resolution of which will profoundly influence U.S. competitiveness in AI-related advancements.

AI-ASSISTED INVENTIONS AND WORKS

Patents

AI tools are increasingly becoming integral to the inventive process across a wide range of industries, accelerating innovation by generating, refining, and even suggesting novel ideas. For instance, in the biopharmaceutical industry, AI facilitates the discovery of new molecules and compounds, significantly reducing the time and costs involved in developing new drugs.[197] In semiconductor design, as another example, AI-powered automated tools are essential for navigating the complexities of modern chip architectures.[198] And in materials science, a recent study found that AI-assisted researchers "discover 44 percent more materials, resulting in a 39 percent increase in patent filings and a 17 percent rise in downstream product innovation."[199] Given these efficiency gains, the patentability of AI-assisted innovations is key to maintaining incentives for private sector investment and U.S. technological leadership.

The transformative potential of AI-assisted inventions, however, is also raising questions about how the USPTO will interpret U.S. patent law regarding the use of AI in the inventive process. Specifically, current U.S. patent law limits inventorship to natural persons, sparking debate over the patent eligibility of AI-assisted innovations. Industries that rely heavily on patent rights—such as pharmaceuticals, biotechnology, and semiconductor manufacturing—are particularly invested in clarification on this question.

The transformative potential of AI-assisted inventions, however, is also raising questions about how the USPTO will interpret U.S. patent law regarding the use of AI in the inventive process.

Under the Biden administration, the federal government initiated several steps to provide answers. Following President Biden's 2023 Executive Order on AI, for instance, the USPTO issued its "Inventorship Guidance for AI-Assisted Inventions" in February 2024.[200] These guidelines do well in clarifying some previous misconceptions or murky areas around AI-assisted inventions—namely, that inventors and joint inventors must be natural persons and that AI-assisted inventions are not categorically unpatentable for improper inventorship.

Clearly stating that AI-assisted inventions are eligible for patent protection is a positive step forward and should be encouraged by the administration. At industry roundtables conducted by CSIS, large and small firms alike underscored the importance of recognizing AI-assisted inventions as patentable.[201] Humans still direct and shape these technologies, and preserving patent rights for AI-driven work ensures they can collaborate productively and push innovation forward.

First Solar Exhibit 2014, Page 49 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Nevertheless, the USPTO's 2024 guidelines also introduce areas of ambiguity that could deny AI-assisted inventions patent protection, thereby deterring innovation. For example, the application of "conception" and joint inventorship law—traditionally used to resolve disputes among human collaborators—now serves as the framework for determining whether a human made a sufficiently "significant contribution" for an AI-assisted invention to be patentable. This novel use of the law raises concerns that some AI-assisted inventions could be denied patent rights despite their novelty and usefulness, creating uncertainty for inventors and businesses.

A clear U.S. approach to the patentability of AI-assisted inventions would bring the United States in line with other jurisdictions, where AI's role in the inventive process is viewed differently, and address the potential of the United States falling behind in AI innovation. Courts in Germany and the United Kingdom, for instance, have allowed patents for extensively AI-supported inventions provided a human is named as the inventor.[202] These systems treat AI-related inventorship primarily as a question of ownership, while the USPTO guidelines, rooted in uniquely American inventorship law, frame the issue as a matter of patentability. This divergence could result in AI-enabled inventions being patented abroad but not in the United States, thereby discouraging innovation within U.S. borders.

Further clarification is required in several additional areas to mitigate ambiguities that increase litigation risks and create uncertainty for innovators. Left unaddressed, such ambiguities could chill the use of AI in the inventive process and incentivize U.S.-based inventors to patent their AI-enabled inventions overseas.

- The USPTO guidelines do not explore certain gray areas, such as what might constitute the minimal requirements for human contribution to satisfy inventorship, or the threshold of "significant contribution" by a human when judged against AI's contribution.
- The guidelines suggest that inventors should disclose the use of AI in the inventive process, but not necessarily other technological tools, such as computers and algorithms, while failing to clearly define what the USPTO considers to be an "AI tool." Furthermore, treating AI as categorically different from other advanced tools may be unwarranted, particularly given AI's current capabilities and uses.
- Further clarification of the "obviousness" of AI-assisted inventions is needed. (One patentability requirement is that the invention is nonobvious, meaning that it is not readily apparent to someone with ordinary skill in the relevant field.) For example, clarification is needed on whether using certain AI models or certain prompts for invention generation would be considered "obvious" and thus possibly invalidate patentability.

Copyrights

As with patents, the intersection of copyright and AI raises critical questions about the protection of works created, in whole or in part, using AI technologies.[203] Should such works be eligible for copyright protection, and if so, under what conditions?

First Solar Exhibit 2014, Page 50 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

The U.S. Copyright Office (USCO) has begun to grapple with this issue, issuing a series of decisions and guidance clarifying its position on the copyrightability of AI-generated works. Thus far, the USCO has consistently held that works generated entirely by AI, or where the human contribution does not meet the threshold of creative authorship, are not eligible for copyright protection under U.S. law.

