Senate Judiciary Committee Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market, May 21, 2024

Senator Grassley's Written Questions for Professor Mossoff

1. The Biden Administration is considering changing march-in rights policy under the Bayh-Dole Act as a way to reduce the price of prescription drugs. Professor Rai testified that she believed this was a "careful" approach and would provide a "gentle nudge" to deal with high prescription drugs costs. Do you agree with Professor Rai? What's your opinion on the Administration's proposed changes with respect to march-in rights?

The march-in guidelines announced by the National Institute of Standards and Technology on December 7, 2023 are neither "careful" nor a "gentle nudge." It represents an unprecedented claim to regulatory powers by administrative agencies to impose price controls on all patented products and services in the marketplace according whenever an agency official deems there is an "unreasonable price" (undefined in the proposed guidelines.) I direct you to pages 6-17 of my written testimony that sets forth the statutory analysis of the proposed guidelines lack any statutory authorization in the Bayh-Dole Act, contradict the express function of the Bayh-Dole Act, and will ultimately be ineffective and not lower drug prices.[1]

2. In Dr. Feldman's written and oral testimony, he suggests that the Committee consider several policies dealing with orange book listings, re-examination, litigation, generic approval standards, and incentives for patent challenges. Do you agree with these 5 specific proposals to address the high cost of drugs? Why or why not?

I do not agree with Dr. Feldman's proposals, for at least two reasons. First, his proposals violate the principle of good governance that Congress should follow in adopting evidence-based policymaking. The essential governing principle of evidence-based policymaking should guide the Congress in considering whether to adopt any legislation generally and patent laws specifically given the key role of the U.S. patent system as a driver of economic growth and innovation in healthcare, as I explained in my written testimony.[2] In this regard, Dr. Feldman's proposals would create new significant legal and regulatory burdens for patent applications and for patent owners in the biopharmaceutical sector. These innovators innovations have vastly improved the quality and length of life of all Americans. This is the baseline or framework by which to assess any

[1] *See* Adam Mossoff, Written Testimony, Senate Judiciary Committee Hearing on "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market" 6-17 (May 21, 2024), https://www.judiciary.senate.gov/download/2024-05-21-testimony-mossoff.

[2] *See id*., at 4-6.

proposed legal or regulatory restrictions on drug innovators in receiving and using their property rights in their inventions. If there is a true need for real reform, it is easy to meet this evidentiary burden: mandates should be adopted only on the basis of rigorous studies and verifiable evidence that these new legal rules ameliorate proven systemic inefficiencies or other problems in the patent system. But Dr. Feldman's proposals do not meet this burden. His proposed new legal and regulatory restrictions for patent applications and for existing patent owners are not justified by empirical data or studies that justify the increased costs to innovators that would be created by his proposals—costs that undermine and frustrate the function of the patent system as a spur for invention and economic growth in the U.S. and in flourishing societies worldwide.

Given the absence of proper empirical support, Dr. Feldman's proposals would be ineffectual, unjustified, or will cause additional and unnecessary harms to innovators through increased costs and uncertainty that reduce investments and slow the pace of innovation in new drugs. At best, some of Dr. Feldman's proposed new laws or regulations already exist. If they do not exist, these new regulatory powers or restrictions on patent owners would impose additional costs and uncertainty on innovators, leading to higher drug prices given increased costs of regulatory compliance. All of these problems result from the fact that the bills and proposals are based on rhetorical assumptions that are not supported by evidence or rigorous statistical studies. Dr. Feldman's proposals continue to make the same mistaken assumption as I-MAK and other activists that the complex mix of laws, regulations, and public and private institutions that are determinants of drug prices should be ignored by Congress, the FDA, and the PTO. Instead, Dr. Feldman simplistically reduces these multidimensional causes of drug prices to a single cause: patents.

