The Heritage Foundation

ISSUE BRIEF

No. 5293 | NOVEMBER 14, 2022

EDWIN J. MEESE III CENTER FOR LEGAL AND JUDICIAL STUDIES

# For Biomedical Innovation, Congress Should Follow the Maxim "First, Do No Harm"

*Adam Mossoff*

## KEY TAKEAWAYS

Congress should oppose any effort to slip the Interagency Patent Coordination and Improvement Act into any must-pass legislation.

This bill is a solution in search of a problem. It would create unneeded regulations for biomedical inventions and undermine U.S. innovation leadership.

America needs a technology-neutral patent system that promotes new innovation and encourages economic growth. This legislation would threaten that goal.

As the 117th Congress enters its final months, there is the usual push to include bills in omnibus legislation. This effort includes a bill that would make significantly harmful changes in the legal system that has driven U.S. global leadership in biomedical innovation: the patent system.[1]

The bill is the Interagency Patent Coordination and Improvement Act of 2022, which would create new a new administrative task force for information sharing between the U.S. Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA).[2] The ostensible purpose is for the USPTO and FDA to coordinate their review and approval of patent applications and regulatory approval of new drugs and other innovative medical treatments.

Congress should resist the anodyne rhetoric about "patent quality" and "lowering drug prices," which are the

asserted justifications for the Interagency Patent Coordination and Improvement Act. This is especially important when this bill would make fundamental changes in the patent system—the innovation engine, rooted in the Constitution, that has driven the U.S. innovation economy for centuries.[3] These changes would upend the U.S. patent system's historically successful role in promoting and distributing new innovations. This is especially true for the innumerable life-saving medical breakthroughs in the modern biopharmaceutical sector.[4]

## Expanding the Administrative State at the USPTO and FDA

The Interagency Patent Coordination and Improvement Act, introduced by Senators Dick Durbin (D–IL), Chuck Grassley (R–IA), and Thom Tillis (R–NC), initially sounds appealing: It proposes to create a new agency task force and formal administrative processes for the sharing of information on a new drug when the USPTO reviews and issues a patent on this drug and the FDA reviews and approves the use of this new drug by patients. Of course, the USPTO already publishes all issued patents and the records of the underlying patent applications are publicly available as well, and the FDA identifies all patents covering drugs it approves for use in the Orange Book, the FDA's official list of patents covering approved drugs.[5] Moreover, federal courts have long recognized that the statutory and regulatory standards that are applied by the FDA in determining the safety and effectiveness of drugs used by health care patients are not the same as the statutory standards under the Patent Act that are applied by the USPTO in determining whether a patent application on a new drug should be issued as a valid patent.[6]

Why, then, the need for information sharing between the FDA and the USPTO? The bill's advocates claim that drug innovators are misleading these two agencies by filing contradictory submissions in the drug approval and patent examination processes, respectively.[7] They allege that drug innovators engage in this practice to improperly obtain additional patents, such as mere changes in dosage amounts, so that they create a massive number of patents around a single drug—called pejoratively a "patent thicket." This "patent thicket," they claim, effectively prevents generic drug companies from making competitive versions of this drug, which keeps drug prices higher than they would have been but for the generic competitor entering the market. Advocates for the Interagency Patent Coordination and Improvement Act argue that "the lack of coordination between the PTO and FDA may lead to patent thickets, enabling manufacturers to obtain patents that do not satisfy the Patent Act's requirement[s]."[8]

That's their argument, but it's not the reality.

## No Evidence of a Systemic Problem

The Interagency Patent Coordination and Improvement Act is a classic example of a solution in search of a problem. There is no evidence that drug innovators routinely make inconsistent or contradictory statements in submissions filed at the FDA and the USPTO. What *do* exist are unreliable and unverified patent numbers concocted by advocacy organizations like I-MAK, which exists solely to attack what it calls "unjust patent monopolies" as a "root cause of the high cost of medicines."[9] I-MAK's drug patent numbers are junk science.[10] They differ by *orders of magnitude* from the drug patent numbers in the Orange Book.[11] To take just one example, I-MAK asserted in 2018 that 68 patents covered the drug Lyrica, a groundbreaking drug to treat pain caused by nerve damage from diabetes and other conditions, but the FDA's Orange Book identifies only three patents covering Lyrica.[12]

Earlier this year, in response to a request from Senator Tillis,[13] I-MAK refused to disclose its data or explain the statistical methodology it uses to reach the drug patent numbers it publishes in splashy, colorful reports.[14] Instead, I-MAK Executive Director Tahir Amin regurgitated his organization's accusations about "pharmaceutical companies gaming the patent system."[15] At the same time, in a bit of irony apparently lost on Mr. Amin, he accused drug innovators of "opaque" patenting practices.[16] But Mr. Amin at least admitted in his response to Senator Tillis something that I-MAK has not always acknowledged in its reports: It includes *abandoned patent applications* in its numbers of "total patents" covering a drug.[17] As any patent lawyer will tell you, it is outright false to equate a patent with an abandoned patent application—but I-MAK's policy rhetoric is unconstrained by facts.