In March 2023, the USCO issued its first guidance on the registration of works generated by AI.[204] It emphasized that while technological tools, including AI, can play a role in the creative process, the key criterion is the degree of human creative control over the final work. Specifically, the USCO stated that copyright protection hinges on whether a human author "actually formed" the traditional elements of authorship—such as the arrangement, selection, or expression of content—and that these determinations will be made on a case-by-case basis. The USCO followed up this guidance with a report released in January 2025, stating that "while assistive uses that enhance human expression do not limit copyright protection, uses where an AI system makes expressive choices require further analysis" and that entering a prompt alone is unlikely to meet the requirement of "sufficient human contribution" for copyright protection.[205]

While the USCO's position provides some clarity, its relatively narrow view of human authorship in AI-assisted works leaves significant legal uncertainties. No court has yet ruled on the issue, leaving open questions about the threshold of human involvement required for copyright protection, the status of AI-generated components within larger works, and the potential implications for creative industries that are increasingly relying on AI tools.

As AI continues to revolutionize artistic and creative processes across industries—including visual arts, music, literature, and film—these unresolved issues will play a pivotal role in shaping the future of copyright law and its ability to foster innovation while protecting the rights of creators. The development of clear, forward-thinking policies will be essential to ensuring that the U.S. copyright system can adapt to these transformative technologies.

COPYRIGHT INFRINGEMENT

While the eligibility of AI-generated works for copyright protection remains a critical policy debate, the issue currently receiving the most attention at the intersection of AI and IP is the potential copyright infringement of generative AI models due to

1. the use of potentially copyrighted material for the training of AI models; and
2. the potential infringement by the output of generative AI models on copyrighted works.

In August 2023, the U.S. Copyright Office issued a Notice of Inquiry (NOI) soliciting public comments regarding the collection and curation of sources for AI datasets, the methodologies employed in training AI models with these datasets, and the necessity for obtaining permission or providing compensation to copyright owners when their works are incorporated into this process.[206] Reflecting the significance of this issue, the inquiry received over 10,000 comments from stakeholders and the general public, which the U.S. Copyright Office is in the process of evaluating.

First Solar Exhibit 2014, Page 51 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Meanwhile, the issue of copyright infringement and AI training continues to work its way through the U.S. judicial system. A Delaware federal court issued the first court ruling on the issue in February 2025, in Thomson Reuters Enterprise Centre GMBH v. ROSS Intelligence Inc., siding with Thomson Reuters on its copyright infringement claim and rejecting Ross's fair use defense.[207] However, the AI algorithm in question was deemed to not be "generative AI," leaving open questions about the implications for future decisions and precedent.

When considering this issue, the administration should remain aware that there is no one-size-fits-all model for the wide variety of data used to train AI models, which includes public data, third-party private data, first-party private data, synthetic data, and trade secrets. It is imperative to ensure that, while enabling transparency, policies do not ultimately force the disclosure of valuable and proprietary information from companies that have invested in creating those intellectual assets and making sure trade secrets continue to be protected.

First Solar Exhibit 2014, Page 52 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

4

The Path Forward

Intellectual property is a cornerstone of the United States' innovation ecosystem, underpinning economic growth, technological advancement, and national security. In an increasingly competitive global landscape, strong and secure IP protections are not just legal safeguards–they are strategic assets that empower U.S. innovators to lead in critical and emerging technologies. However, maintaining this leadership requires more than incremental improvements; it demands a comprehensive, whole-of-government approach that treats IP policy as an integral part of the nation's broader economic and security strategies.

This administration must recognize that IP is a critical vector in the competition for global technological supremacy and economic influence. U.S. leadership in innovation hinges on the strength of its IP system, yet this system faces significant challenges, such as underinvestment in the USPTO, inconsistent government priorities, and growing competition from foreign jurisdictions. Addressing these challenges requires bold actions to revitalize the U.S. IP system, increase coordination across government agencies, and ensure that IP protections are fully aligned with the nation's economic and national security priorities.

This section outlines key recommendations for the new administration to strengthen the IP system, bolster U.S. competitiveness, and reaffirm the United States' position as the global leader in innovation. By making targeted investments, fostering interagency collaboration, and championing the value of strong IP rights, the administration can secure the innovation ecosystem needed to thrive in the twenty-first century.

First Solar Exhibit 2014, Page 53 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Incorporate IP Policy into U.S. Economic and National Security Strategy

Publicly reaffirm the importance of strong and secure IP rights. The president should make a formal and public statement recognizing that robust IP rights are a cornerstone of the U.S. innovation ecosystem and are instrumental to the nation's economic and national security. This declaration would underscore the administration's commitment to fostering an environment where innovation can thrive, investments are protected, and U.S. ingenuity leads on the global stage.

By publicly affirming the critical role of secure, stable, and predictable IP protections and clear rights of enforceability, the president can set a tone that influences policymakers, international allies, and the private sector alike. This would reinforce the message that safeguarding IP rights is not merely a matter of economic policy but a strategic imperative for maintaining U.S. leadership in critical and emerging technologies. Furthermore, such a statement would serve as a call to action for addressing the gaps and challenges in the current IP system, aligning domestic reforms with broader international objectives to uphold and strengthen the global IP framework.

Strengthen the position of the IP enforcement coordinator and appoint a pro-IP leader to champion IP rights and innovation. The Office of the Intellectual Property Enforcement Coordinator (IPEC) is a part of the Executive Office of the President, established in 2008 to advise the president and coordinate across agencies to develop the United States' overall IP policy and strategy, to promote innovation and creativity, and to ensure effective IP protection and enforcement, both domestically and abroad.[208] However, the office went unfilled under the Biden administration, as their nominee was nominated late in the administration's tenure and never confirmed by the U.S. Senate.

The new administration should not only appoint a pro-IP leader to this position to champion secure, stable, and predictable IP rights in the United States and defend U.S. IP from theft and coercive transfer abroad, but should also strengthen the position and empower the IPEC to ensure coherence, coordination, and strategic foresight across the U.S. IP policy landscape with the explicit objective of promoting innovation, technological leadership, and national security. This elevated position should operate within both the National Security Council and the National Economic Council, reflecting the critical intersection of innovation policy with economic security and national security.