Orange Book Listings: The Interagency Patent Coordination and Improvement Act of 2023 (S.79) supported by Dr. Feldman and the additional authority he proposes for the Food and Drug Administration (FDA) to obtain additional information from the Patent and Trademark Office (PTO) is both unnecessary and harmful to the efficient operations of the PTO and FDA. Both the FDA and the PTO already have existing extensive legal authority to share information and consult with each other. Patent examiners work to ensure that they have the resources and information pertinent to perform their duties in examining patent applications, and they have the authority under Rule 105 to obtain all pertinent information.[3] Rule 105 authorizes examiners to access sources of information on inconsistent statements or prior art that are not otherwise publicly available. The Court of Appeals for the Federal Circuit has construed Rule 105 broadly that it authorizes an examiner to obtain "such information as may be reasonably necessary to properly examine" a patent application, and that this authority is bounded only by requests for information by an examiner that are "arbitrary and capricious."[4]

S.79 and the additional powers proposed by Dr. Feldman further beg the question why Congress is directing only a single agency—the FDA—to aid the work of examiners in obtaining pertinent information relevant to a patent application. Other agencies have similarly pertinent technical information on inventions that equally fall within their regulatory oversight functions, and innovators also apply for patents on these inventions. This would include, but is not be limited to, the machines, processes, chemical molecules, etc. that fall within the regulatory oversight and

[3] *See* 37 C.F.R. § 1.105.

[4] Star Fruits S.N.C. v. United States, 393 F.3d 1277 (Fed. Cir. 2005).

approval regimes run by the Federal Aviation Administration (FAA), Environmental Protection Agency (EPA), Securities and Exchange Commission (SEC), Nuclear Regulatory Commission (NRC), U.S. Department of Agriculture (USDA), U.S. Department of Transportation (USDOT), and many others. The same generalized concerns about systemic abuse by individuals making contradictory statements between agencies are just as salient for all of the inventions that are subject to regulatory controls of the myriad of these other agencies within the administrative state. This is particularly important given the absence any legitimate and reliable evidence of systemic abuse of the sort alleged by Dr. Feldman, I-MAK, and others that drug innovators are making false or contradictory statements of fact under the relevant laws and regulations of the FDA and PTO.

More importantly, the Senate Judiciary Committee should remain committed to the principle of *technology neutrality* that has long been a key factor in the historical success of the U.S. patent system as a driver of the U.S. innovation economy. As I explained in my Heritage Report, *For Biomedical Innovation, Congress Should Follow the Maxim "First, Do No Harm,"*:

> 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.
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> 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.
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> 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.[5]

Re-examination: As with the prior proposal, what appears superficially to be a moderate or commonsensical proposal about reexamination is belied by the evidence. The proposal to make reexaminations mandatory for all Orange Book listings reflects the well-known fallacy in economics known as the *nirvana fallacy*. This fallacy assumes a current problem and its associated costs can be solved by a new regulation that would be cost free—a nirvana world in which new public institutions, regulations, and processes are cost free as compared to the costs of the current

[5] Adam Mossoff, *For Biomedical Innovation, Congress Should Follow the Maxim "First, Do No Harm"* (Heritage Report, Nov. 14, 2022), https://www.heritage.org/government-regulation/report/biomedical-innovation-congress-should-follow-the-maxim-first-do-no.

private or public institutions creating the inefficiencies or other policy failings. In this case, Dr. Feldman's proposal is a double fallacy: he asserts that there are costs—what he obliquely calls "stakes"—of "invalid patents" in healthcare, and he necessarily assumes that his proposed reexamination mandate would address these "stakes" without creating additional costs or new costs for innovators. In fact, he refers to his mandatory proposal as only creating "routine reexamination," but reexaminations, let alone reexaminations, are neither routine nor cost free. This systemic mandate for all patents in the Orange Book would create extensive new costs at the PTO and for drug innovators. As a result, his purported goal of lowering drug prices will not be achieved given the unforeseen negative effects on millions invested in legitimate inventions in the further development of new innovative versions of existing products, such as new technologically complex auto-injectors. These are valid innovations, despite aspirations to the contrary by I-MAK and Dr. Feldman, just as automobile companies invest millions to develop updated versions of cars with computer-based self-driving capabilities or high-tech companies like Qualcomm and InterDigital develop invest millions to invent new versions of mobile telecommunications technologies—from 2G to 5G.