## Upending the Technology-Neutral U.S. Patent System

It is bad enough when misleading rhetoric and junk science data drive proposed legislation and policymaking. It is even worse when this legislation would fundamentally rearrange the mechanics of the carefully balanced innovation engine of the patent system.

One of the key dangers of the Interagency Patent Coordination and Improvement Act is that it alters one of the core principles of the patent system as a *technology-neutral* system in securing property rights in inventions. The Founders recognized in the Constitution that patents secure an "exclusive right"—a property right in innovation that serves as the launching pad for new markets.[18] Patents have promoted research, incentivized venture capital investments, and driven new commercial deals and market

structures from the Industrial Revolution of the 19th century to the health care revolution of the 20th century and the mobile revolution of the 21st century.[19] Property rights serve as launching pads for production and commercial activities, whether in homes, automobiles, factories, movies, laptops, or new drugs. But they do this only if they are protected by institutions and legal rules defined by the rule of law—secured *equally* to everyone.[20]

From the Patent Act of 1790 enacted by the First Congress through the most recent Patent Act of 1952, the U.S. patent system has applied the same legal rules and processes to all inventions. This is the principle of *technology neutrality*. It is the patent version of the basic idea that the right to property is secured equally to all owners regardless of who they are and what they own.

The Interagency Patent Coordination and Improvement Act turns this vital legal and economic principle on its head: It will create new administrative agencies and officials, as well as new regulatory rules and processes, for reviewing patent applications for biomedical innovations such as a new cure for cancer. Patent applications for inventions in 6G, the Internet of Things, or even a new jet engine will *not* be subject to these new administrative processes and procedures.

Patent legislation should not target specific technologies, whether drugs, mobile tech, or combustion engines, by creating special legal rules and administrative institutions in the patent system. This by itself is sufficient reason to oppose the Interagency Patent Coordination and Improvement Act. At best, it portends innumerable unintended consequences for the patent system, threatening to undermine its core function: the promotion and dissemination of new innovations. At worst, it creates new administrative processes that will ultimately prove to be destructive of this innovation system.

## The Growing Administrative State Threatens the Patent System

These are not merely "academic" or speculative predictions of how a new administrative agency can negatively impact the patent system. Congress created the Patent Trial and Appeal Board (PTAB) in the America Invents Act of 2011 given the same complaints we hear today about the lack of "patent quality" and that patent owners are allegedly abusing these "bad patents." The PTAB's sole mission is to cancel these wrongly issued patents, which sounds like a laudable goal. As described earlier this year in another Heritage *Legal Memorandum*, these same complaints about low-quality patents represented a policy narrative that was more rhetoric than fact.[21]

In the past decade, the PTAB has destabilized the U.S. patent system and undermined its function in securing reliable and effective property rights in new innovations.[22] In the words of federal judges, the PTAB engages in procedural "shenanigans" and has become a dreaded "patent death squad."[23] In its first decade, the PTAB has canceled more than *38,000* patent claims through willy-nilly decision-making that violates basic norms of due process and the rule of law.[24] Another federal judge has stated that the PTAB's assertion of "unchecked discretionary authority is unprecedented."[25]

The PTAB's seemingly unconstrained administrative power is exploited by Big Tech. Big Tech companies are the most frequent petitioners at the PTAB.[26] The PTAB serves their predatory infringement practices in pirating patented inventions from individual inventors, universities, startups, and other patent owners that lack Big Tech's massive war chests and therefore cannot afford to fight back.[27] The PTAB is a dark portent of what will become of a new administrative agency that is created solely to prevent patents from issuing given policy rhetoric about allegedly "bad patents."