This strengthened IPEC would serve as a key adviser to the president, responsible for aligning IP policy across the entire executive branch with broad objectives in economic statecraft, industrial competitiveness, and technological leadership. Their mandate would include facilitating interagency collaboration to ensure that U.S. policies—including patent reform and research funding—are coordinated, strategically targeted, and effectively implemented to promote strong and secure IP rights and U.S. innovation.

This position would also act as a central point of engagement with the private sector, academia, and international allies, helping to shape policies that support private sector led innovation

First Solar Exhibit 2014, Page 54 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

ecosystems and incentivize even more private sector investment, while safeguarding U.S. leadership in critical and emerging technologies. By updating this role, the administration would signal its commitment to prioritizing innovation as a cornerstone of U.S. competitiveness and security in the global landscape.

Bolster the U.S. Patent and Trademark Office

End the practice of fee diversion at the USPTO. The USPTO is a fully fee-funded agency. It does not receive any tax-payer money, instead funding its operations through fees paid by customers, such as for patent-related services and products during the patent application process. Nevertheless, unlike its counterparts in Europe and China, the USPTO struggles with outdated technology, underpaid patent examiners, and high turnover, all of which undermine the efficiency and expertise of its workforce and hampers its ability to effectively serve innovators and maintain the United States' competitive edge in the global IP landscape.

The underfunding of the USPTO is largely due to "fee diversion," that is, the diversion of funding allocated through patent application and maintenance fees away from the USPTO.[209] Instead of being reinvested into the USPTO, these fees have been diverted by Congress for other purposes, leaving the office under-resourced.[210] Since 2010, hundreds of millions of dollars in patent fees have been diverted away from the USPTO.[211]

To ensure the long-term success of the USPTO and support innovation in the United States, the practice of fee diversion should end, allowing the USPTO to retain all fees it collects and reinvest them in modernizing its technology, improving examiner compensation, and stabilizing its workforce. By addressing these critical funding issues, the USPTO will be better equipped to meet the demands of a rapidly evolving global IP ecosystem and continue to drive U.S. economic growth and innovation.

Reduce patent backlog through USPTO hiring and technology adoption. The USPTO is dealing with a historic patent backlog, standing at 826,736 unexamined applications and 20.3 months average pendency for patents as of December 2024.[212] This long wait time for patent application decisions leaves inventors and firms in limbo, with uncertainty undermining their ability to make decisions, secure financing, and develop their business.

To reduce this backlog, the USPTO should be allowed to hire additional patent examiners, who have typically played a key role in reducing patent pendency times.[213] Indeed, the USPTO has been tackling the current backlog in part via a concerted hiring effort.[214] The agency hired 644 patent examiners in FY 2023 and was on target to exceed its goal of hiring 850 examiners in FY 2024. This push should continue through FY 2025, as planned.

Further, the USPTO should continue to invest in upgrading its IT systems to boost examiner efficiency, as highlighted in the office's January 2025 Artificial Intelligence Strategy.[215] This includes modernizing its existing data and research programs to provide examiners with powerful AI tools that they can use to more efficiently complete the examination process.

First Solar Exhibit 2014, Page 55 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Relax return-to-office mandates for USPTO workers. Remote work has been a cornerstone of operations at the USPTO for decades. The USPTO began its telework program in 1997, and, as of 2023, nearly 13,000 of the USPTO's approximately 14,000 employees worked remotely.[216] While there may be benefits to in-person work at the USPTO, the mandate that federal government employees come back to the office five days per week may be virtually impossible for the agency, with remote workers all over the country, to comply with, and may ultimately diminish the overall workforce and capacity of the USPTO at a crucial time in U.S. innovation and economic security policy.

Implement patent examination reform. Though the quality of the examinations of patent applications has improved over the last several administrations, the current patent examination process at the USPTO still results in a high number of errors, undermining the quality and reliability of the U.S. patent system.[217] This large number of errors primarily stems from erroneously denying patent applications, as opposed to erroneously approving patent applications. A 2024 study by the Sunwater Institute estimates that 5–8 percent of all patents granted by the USPTO were issued in error (erroneous approvals), while 18–26 percent of rejected applications were improperly denied (erroneous denials).[218]

While policy discussions often focus on reducing erroneous approvals, it is imperative to recognize that both types of errors harm the innovation ecosystem. Furthermore, there are inherent tradeoffs between erroneous approvals and erroneous denials: Reducing erroneous approvals by making guidelines stricter may inadvertently lead to an increase in erroneous denials, and vice versa. Therefore, the USPTO should adopt a balanced approach that prioritizes error reduction across both categories instead of focusing primarily on reducing erroneous approvals. This balanced approach would minimize negative impacts on innovation, foster stronger IP protections, and enhance the efficiency of the patent system as a whole.

Uphold, Strengthen, and Lead the International IP System

Remain engaged in international IP bodies and commit to robust and reliable IP protections globally. The United States has greatly benefited from the international IP system, which hinges on principles of nondiscrimination such as those embodied in National Treatment and Most Favored Nation status and championed through international treaties and institutions. To maintain global IP stability and fairness, the United States must reaffirm its commitment to these principles and remain engaged in these institutions to ensure its interests are represented.