Litigation: Proposals to limit or otherwise impose new restrictions on an innovator seeking protection of its valid property rights against infringers represent the same nirvana fallacy. Paetnt bills in the past, such as the Innovation Act, that would have imposed additional limitations and restrictions on patent owners filing lawsuits, and these bills rightly failed in Congress given the ill effects their proposals would have on individual inventors, universities, and startups—core drivers of innovation who rely on patents to recoup R&D and commercialize their inventions in the marketplace. Arbitrary proposals such as restricting a patent owner to sue for infringement for only one drug patent in a family will have similar ill effects on innovators. Multiple patents exist on single consumer products—from golf balls to smartphones to drugs—and it is an arbitrary and capricious restriction to establish a single-patent rule for infringement. Lastly, and perhaps most importantly, Dr. Feldman's proposal would likely violate the Due Process and Takings Clauses of the Constitution, because it eliminates the ability of the owners of valid property rights to sue in Article III court when these property rights are infringed. This is tantamount to prohibiting an owner of multiple parcels of real estate that are being repeatedly trespassed from suing for protection from and renumeration for the violation of all the power-owner's rights. This eviscerates the right to exclude that the Supreme Court has consistently recognized as the essence of a property right, and has thus rightly recognized as a per se trigger for an unconstitutional taking when this right to exclude is eliminated by a law or regulation.[6]

Generic approval standards: I am not an expert on the FDA approval process for generics, and thus I defer to healthcare law experts and drug innovators on this proposal by Dr. Feldman. With that said, the governing principle of evidence-based policymaking still applies to this proposal, as does the nirvana fallacy. There must be evidence, based in reliable and verified data and analyzed according to transparent, rigorous, and replicable methods of analysis accepted by empirical researchers, that establishes that there is an inefficiency or other cost that will be (1) resolved by the proposed regulation, and (2) the inescapable and necessary costs in the proposal will not be greater than the existing costs of this proven problem. As doctors are wont to say: The cure cannot be worse than the disease. Policy-driven rhetoric, policy-based evidence-making of the sort now

[6] *See* Cedar Point Nursery v. Hassid, 141 S. Ct. 2063 (2021).

confirmed in I-MAK's numbers of patents and market exclusivity periods, or simple, bald-faced assertions of a problem are insufficient. These should be soundly rejected by the Committee.

Incentives for patent challenges: Again, I am not sufficiently versed in the empirical studies of Hatch-Waxman procedures to comment on whether these proposals are justified by the evidence. With that said, I can state that experience has shown that any systemic changes to the complex regulatory regime created by the Hatch-Waxman Act should be approached with extreme caution given the intricate institutional balance achieved by the Hatch-Waxman Act and its complicated legal and regulatory mechanisms. Off-hand proposals to alter its rules and institutional mechanisms can represent an ignorance of how regulatory and legal institutions function in the real world—the essence of someone committing the nirvana fallacy. Alternatively, such proposals can also represent a deliberate disregard for the need for evidence of systemic costs and inefficiencies as a necessary justification for new legal and regulatory restrictions that restrict or limit existing property rights within complex public and private institutions.

3. Do you agree with the various proposals to address issues with terminal disclaimers and obviousness-type double patenting? Please explain.

Senator Welch has proposed S.3583, which addresses the alleged problem of "patent thickets" by rendering unenforceable all but one patent joined by a terminal disclaimer. This bill is similar to Dr. Feldman's third policy proposal on litigation, as discussed above. S.3583 would apply to only patents covering a drug or biological product. This bill is bad policy and bad law.

First, reiterating a key point in my answer to your first question, patent law and policy should remain committed to the principle of technology neutrality. This principle of technology neutrality has been a key factor in the success of the U.S. patent system as a property rights system in driving economic growth and innovation. Thus, Congress should not craft special legal rules for specific types of patents in specific sectors of the innovation economy. This is not only good policy proven by more than two centuries of the historically unprecedented success of the U.S. patent system, it is also now an obligation for the U.S. in the modern era under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In this regard, terminal disclaimer practice is not a specific practice among patent lawyers working only in the life sciences and biopharmaceutical sector. This is a general patent law practice. Yet, S.3583 creates a new litigation restriction based on this general patent law practice for a single type of patent covering a specific set of technologies—pharmaceutical innovations. It breaches the principle of technology neutrality in the basic patent laws by officially creating a new legal restrictions for one technology that is different from the legal rules for all other technologies. According to the principle of evidence-based policymaking, there is no justification for doing so, especially given the evidence that the equally important principle in U.S. patent law of technology neutrality has been key factor in its success in establishing the U.S. as a global technology leader.