## Lack of Legislative Process

Even without this fundamental concern about creating more instability in the patent system with more discretionary administrative processes that upend how this property rights system has successfully grown the U.S. innovation economy, there are additional procedural concerns about an effort to slip the Interagency Patent Coordination and Improvement Act into an omnibus bill. Because no companion bill has yet been introduced in the House of Representatives, the Interagency Patent Coordination and Improvement Act could be rammed through Congress without going through the full committee process in both houses. A proper bicameral process would ensure hearings and evidence submitted for the record to confirm whether this bill is justified or not. Given the serious concerns about whether this bill is even needed, as well as its potentially deleterious impact on the patent system, these issues deserve to be aired in hearings with a properly developed, evidence-based record. None of this will occur if supporters succeed in inserting it into an omnibus bill.

In fact, the proposed statutory text of the Interagency Patent Coordination and Improvement Act itself tacitly acknowledges that there is a profound dearth of evidence as to whether the proposed new agency task force and other administrative processes in the USPTO's review of patent applications for biomedical innovations are necessary or not. The bill proposes a four-year study *after its enactment* of whether the information

sharing between the FDA and USPTO is in fact necessary in the USPTO's review of patent applications.[28] Yet the bill nonetheless mandates the immediate implementation of the new administrative tribunals and regulatory rules to address the policy complaints and junk science data that are driving the bill.

## Congress Should Adopt Only Evidence-Based Policies

The Interagency Patent Coordination and Improvement Act places the proverbial cart before the horse: Why build the cart in the first place if it is not even proven that the cart is necessary? By creating yet another administrative agency and a whole new set of rules and procedures, such legislative action guarantees only more wasteful governmental action and more fuel for the growth of the leviathan that is the administrative state. This is bad policy by itself. It is even worse when it threatens the historically proven functioning of the patent system as an efficient and effective, if not wildly successful, property rights system in encouraging and promoting new innovations that drive the growth of the U.S. innovation economy.[29]

As a former chief economist at the USPTO has stated, Congress and agencies should engage in evidence-based policymaking, not policy-based evidence-making.[30] If Congress is concerned that yet-unproven conflicts between submissions at the USPTO and submissions at other agencies might materially affect whether the USPTO would grant patents or not, then it should first propose that the USPTO and other federal agencies study the issue. At a minimum, it should establish that this is in fact a problem *before* it creates new administrative agencies, regulatory rules, and regulatory processes as an alleged solution to this unproven concern.

Consistent with the U.S. patent system's technology-neutral principle, a study of the efficacy of information sharing between the USPTO and federal agencies should not be limited to one field of technology such as biomedical innovation. Patented inventions are governed by hundreds of different agencies throughout the modern administrative state, among them the Federal Trade Commission, Occupational Safety and Health Administration, and Environmental Protection Agency, to name just a few.[31] Thus, if Congress deems that a study whether there should be information sharing between the USPTO and other federal agencies is needed, it should authorize a study that informs policymakers in all relevant agencies regarding all technological inventions that are secured by patents at the USPTO.

## Conclusion

In sum, Congress should oppose any effort to slip the Interagency Patent Coordination and Improvement Act into an end-of-year and end-of-Congress omnibus bill. This effort to circumvent the regular legislative process only confirms the absence of a proven, evidence-based justification for this bill.

But this bill is worse than a solution in search of a problem. It would promote the continued growth of the leviathan administrative state and portends a fundamental change in the U.S. patent system. Both threaten to undermine the efficient functioning of the U.S. patent system as a technology-neutral property rights system that has successfully promoted new innovations and spurred the growth of the U.S. economy. In the face of such a bill, Congress should heed the maxim in health care: "First, do no harm."

**Adam Mossoff** is Visiting Intellectual Property Fellow in the Edwin J. Meese III Center for Legal and Judicial Studies at The Heritage Foundation.