Specifically, the new administration should ensure that Chinese firms and inventors receive the same treatment under U.S. IP laws as their counterparts from other nations. Any concerns regarding unfair practices should first be addressed through negotiations or, if needed, multilateral forums like the World Trade Organization. A retaliatory approach risks undermining the global IP system, provoking countermeasures from China that would harm U.S. firms and innovators.

Push back on demands to erode IP rights in the name of access to innovation. The administration should oppose measures that weaken IP rights in the name of access to innovation,

First Solar Exhibit 2014, Page 56 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

recognizing that a high-functioning global system of IP rights is essential to bringing more developing countries into the innovation ecosystem as effective partners.

For instance, in recent years, some developing nations have demanded additional IP waivers and forced technology transfers under the TRIPS Agreement, including Colombia's proposal for a comprehensive review aimed at renegotiation.[219] If granted, these waivers, originally designed for extraordinary circumstances, risk becoming the norm and undermining the very IP protections that enabled rapid vaccine breakthroughs. The new administration should firmly oppose broadening TRIPS waivers for U.S.-owned IP. Instead, the administration can champion collaborative solutions—e.g., voluntary licensing, tiered pricing, and capacity-building—that meet urgent global health needs without diluting strong, predictable IP rights. By defending TRIPS as it was intended, the United States will protect its innovators, foster worldwide R&D investment, and ensure preparedness for future crises.

Call out China and other bad actors in the international IP system. As highlighted above, China has empowered its courts to utilize the international IP system to advance the state's economic interests.[220] While the European Union has initiated WTO proceedings against these "unfair and illegal trade practices," the Biden administration did not fully support European efforts and instead aligned with certain Chinese arguments.[221] The new administration should adopt a stronger international posture, backing the European Union's WTO consultations and publicly affirming the need for fair, transparent IP protections.

Moreover, the USTR's Special 301 Reports have recently failed to address abuses, such as in compulsory licensing. By refraining from condemning such practices, the United States tacitly validates countries that misuse TRIPS exceptions for industrial policy or medical tourism.[222] The new administration should restore the practice of publicly highlighting IP system abuses, thereby signaling to both allies and adversaries that the United States is committed to maintaining robust, reliable IP standards worldwide.

Reduce Uncertainty in the U.S. IP System

Revisit USPTO guidelines on patentability of AI-assisted inventions. To ensure that the United States is poised to reap the full benefits of AI, AI-assisted innovation must not just be protected, but encouraged. Several countries in Europe have made it clear that AI-assisted inventions are patentable in their jurisdictions. In contrast, recent guidance on U.S. law, such as the application of "conception" and joint inventorship law, may become areas of deep uncertainty without clearer guidance, potentially hindering U.S. businesses and inventors. To provide a stable and secure environment, the USPTO should revisit its February 2024 guidelines, addressing the questions raised by stakeholders regarding the patentability of AI-assisted inventions.

Update Section 101 guidelines to provide clarity for innovators. To restore confidence and certainty in the patent system, the USPTO should update its Section 101 guidelines to provide clearer and more predictable standards for patent eligibility. The current ambiguity, particularly with regard to abstract ideas, natural phenomena, and laws of nature, has caused confusion

First Solar Exhibit 2014, Page 57 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

among innovators and hindered investment in critical emerging technologies. By offering more detailed and transparent guidance, the USPTO can reduce uncertainty for inventors, helping them better navigate the patent application process. Clearer guidelines will promote innovation by providing a more stable environment for businesses and researchers and thus enable them to pursue patents for transformative technologies without fear of unexpected rejections based on shifting interpretations. This will help ensure that the U.S. patent system remains a strong driver of innovation and economic growth.

Reject government overreach on patent rights. The administration should reinforce the seminal role of government in the U.S. innovation ecosystem by affirming mechanisms that promote the commercialization of new technologies from advances in scientific knowledge. This includes preserving the Bayh-Dole Act's successful framework by resisting proposals that seek to expand federal march-in authority or reinterpret Section 1498 to weaken patents as a tool for reducing drug prices. These measures threaten to deter private investment in university research, stifle the commercialization of federally funded innovations across multiple sectors, and undermine regional economies heavily dependent on federal R&D support. Moreover, the vast majority of drugs are ineligible for march-in, making it an ineffective means of actually lowering consumer costs. In the end, broadening government power to forcibly license patented inventions jeopardizes the certainty and stability that drive U.S. innovation, without resolving the challenges of affordability in the pharmaceutical market.

Advocate for reinstating the historical presumption of injunctive relief. The administration should support the reinstatement of the presumption that patent owners are entitled to injunctive relief when infringement is proven, returning to the historical balance that spurred innovation and investment. Since the 2006 eBay v. MercExchange decision weakened the availability of injunctions, large, well-funded companies have been able to use protracted litigation to profit from unlicensed technologies, leaving innovators undercompensated and discouraging risk-taking in R&D. Restoring an expectation of injunctions would restore the value of IP by allowing patent owners to effectively prevent infringers from producing or selling infringing products, and by strengthening patent owners' bargaining positions in licensing negotiations, making it less likely that resources are drained in lengthy court battles and more likely that licenses reflect fair market value. Such a policy shift would also enhance U.S. competitiveness by aligning with other advanced economies—like China, Germany, Japan, and the United Kingdom—that regularly grant injunctions, thus preserving the United States' status as a premier venue for inventors to patent, invest, and innovate.