Second, there is no legal justification for rendering a patent unenforceable that has been successfully prosecuted and has not been subject to challenge either in court or in an administrative proceeding at the Patent Trial and Appeal Board. Congress made the express decision that a patent

otherwise subject to obviousness double patenting can be valid provided this patent does not provide the patent owner with any extra patent term. In doing so, Congress sought to ensure that innovators had the incentive to engage in further research and development of new inventions based on new uses and other features of a prior invention, learning more about this prior invention and its characteristics and claiming those discoveries so long as their rightfully obtained patent protections for the fruits of their prior inventive labors are not extended in time. This law, and its underlying policy justification, are valid. There is no empirical evidence of systemic abuses requiring Congress to make a systemic alternation to the patent system.

If Congress is concerned about this issue, it could consider alternative mechanisms to encourage and protect this form of follow-on experimentation that do not require the innovator to seek additional patents. In some countries, for example, a patent-owner can extend the patent examination process and add claims to a single patent as similar experimentation reveals new inventions. That is not currently available in the U.S., but it is an example of an alternative approach that Congress could and should explore if it is serious about acting in this area.

What Congress must avoid is rendering unenforceable otherwise valid patents, granted by the PTO, and not invalidated by any competent legal institution following due process and the norms of the rule of law expected of any property owner under U.S. law.

Questions from Senator Tillis
for Adam Mossoff
Witness for the Senate Committee on the Judiciary
Hearing "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market"

1. Could you please explain what issues you see with I-MAK's methodology and how their data may not be reliable for policy makers to rely upon?

The principal problem with I-MAK's numbers of patents for specific drugs and similarly reported total years of exclusivity of specific drugs is that I-MAK's numbers are unverified and unreliable. There is evidence that I-MAK created these numbers of patents and exclusivity periods to advance its preexisting policy position as an advocacy organization that "a root cause of the high cost of medicines is an outdated patent system" that creates "unjust patent monopolies."[1] For instance, I-MAK does not merely count patents and publish white papers stating these numbers (I-MAK calls its policy white papers "reports" to give them a fake patina of empirical objectivity). I-MAK actively engages in legal actions seeking to invalidate drug patents; it was the first advocacy organization that challenged a drug patent at the Patent Trial and Appeal Board.[2] Given its policy view that drug prices result from "patent monopolies," I-MAK publishes white papers with stylized tables and charts with eye-popping numbers representing total patents or total exclusivity periods for specific drugs. I-MAK does not disclose in its white papers its statistical methodology or the specific patents it has counted to reach these numbers. Congress and policymakers should not rely on I-MAK's white papers (ersatz "reports") because of the growing evidence that there are serious problems with the veracity of the numbers presented in I-MAK's white papers.

In 2022, I published the results of a "spot check" of some of I-MAK's numbers of patent numbers on some top-selling drugs.[3] I compared I-MAK's numbers of patents to the total numbers of patents listed in the Orange Book for the same drugs. As I explained at the time, the Orange Book provides

[1] *Drug Pricing Crisis*, https://www.i-mak.org/health-equity/#pricing (accessed June 20, 2021).

[2] *See First-Ever U.S. Patent Challenges Dispute Gilead's Monopoly on Hepatitis C Drugs that Blocks Millions from Treatment* (New York: I-MAK, Oct. 25, 2017), https://www.i-mak.org/2017/10/25/first-ever-us-patent-challenges-gilead-hepatitis-c/.

[3] *See* Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents* (Jan. 19, 2022), https://www.hudson.org/technology/unreliable-data-have-infected-the-policy-debates-over-drug-patents.

an important comparative baseline for evaluating I-MAK's numbers of patents. First, the Orange Book is the official, public listing of patents covering drugs that would be infringed by a generic drug company if it made, used, or sold a drug without authorization. The Orange Book, maintained by the Food and Drug Administration (FDA), has been called "the gold standard reference for generic drug substitution."[4] Second, the Orange Book serves a key role in the Hatch-Waxman regime,[5] which is relevant given that the accusations of "patent thickets" and "evergreening" by I-MAK and others that generic drug companies are allegedly unable to produce drugs in competition with drug innovators, undermining the effective implementation of this law. For this reason, the Orange Book is the best source for an official, public listing of the relevant patents that cover a (small molecule) drug, especially from the perspective of a generic seeking to make and sell this drug in competition with a drug innovator.