## Endnotes

1. *See* Adam Mossoff & Amesh Adalja, *Patents as a Driver of the Unprecedented Biomedical Response to COVID-19*, 59 1 (2022), https://journals.sagepub.com/doi/epub/10.1177/00469580221124819.
2. *See* S. 4430, 117th Cong. (2022), https://www.congress.gov/bill/117th-congress/senate-bill/4430.
3. *See* Adam Mossoff, *The Constitutional Protection of Intellectual Property*, 282, March 8, 2021, https://www.heritage.org/economic-and-property-rights/report/the-constitutional-protection-intellectual-property.
4. *See* Adam Mossoff, *Gutting Patent Protections Won't Cure COVID-19*, Townhall (May 23, 2020), https://townhall.com/columnists/adammossoff/2020/05/23/gutting-patent-protections-wont-cure-covid19-n2569308 ("Nearly all of the medical breakthroughs in the past century would have been impossible without reliable and effective IP rights. These include recent developments, such as the antiretroviral therapies that have brought America's HIV/AIDS death rate down by 80 percent, and the cancer therapies that have cut mortality rates by nearly a quarter since the early 1990s.... America has had the strongest IP protections in the world—and as a result, we're far more innovative than other nations. The United States accounts for about 5 percent of the world's population and a quarter of its economic output, but invents two-thirds of all new drugs.").
5. *See* U.S. Food & Drug Administration, *Orange Book Preface*, (42d ed. 2022), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface#:~:text=The%20publication%2C%20Approved%20Drug%20Products,Act%20(the%20FD%26C%20Act) ("[T]his publication...provides patent information concerning approved drug products in the Orange Book.").
6. *See* In re Brana, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ("FDA approval...is not a prerequisite for finding a compound useful within the meaning of the patent laws."); Application of Watson, 517 F.2d 465, 476 (C.C.P.A. 1975) ("[T]he standards established by statute for the advertisement, use, sale or distribution of drugs are quite different than the requirements under the Patent Act for the issuance of a patent.... [T]he Food and Drug Administration has been given the responsibility of enforcing the Federal Food, Drug, and Cosmetic Act."); In re Anthony, 414 F.2d 1383, 1395 (C.C.P.A. 1969) ("Congress has given the responsibility to the FDA, not to the Patent Office, to determine in the first instance whether drugs are sufficiently safe for use that they can be introduced in the commercial market....").
7. The Interagency Patent Coordination and Improvement Act expressly signals that this is a concern in its statement that there is a need to "share information" between the USPTO and other agencies to ensure "accuracy and consistency" by "[e]ntities submitting patent applications." Interagency Patent Coordination and Improvement Act, § 2(2), *supra* note 2.
8. *See* Alvin Lee, *Senators Urge Regulators to Block and Clear Patent Thickets*, (June 23, 2022), https://www.jdsupra.com/legalnews/senators-urge-regulators-to-block-and-1332158/ (describing this argument).
9. I-MAK, *Drug Pricing Crisis*, https://www.i-mak.org/health-equity/#pricing (accessed Nov. 4, 2022).
10. *See* Adam Mossoff, *Unreliable Data Have Infected the Policy Debates over Drug Patents* (Hudson Institute, Jan. 2022), https://www.hudson.org/technology/unreliable-data-have-infected-the-policy-debates-over-drug-patents.
11. *See supra* note 5 and accompanying text.
12. *See id*., at 3.
13. *See* Adam Mossoff, *Thank You, Senator Tillis, for Recognizing the Need for Evidence-Based Policymaking in Patent Law*, (Feb. 15, 2022), https://ipwatchdog.com/2022/02/15/thank-senator-tillis-recognizing-need-evidence-based-policymaking-patent-law/id=145875/.
14. *See* I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices* (2018), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.
15. *See* Eileen McDermott, *I-MAK Defends Integrity of Its Patent Data in Response to Tillis Letter*, (March 9, 2022), https://ipwatchdog.com/2022/03/09/mak-defends-integrity-patent-data-response-tillis-letter/id=147282/.
16. *Id.*.
17. *See* Letter from Senator Thom Tillis to Robert Califf, Commissioner of FDA, and Drew Hirshfeld, acting Director of the USPTO (April 1, 2022), https://ipwatchdog.com/wp-content/uploads/2022/04/4.1.2022-TT-Ltr-to-USPTO-FDA-re-IMAK-patent-data-Final.pdf ("[I]n its letter, I-MAK acknowledges that it is counting patent applications among its figures. But, in its October 2017 report on three cancer drugs, for instance, I-MAK calculates a figure that it terms 'total patents,' but this number includes not just patents, but also pending patent applications, and even fully abandoned patent applications.").
18. U.S. Const. art I, § 8, cl. 8 ("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.").
19. *See*, *e.g.*, Jonathan Barnett, *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* (Oxford Univ. Press, 2021); B. Zorina Khan, *Inventing Ideas: Patents, Prizes, and the Knowledge Economy* (Oxford Univ. Press, 2020); Stephen Haber, *Patents and the Wealth of Nations*, 23 811 (2016), https://papers.ssrn.com/abstract=2776773.