Empower the PTAB to employ discretionary denial of petitions to reduce duplicative litigation. To improve the efficiency of patent litigation, the PTAB should exercise its discretion to deny petitions in cases where parallel litigation is already underway in district courts. When a patent is being actively challenged in district court, allowing the same challenge to proceed at the PTAB often leads to duplicative litigation, wasting resources and creating unnecessary delays and costs for patent owners and challengers alike. By limiting the scope of PTAB challenges in these cases, the USPTO can help ensure that patent disputes are resolved more efficiently, prevent contradictory rulings between courts and the USPTO, and allow the legal system to focus on

First Solar Exhibit 2014, Page 58 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

substantive issues rather than procedural ones. This approach would reduce redundancy and make the U.S. patent system more streamlined and effective for all parties involved.

First Solar Exhibit 2014, Page 59 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

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First Solar Exhibit 2014, Page 60 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

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First Solar Exhibit 2014, Page 61 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Appendix A

Proposed IP Legislation

In the last Congress, legislators proposed numerous bills to address the challenges highlighted in this report and other perceived challenges with the U.S. IP regime. This section summarizes the most pressing IP-related bills currently pending in Congress.

Patent Eligibility and Restoration Act (PERA)

The Patent Eligibility and Restoration Act of 2023 is a bipartisan, bicameral bill intended to clarify patent eligible subject matter and restore patent eligibility to inventions in fields such as information technology and biotechnology.[223] The bill explicitly reverses the Supreme Court decisions that led to the establishment of the Alice/Mayo test in the early 2010s, instead specifying several categories of patent-ineligible subject matter. By clarifying and restoring patent eligibility, the bill sponsors intend to incentivize additional investment, spur startup creation, and boost innovation in technologies such as artificial intelligence, personalized medicine, and medical diagnostics.

Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act

The Promoting and Respecting Economically Vital American Innovation Leadership Act is a bipartisan, bicameral bill intended to correct the design flaws in the PTAB introduced in the America Invents Act of 2011.[224] For instance, the PREVAIL Act aims to address the issue of duplicative litigation by ensuring that only a single forum—PTAB or district court—hears a challenge, creating a standing requirement, and limiting PTAB challenges to one per patent. The bill also aligns

First Solar Exhibit 2014, Page 62 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

the standards of proof for invalidation between the PTAB and district courts, and would end the practice of fee diversion, requiring fees paid to the USPTO be used only for USPTO activities.

Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive (RESTORE) Patent Rights Act

The Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive Patent Rights Act of 2025 is a bipartisan, bicameral bill intended to restore the presumption that courts will issue injunction in patent infringement cases, thereby strengthening protections for U.S. inventors, entrepreneurs, universities, and startups.[225] The bill would return to the status quo prior to eBay vs. MercExchange, returning to patent owners a rebuttable presumption that an injunction is warranted after a court makes a final ruling that their rights are being infringed.

Inventor Diversity for Economic Advancement (IDEA) Act

The Inventor Diversity for Economic Advancement Act of 2024 is a bipartisan, bicameral bill that would require the USPTO to collect demographic data in patent applications. Inventors would have the option to specify their gender, race, and military or veteran status.[226] The bill also requires the USPTO to make this data public and publish an annual public report about the data. By collecting this information, bill sponsors intend for the USPTO to gather and publish additional data that will allow for further study on how to maximize the inventiveness of the U.S. people.

First Solar Exhibit 2014, Page 63 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Appendix B

U.S. IP Regulation

Over the last decade, the U.S. government has deliberated over several regulatory actions with profound implications for U.S. innovation, economic security, and national security. This section summarizes those actions, as well as their impact on the U.S. IP regime and the U.S. innovation ecosystem.

March-In Rights

The Bayh-Dole Act has been a tremendous driver of U.S. innovation by enabling and incentivizing universities and other research institutions to collaborate with the private sector to commercialize publicly funded research.[227] Since its enactment, the act has led to over $1.3 trillion in U.S. economic growth, created more than 4.2 million jobs across the country, and contributed to the success of over 11,000 new startup companies from universities throughout the United States.[228] Indeed, it has been so successful that numerous other nations have implemented similar laws, hoping to emulate the success of the United States.[229]

In addition to these incentives to collaborate, Bayh-Dole includes several safeguards to ensure that publicly funded innovations are used in a reasonable manner. One such safeguard, known as "march-in rights," authorizes federal agencies to require a patent owner to grant a license when they determine that they are not moving to commercialize the publicly funded technology, or that action is needed to protect public health or safety.[230] In simpler terms, march-in rights authorize the government to force patent owners to grant others permission to use their publicly funded inventions under specific circumstances.

First Solar Exhibit 2014, Page 64 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

While no federal agency has employed march-in rights to date, march-in rights have become a focal point of activists seeking to lower drug prices since at least the Biden administration. On December 7, 2023, the Biden White House announced a proposed framework for the federal exercise of march-in rights, while NIST concurrently released a draft of the framework describing several ways that federal agencies might consider price as a factor in determining whether to exercise march-in rights.[231]

However, the proposal was met with resounding criticism from the private sector, the university community, and experts for several reasons. First, employing march-in rights is highly unlikely to meaningfully lower drug prices. One recent study found that just 1.3 percent of novel medicines approved by the FDA between 2011 and 2020 were funded solely with government support, and therefore could be subject to march-in if the statutory conditions applied.[232] What's more, the same study found that 92 percent of these novel medicines had no federally funded IP, and were instead directly funded by private firms. Indeed, corporations developing products based on discoveries arising from federally funded research frequently invest substantially more than the government, as well as conducting further research, product development, clinical trials, manufacturing technology development, and distribution infrastructure deployment, resulting in entirely new portfolios of privately owned IP.[233] Put simply, the vast majority of drugs are not eligible for march-in rights.