Since I published my 2022 essay, the Orange Book has become the subject of critiques by I-MAK, the Federal Trade Commission (FTC) and others for either listing too many patents or failing to list all the relevant patents. On the one hand, I-MAK accuses drug innovators of *failing to list all relevant patents* in the Orange Book, claiming in its white papers and letters to officials that it has found numbers of patents covering drugs that are larger by orders of magnitude than the total patents listed for these same drugs in the Orange Book. These accusations have driven policy efforts for greater collaboration between the FDA and the Patent and Trademark Office (PTO); these efforts have been driven by the (unproven) accusations that drug innovators are obtaining patents they somehow should not have obtained given vague accusations of discrepancies between filings in the FDA and the PTO, as evidenced in part by more patents existing than those listed in the Orange Book. On the other hand, the FTC is now accusing drug innovators of *listing too many patents*, including what the FTC deems to be junk patents that should not have been issued by the PTO. In its letters to the FDA, though, the FTC offers no legal analysis or evidence why the patents it identifies are invalid. Nonetheless, drug innovators are now caught in contradictory accusations—they are either listing *too few patents* in the Orange Book according to I-MAK or are listing *too many patents* according to the FTC. The laws of logic dictate that both I-MAK's and the FTC's claims cannot both be true at the same time. Your question asks about only I-MAK's unreliable numbers and so my answer is limited to I-MAK's policy argument and the numbers of patents it has created to support it, but the development in the debates over drug prices and drug patents of contradictory claims about strategic behavior by drug innovators underscores how much this debate is driven by rhetoric and arguments without any basis in evidence or logic.

My spot check between I-MAK's numbers of drug patents and the number of patents in the Orange Book revealed significant concerns about the reliability and accuracy of I-MAK's drug patent numbers.

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[4] Jennifer Gershman, *4 Interesting Facts About the Orange Book*, PHARMACY TIMES (Mar. 13, 2018), https://www.pharmacytimes.com/view/4-interesting-facts-about-the-orange-book.

[5] *See* U.S. Food and Drug Administration, *Orange Book Preface*, https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last accessed Jan. 31, 2023) ("On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (Hatch-Waxman Amendments). The Hatch-Waxman Amendments require FDA to, among other things, make publicly available, with monthly supplements, a list of approved drug products. The Orange Book and its monthly Cumulative Supplements satisfy this requirement.").

In its 2018 *Overpatented, Overpriced* white paper, for example, I-MAK asserts in a chart that Lyrica has 68 patents covering it. In contrast, the Orange Book lists only 4 patents covering Lyrica; in actuality, there are 3 patents, as one of the 4 patents is a reissue patent. Also, in contrast to I-MAK, the Orange Book lists the actual patents, not just a simple number of total patents covering the drug as I-MAK does in its 2018 white paper. This discrepancy in the numbers of patents for Lyrica is shockingly large—I-MAK asserts 68 patents cover Lyrica and the FDA identifies only 3 patents covering Lyrica.[6] This is a difference by *orders of magnitude* between the official, public listing of patents and I-MAK's numbers of drug patents. This is not merely a rounding error in whatever (undisclosed) algorithm I-MAK used to reach its conclusion of 68 patents on Lyrica.

Similar discrepancies by orders of magnitude are found in I-MAK's claims about the total patents covering Xarelto. I-MAK states in 2018 *Overpatented, Overpriced* that 30 issued patents cover Xarelto with an additional 49 pending patent applications covering this same drug. In its *America's Bestselling Drugs of 2019* white paper the following year, I-MAK increased the number of issued patents covering Xarelto to 32 and increased the number of pending patent applications to 51. I-MAK has provided no explanation for the basis for the higher numbers between 2018 and 2019.

As with Lyrica, there is a vast discrepancy between I-MAK's numbers and the listing of relevant patents covering Xarelto in the Orange Book. Whereas I-MAK identifies 32 total patents covering Xarelto, the Orange Book identified only 6 patents covering Xarelto and its uses by patients.[7]

A third and final example of vast differences between I-MAK's numbers of drug patents and the patents listed in the Orange Book is found in I-MAK's claims about the total patents covering Eliquis. In its 2018 *Overpatented, Overpriced* white paper, I-MAK states that 27 issued patents and another 48 patent applications cover Eliquis. In its *America's Bestselling Drugs of 2019* white paper issued the following year, I-MAK increases these numbers for Eliquis, asserting that 31 issued patents cover the drug and there were now 49 total patent applications. Similar to Lyrica and Xarelto, there is a large contrast with the Orange Book listing of patents for Eliquis. The Orange Book identifies 3 patents covering Eliquis and its uses, not the 27 patents or 31 patents claimed by I-MAK in 2018 and 2019, respectively.