20. *See* Hernando de Soto, *The Mystery of Capital: Why Capitalism Triumphs in the West and Fails Everywhere Else* 74 (Basic Books, 2000) ("Perhaps the most significant cost was caused by the absence of institutions that create incentives for people to seize economic and social opportunities to specialize within the marketplace. We found that people who could not operate within the law also could not hold property efficiently or enforce contracts through the courts.... Being unable to raise money for investment, they could not achieve economies of scale or protect their innovations through royalties and *patents*.") (emphasis added).
21. *See* Adam Mossoff, *Innovation and Leviathan: The Patent System Is Assimilated into the Growing Administrative State*, 300 (April 5, 2020), https:// www.heritage.org/economic-and-property-rights/report/innovation-and-leviathan-the-patent-system-assimilated-the.
22. *See* Alden Abbott et al., *Crippling the Innovation Economy: Regulatory Overreach at the Patent Office*, (Regulatory Transparency Project of the Federalist Society, Aug. 14, 2017), https://rtp.fedsoc.org/wp-content/uploads/RTP-Intellectual-Property-Working-Group-Paper.pdf.
23. *See* Adam Mossoff & David Lund, *The Problems with the PTAB*, IAM (Nov.–Dec. 2017) (quoting a former federal judge who called the PTAB a "patent death squad"); Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2155 (2016) (Alito, J., concurring in part and dissenting in part) ("Can Congress really have intended to shield such shenanigans from judicial scrutiny?"). *See also* Gene Quinn, *Parlor Tricks and Shell Games: How the Invisible Hand of the PTAB Supports Challengers*, (Aug. 20, 2018), https://www.ipwatchdog.com/2018/08/20/parlor-tricks-shell-games-ensure-invisible-hand-ptab/ ("[T] rial by ambush...has become common at the PTAB. Panels are expanded without warning or explanation. APJs not assigned to cases deliberate with APJs assigned, which is a clear violation of the Administrative Procedures Act.").
24. *See* Elliot C. Cook & Daniel F. Klodowski, *Claim and Case Disposition*, , https://www.finnegan.com/en/at-the-ptab-blog/claim-and-case-disposition. html(reporting data as of February 28, 2022, that the PTAB has canceled more than 38,000 patent claims) (last visited August 2, 2022). *See also supra* note 23 (citing sources that discuss numerous procedural shenanigans and other violations of basic norms of the rule of law).
25. Shaw Industries Group, Inc. v. Automated Creel Systems, Inc., 817 F.3d 1293, 1302 (Fed. Cir. 2016) (Reyna, J., concurring).
26. Adam Mossoff, *Big Tech's Sticky Fingers Are Still at Work in Washington*, (June 21, 2022), https://issuesinsights.com/2022/06/21/big-techs-sticky-fingers-are-still-at-work-in-washington/ ("The top five PTAB petitioners are Big Tech firms—Google, Apple, Samsung, Microsoft, and LG Electronics.").
27. *See*, *e.g.*, Honorable Paul R. Michel, *Big Tech Is Abusing the U.S. Patent Challenge System*, (Feb. 18, 2022), https://news.trust.org/ item/20220218102516-a1p08/; Adam Mossoff, *Google's Loss to Sonos Settles It: Big Tech Has an IP Piracy Problem*, (Jan. 13, 2022), https://techcrunch. com/2022/01/13/googles-loss-to-sonos-settles-it-big-tech-has-an-ip-piracy-problem/; Jonathan M. Barnett, *Why Big Tech Likes Weak IP*, (Spring 2021), https://www.cato.org/regulation/spring-2021/why-big-tech-likes-weak-ip.
28. Interagency Patent Coordination and Improvement Act, § 3, *supra* note 2.
29. *See* Mossoff, *supra* note 20.
30. *See* Alan Marco, *Why the Patent System Should Look More Like Indiana and Less Like Kentucky*, (Aug. 3, 2017), https:// youtu.be/HJhSD8ABt3s?t=759.
31. *See Watson*, 517 F.2d at 476 ("[T]there is no question...that the public must be protected absolutely against the advertising and sale and other distribution of harmful drugs.... Congress has recognized this problem and has clearly expressed its intent to give statutory authority and responsibility in this area to Federal agencies different than that given to the Patent Office. This is so because the standards established by statute for the advertisement, use, sale or distribution of drugs are quite different than the requirements under the Patent Act for the issuance of a patent. For example, the Federal Trade Commission has been given the responsibility of enforcing the Wheeler–Lea amendments to the Federal Trade Commission Act. Also, the Food and Drug Administration has been given the responsibility of enforcing the Federal Food, Drug, and Cosmetic Act.").