Second, while utilizing march-in rights is unlikely to lower drug prices, employing march-in rights is likely to undermine the United States' innovation ecosystem. Employing march-in rights as a means of price control creates an uncertain environment surrounding the commercialization of university research, particularly given the lack of clear guidelines for federal officials when it comes to determining whether the market price of an innovation is "unreasonable" or "extreme and unjustified." Therefore, the prospect of march-in—which is at the discretion of federal officials—will increase the already considerable risks associated with the commercialization of university-based research, deterring investment in drugs or other technologies that result from federally funded research.

The ripple effects of undermining the patent system, although narrowly intended to lower drug prices for consumers, could negatively impact innovation in many other areas. The proposed framework's amendments purportedly would expand the federal government's march-in authority across all sectors of the economy, allowing federal agencies to forcibly issue licenses for patents developed with public funds across all market sectors on the basis of product price. The NIST RFI outlines potential scenarios involving patents as varied as 3D printing technology, vehicle-to-everything communications technology, face masks, and water purification technology.[234] This looming threat would create uncertainty that could inhibit the flow of capital into university R&D and threaten the flow of new ideas from universities to the market across numerous sectors.

Finally, the uncertainty produced by the federal government expanding its view of march-in authority could harm U.S. regional economies and their R&D networks that depend on federal support. For instance, while approximately half of all U.S. higher education R&D expenditures exceeding $150,000 receive federal backing, the distribution varies considerably among

First Solar Exhibit 2014, Page 65 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

states. Arizona and Texas, for example, derive about 40 percent of their higher education R&D expenditures from federal sources, whereas universities in states such as Alaska, Colorado, and Maryland rely on federal support for approximately 75 percent of their funding.[235] Consequently, states with a higher federal share of higher education R&D spending are poised to experience more significant adverse effects from this policy shift. Rather than fostering inclusive economic growth, expanding the government's march-in authority would exacerbate regional disparities and negatively impact federally supported higher education R&D spending across states.

Section 1498—Government Patent Use

A long-standing point of contention in U.S. patent policy is federal government use of technology protected by privately owned patents. Historically, sovereign immunity, a common law doctrine that protects governments from being sued without their consent, would have shielded the government from patent infringement lawsuits. However, throughout the nineteenth century, courts consistently upheld patent owners' rights via the Fifth Amendment Takings Clause and mandated the government pay patent owners for infringement.[236] Then, in the late nineteenth century, several Supreme Court decisions created some confusion about the scope of protection, prompting Congress to provide for a remedy for patent infringement due to acts by or for the U.S. government in 1910, with amendments introduced in 1918 and 1941. This law is codified as Title 28, Section 1498, of the U.S. Code.

Section 1498 entitles patent owners to seek "reasonable and entire compensation" when the government (or a government contractor on behalf of the government) infringes on a patent. Under this statute, the patent owner can seek damages in the Court of Federal Claims, balancing inventors' rights against the government's need to access critical technologies under extraordinary circumstances.[237]

Recently, some policymakers and advocates have reinterpreted Section 1498 as a mechanism to lower drug prices.[238] Specifically, instead of recognizing Section 1498 as granting patent owners the right to receive compensation, advocates claim that the statute grants the government the right to infringe on any patent so long as it compensates patent owners to a "reasonable" degree, and, therefore, the government should use this power to partner with private generic drug manufacturers to infringe on pharmaceutical patents and produce cheaper drugs. Notably, while Section 1498 has been invoked in some cases in the past, it has largely been limited to traditional military or government use cases, making this new interpretation a significant and disruptive departure from past practice.[239]

Employing Section 1498 as a means of price control is likely to create tremendous uncertainty for private firms since it lacks clear guidelines on when such an action might be taken and what precisely constitutes "reasonable and entire" compensation. By undermining confidence that patent rights would be upheld and their infringement fairly compensated, such an expanded use of Section 1498 would diminish the value of biopharmaceutical patents and discourage private sector investment in R&D—an already lengthy, expensive, and high-risk endeavor. Furthermore, similar to calls for using march-in rights, this reinterpretation of Section 1498 is not limited to

First Solar Exhibit 2014, Page 66 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

biopharmaceuticals, and therefore risks chilling innovation across sectors by weakening the incentive structure at the core of America's innovation ecosystem. If companies fear their IP rights could be overridden, they may hesitate to fund the next breakthrough innovation.

Moreover, Section 1498 is poorly suited to serving as a price-control tool. Just as the government cannot systematically pay below-market prices for land acquired through eminent domain, it cannot simply use Section 1498 to acquire patented drugs at arbitrarily low rates. The federal government would be liable for potentially large and unpredictable damages—awards determined only after protracted litigation in the Court of Federal Claims. This exposes taxpayers to significant financial risk and complicates healthcare budgeting—hardly an efficient strategy for containing costs—while injecting tremendous uncertainty into the biopharmaceutical industry.

Practical challenges also limit Section 1498's utility in broader drug pricing. The provision applies only to federal operations; it does not authorize states, municipalities, or private buyers to use infringed patents, nor does it exempt private entities from liability if they provide such products beyond a strictly federal scope. Expanding Section 1498 to encompass non-federal markets would not just be legally doubtful; it would also shift enormous liability onto the federal government, with state and private actors effectively making coverage decisions while Washington foots the compensation bill. Rather than fixing drug prices, employing Section 1498 in this way would create more uncertainty, misaligned incentives, and potential budgetary burdens for the federal government—undermining the core goal of affordability and threatening innovation across America's biopharmaceutical landscape.