These unverified, vast discrepancies between the Orange Book listings and I-MAK's number of drug patents raise serious questions about the unreliability and veracity of I-MAK claims. These concerns are even more pressing given that I-MAK is an advocacy organization that believes that "a root cause of the high cost of medicines is an outdated patent system" that creates "unjust patent monopolies."[8] Thus, I-MAK uses its numbers of drug patents in its advocacy work, and promotes others to use them as well, to convince Congress and officials to create new laws and policies that impose new restrictions and costs on drug innovators. This is being done on the basis of unverified numbers of patents and on an undisclosed statistical methodology for reaching these numbers.

[6] Even if one includes the additional patents listed in the Orange Book for Lyrica CR, this adds only 3 patents. Thus, this would bring the total number of patents covering both Lyrica and Lyrica CR to 6 patents.

[7] The Orange Book currently lists only 4 patents for Xarelto.

[8] I-MAK, "Drug Pricing Crisis," https://www.i-mak.org/health-equity/#pricing (accessed June 20, 2021).

Lastly, it bears emphasizing that my essay is not the only published source of information identifying serious concerns about the unreliability and veracity of I-MAK's patent numbers. Such concerns were confirmed at the Joint PTO-FDA Public Listening Session on Collaboration Initiatives held at the PTO on January 19, 2023. At the Listening Session, Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis, explained that Novartis had expended significant time and resources to reverse engineer I-MAK's claim in its 2017 white paper that a Novartis drug, Gleevec, was covered by "a total of 73 patents."[9] Mr. Salsberg stated that "the real number of issued US patents on Gleevec was five, with another one to four possibly covering some of the ways of making it, but only if those methods were (optionally) used. At least in our case, I-MAK appears to have reached its inflated figures by including *44 abandoned patent applications* that never issued as patents, as well as a variety of patents that don't cover our drug."[10]

Although I-MAK now claims to have published its datasets on its website and it offers generalized statements of its methods that essentially state that it carefully counts patents, I-MAK has never explicitly or directly explained the contradictions I identified in my 2022 essay between its numbers of patents in its previous white papers (which are still relied on by academics and commentators) and the patent numbers found in the Orange Book and in court opinions. I-MAK has also never responded to Mr. Salsberg's analysis of how I-MAK's patent numbers on Gleevec confirmed that I-MAK was counting *44 abandoned patent applications* in I-MAK's assertion that 73 total issued patents covered the drug Gleevec. It has neither rebutted Mr. Salsberg's analysis, nor has it corrected its 2017 white paper. In sum, I-MAK's numbers continue to be unverified and fundamentally unreliable given unexplained contradictions and evidence of manipulation of the underlying data to advance its policy advocacy position that "unjust patent monopolies" or abuse of the patent system is "a root cause of the high cost of medicines."

Moreover, following the publication of my essay detailing these massive discrepancies between I-MAK's numbers of drug patents and the number of listed patents in the Orange Book, and the publication of other essays raising similar concerns,[11] you sent a letter on January 31, 2022 to Tahir Amin, Co-Founder and Co-Executive Director of I-MAK.[12] In this letter, you requested that Mr. Amin provide a "detailed explanation of your methodology for calculating the number of patents on a drug product that could be replicable by other researchers."[13] You also requested that I-MAK explain why its patent numbers covering drugs "differ so dramatically from public sources," as

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[9] *Statement of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis*, Listening Session on Joint USPTO-FDA Collaboration Initiatives (Jan. 19, 2023), at 6, https://www.regulations.gov/comment/PTO-P-2022-0037-0017.

[10] *Id.* (emphasis added).

[11] *See* Mossoff, *supra* note 3; *UC Hastings' Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called "Evergreening*," C-IP2 BLOG (Mar. 4, 2021), https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreen-drug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-and-quantifying-so-called-evergreening/.