TRIPS Waivers

TRIPS is a World Trade Organization agreement incorporating IP protections into the global rules-based trading system.[240] Active since 1995, TRIPS requires most WTO members to adhere to minimum rules for the protection of IP—e.g., patents, copyrights, and trademarks—and enforce these commitments domestically. By agreeing to uphold these standards, member states benefit from the innovation and economic growth enabled by a reliable IP environment—one that attracts investment, facilitates technology transfer, and drives global R&D collaboration. Recognizing that countries vary widely in economic development and may face crises or special circumstances, TRIPS also includes provisions for limited exceptions or "waivers" as a narrowly focused mechanism for nations to respond to exceptional challenges. Furthermore, TRIPS provides developing economies with technical assistance in setting up their IP regimes and a transition period before they must apply the provisions outlined in the agreement. For instance, "least-developed countries" as defined by the United Nations are not required to fully adhere to the agreement until 2034.[241]

During the Covid-19 pandemic, the TRIPS agreement received considerable attention as developing nations called on WTO members to waive TRIPS IP protections for Covid-19 vaccines based on the argument that allowing any company to manufacture the vaccines would boost production and, ultimately, vaccinations.[242] After two years of deliberations, WTO members, supported by the Biden administration, unanimously agreed to a TRIPS waiver for Covid-19 vaccines, suspending certain

First Solar Exhibit 2014, Page 67 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

requirements regarding the use of Covid-19 vaccine patents.[243] With this waiver in place, states can authorize domestic manufacturers to produce Covid-19 vaccines without the permission of the patent holder and, crucially, to export those vaccines to other countries. Since the implementation of the vaccine waiver some nations have pushed for TRIPS waivers for Covid-19 therapeutics and diagnostics as well.[244]

However, like march-in rights and Section 1498, waiving IP protections for Covid-19 vaccines, diagnostics, and therapeutics risks undermining the U.S. biopharmaceutical innovation system while not achieving the goals of its advocates.

Notably, the TRIPS waiver has had minimal impact on overall vaccine access. No country has yet declared their intent to make use of the TRIPS waiver, as global vaccine demand had plummeted by the time the TRIPS waiver was agreed upon.[245] In December 2022, the board of Gavi, a nonprofit that supplies vaccines to low- and middle-income countries, voted to stop supplying Covid-19 vaccines to most nations due to lack of demand.[246] Currently, the supply of treatments for Covid-19 far outstrips demand. Simply put, in 2025, Covid vaccines, diagnostics, and therapeutics are limited by demand, not supply.[247]

At the same time, TRIPS waivers may undermine the very IP rights that helped the global community overcome Covid-19. Despite their inherent exclusionary rights, IP protections enable and encourage entities who might otherwise be in competition to work together, especially in times of crisis. This is because IP rights provide a secure and predictable legal framework for the sharing of technology and knowledge which ensures that business partners cannot steal or misuse valuable information. For instance, with its robust patent portfolio, BioNTech—an innovative biotech firm—was more willing to share commercially valuable information with Pfizer—the large pharmaceutical firm that delivered the testing, production, and distribution capacities—to rapidly develop an effective, safe, and widely used Covid-19 vaccine.[248] Without secure IP rights, these firms would have been less likely to collaborate for fear that the other would steal shared information to undercut their business in the future. Indeed, IP rights incentivized drug inventors to establish over 140 partnerships with local manufacturers worldwide, boosting supply while also transferring technology and tacit knowledge to these foreign firms.[249]

The transfer of tacit knowledge enabled and incentivized by secure IP rights is especially critical because, in practice, the information contained in a patent is often insufficient to effectively and efficiently create the product on its own. In the same way you cannot hand any person a recipe and expect them to prepare a five-star meal, you cannot hand any firm a patent and expect them to make a high-quality product. In addition to the patent, firms require knowledge of manufacturing procedures, production processes, quality assurance methods, and other protected trade secrets to establish an effective operation.[250] In the case of Covid-19 vaccines, firms were able to establish partnerships and scale up production quickly because of an IP regime that protected the full knowledge chain of patents, trade secrets, and other know-how. Thus, instead of facilitating additional production, waiving patent rights may undermine the partnerships and knowledge-transfer that enabled the rapid scale up and deployment of Covid-19 vaccines in the first place. Firms will be less likely to enter these critical partnerships if their IP is not protected.

First Solar Exhibit 2014, Page 68 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

Another example of the fruits of secure IP rights are mRNA vaccines—an essential tool in the fight against COVID-19. Over decades, the science and technology behind mRNA vaccines was supported by both farsighted government investment and commercialization drawing on considerable private capital that expected a return on investment.[251] The success of mRNA vaccines was not an assured outcome, yet investors took the risk on the understanding that they would receive substantial returns should the technology prove effective. Throughout this long and risky R&D process, the secure and predictable assignment of IP rights let universities, government labs, and large and small companies cooperate effectively to develop the foundational mRNA vaccine technology and, ultimately, deliver vaccines in record time.

For these same reasons, it is imperative to maintain robust IP rights to prepare for future pandemics. Companies will simply not invest in creating new vaccines and therapeutics if they expect to lose ownership of their IP should their massive and risky investments proves fruitful. This risk is especially high in the pharmaceutical industry since—as established by multiple surveys conducted in the 1980s, 1990s, and 2000s—both large and small firms generally have few means other than patents to block second movers from replicating a new drug or other treatment.[252]

Orange Book Challenges

The Approved Drug Products with Therapeutic Equivalence Evaluations list, commonly known as the "Orange Book" due to the color of its cover page, is a list of all nonbiologic drug products approved by the FDA on the basis of safety and effectiveness. It also lists approved generic versions of the drug—drugs that are equivalent to the already approved innovator drug (known as the "brand-name drug")—along with any IP rights associated with the drug or its method of use.[253]

The Orange Book is an essential component of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, which simplified the generic drug approval process. Hatch-Waxman aimed to balance innovation with access and affordability by providing incentives to pharmaceutical companies to research and develop new drugs while creating a more efficient process for the FDA to approve generic drugs.[254] For instance, under Hatch-Waxman, generic drug makers are able to utilize the safety and efficacy data of the approved drug instead of going through the lengthy and expensive clinical trials process.

Hatch-Waxman streamlined the generic drug approval process by creating a new type of drug approval application: an Abbreviated New Drug Application (ANDA). As part of the ANDA process, the applicant must account for any patents listed alongside the reference brand-name drug in the Orange Book. Applicants can specify that 1) no patent is listed, 2) the patents are expired, 3) the ANDA applicants will wait until the patents expire before marketing its product, or 4) the patents are invalid or not infringed. If the applicant claims the patents are invalid or not infringed, it notifies the patent owner. The patent owner can then file a patent infringement lawsuit, which, if filed within 45 days of the notice, automatically prevents the FDA from approving the ANDA for 30 months, until the lawsuit is settled, or until the ANDA holder receives a favorable judgment. This is known as the "30-month stay" and is intended to allow the parties sufficient time to resolve their patent dispute before the generic drug enters the market.[255]

First Solar Exhibit 2014, Page 69 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

In 2023, the FTC challenged over 400 patents listed in the Orange Book. The FTC claims these challenged patents are improper "junk patent listings."[256] Critically, the FDA maintains the Orange Book, yet only holds a "ministerial" role over the listed IP information.[257] The FDA insists that it lacks the expertise to evaluate the IP rights claimed in the Orange Book, and thus simply lists the patent information submitted by biopharmaceutical companies without independently verifying its accuracy or appropriateness. Thus, the FTC claims that firms are exploiting the Orange Book by listing inappropriate patents, thereby benefiting from the 30-month stay, deterring generic drug market entry, and keeping prices high.

However, the FTC's challenges overlook that the system established by Hatch-Waxman has been a tremendous success for pharmaceutical innovators, pharmaceutical competition, and, most importantly, patients. In the 1980s, before Hatch-Waxman took effect, generic drugs filled less than 20 percent of U.S. prescriptions, and few generic drugs entered the marketplace after brand-name drug patents expired.[258] Today, however, generic drugs are common: The FDA has approved over 32,000 generic drugs, which constitute an estimated 91 percent of all prescriptions filled in the United States and save patients and payors hundreds of billions of dollars annually.[259] Hatch-Waxman created incentives and protections for actors throughout the pharmaceutical value chain, who together now produce dozens of new brand-name drugs and hundreds of generic drugs annually in the United States.[260]

Further, the Hatch-Waxman Act already incentivizes generic drug makers to challenge Orange Book patents by providing a 180-day period of exclusivity to the first generic firm that files an ANDA challenging the validity or infringement of the brand-name drug's patents and markets its generic product.[261] Depending on the popularity of the brand name drug, this period of exclusivity could be worth hundreds of millions of dollars.[262] Thus, Orange Book patents are frequently challenged, with higher selling drugs facing more challenges.[263] There is little evidence that patents preventing generic entry are not being challenged already.

Finally, there is evidence that, should the FTC's challenges prove successful, they will have a muted impact on generic drug market entry, and, therefore, on drug prices. The FTC asserts that brand-name drug makers are exploiting the Orange Book to delay generic drug market entry via the 30-month stay provision, suggesting that the provision is preventing the FDA from approving otherwise-ready generic drugs.[264] However, a 2021 study found a median of 3.2 years between the expiration of the 30-month stay and FDA generic drug launch, undermining the FTC's argument.[265] If the 30-month stay were indeed delaying generic drug approval, many generic drugs would be approved shortly after the stay expired.

Indeed, the relationship between Orange Book patents and generic drug market entry is complex. A different 2021 study that reviewed all Orange Book entries found that 32 percent of listed drugs without active patent protection did not have a generic version, while 28 percent of listed drugs with active patent protection nonetheless had an approved generic version. The authors of the second 2021 study concluded that "even valid patents do not necessarily block competition," and cheaper generic drugs do not consistently enter the market after patents expire.[266] Thus, even if the

First Solar Exhibit 2014, Page 70 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

challenged patents are removed from the Orange Book, generic competitors might not enter the market for some time.

All in all, the FTC's challenges on Orange Book patents risk upsetting a highly productive system in an effort to lower drug prices, while ignoring simpler and less disruptive options to improve the Orange Book process. For instance, allegedly improperly listed Orange Book patents may largely stem from uncertainty in the law rather than bad-faith attempts at gamesmanship. The pharmaceutical industry has repeatedly requested the FDA clarify Orange Book patent inclusion criteria over the last several decades, yet the FDA has failed to provide further guidance despite multiple public comment solicitations and a study by the Government Accountability Office.[267] By clarifying requirements and expectations, the FDA can improve the overall Orange Book system without undermining the innovation so vital to U.S. national security.

First Solar Exhibit 2014, Page 71 of 93
Mundra Solar PV Limited v. First Solar - IPR2025-01411

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Mundra Solar PV Limited v. First Solar - IPR2025-01411

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