[12] Letter from Senator Thom Tillis to Tahir Amin, Jan. 31, 2022, https://s3.amazonaws.com/media.hudson.org/1.31.2022-%20LTR%20from%20Senator%20Tillis%20to%20IMAK%20re%20Patent%20Data%20Sources.pdf.

[13] Letter from Senator Thom Tillis to Tahir Amin, Jan. 31, 2022, https://s3.amazonaws.com/media.hudson.org/1.31.2022-%20LTR%20from%20Senator%20Tillis%20to%20IMAK%20re%20Patent%20Data%20Sources.pdf.

well as explain why I-MAK claimed in its 2018 and 2019 reports that some patented drugs will retain market exclusivity for decades into the future when generic versions were already made available to patients in the healthcare market.[14]

In a lengthy letter, dated March 9, 2022, Mr. Amin was unresponsive to your specific requests, neither disclosing I-MAK's data nor detailing I-MAK's methods or analytics used to derive the massive numbers of patents for specific drugs listed in its white papers.[15] Mr. Amin instead argued that not all patents "asserted in litigation" are listed in the Orange Book.[16] In this letter, Mr. Amin decried "the hidden real-world workings of the industry when it comes to patents" and argued that the "system has deliberately been kept opaque by the pharmaceutical industry."[17] While accusing drug innovators of being "opaque" and "hidden [in their] real-world workings," it is notable that Mr. Amin never publicly disclosed I-MAK's data and the specific methods of calculation and analysis I-MAK used to reach the colossal patent numbers it claimed in its 2018 and 2019 white papers, keeping I-MAK's data and methods "hidden" and "deliberately opaque."

In letters sent to the PTO and to the FDA at the same time, you also requested that the agencies undertake an "objective, measured, and appropriate" analysis to address legitimate questions raised about a "false narrative" driven by "unreliable" and "biased" sources like I-MAK and the Evergreen Drug Patent Search database.[18] (Please see my answer to your second question in which I describe problems with this second source of patent numbers in the drug price and patent policy debates). In response to your queries, the PTO just released its *Drug Patent and Exclusivity Study*,[19] and the study does not replicate or confirm any of the massive numbers of patents attributed by I-MAK to the specific drugs in its white papers that it has published over the years.

Despite in the following years posting a large file listing patent and patent application numbers and providing a very generalized description of how I-MAK carefully counts patents in its past and recent white papers, I-MAK still has not responded to your specific request in 2022 that it disclose the *specific patents*—and apparently the specific abandoned patent applications—for the *specific drugs* that it has used to assert vast *total numbers of patents* covering these specific drugs. These are numbers I-MAK, activists, and academics have used to accuse drug innovators of "patent thickets" and "product hopping" that have been repeated in academic scholarship, policy publications, and in driving legislation and regulatory processes by agencies at the PTO, the FDA, and now the FTC. The recent study released by the PTO does not replicate or confirm its numbers

[14] *Id.*

[15] *See* Letter from Tamir Amin to Senator Thom Tillis, Mar. 9, 2022, https://ipwatchdog.com/wp-content/uploads/2022/03/Letter-to-Senator-Tillis-re-I-MAK-Patent-Data-9-March-2022-1.pdf.

[16] *Id.* at 4.

[17] *Id.* at 1, 3.

[18] *See* Letter from Senator Thom Tillis to Janet Woodcock and Drew Hirschfeld, Jan. 31, 2022, https://ipwatchdog.com/wp-content/uploads/2022/02/1.31.2022-LTR-from-Senator-Tillis-to-FDA-and-USPTO-re-Patent-Data-Sources.pdf. *See also* Letter from Senator Thom Tillis to Janet Woodcock and Drew Hirschfeld, Apr. 1, 2022, https://ipwatchdog.com/wp-content/uploads/2022/04/4.1.2022-TT-Ltr-to-USPTO-FDA-re-IMAK-patent-data-Final.pdf.

[19] *See Drug Patent and Exclusivity Study* (June 2024), https://www.uspto.gov/initiatives/fda-collaboration/drug-patent-and-exclusivity-study-available.

of patents either. In sum, I-MAK's numbers of patents remain contradicted by official, publicly available sources of data on drug patents, and they remain unverified and unreliable, especially for purposes of evidence-based policymaking.

2. As an academic, do you believe that the body of recent academic literature that attempts to link patents to high drug prices meets the normal standards of academic rigor in terms of data publication, data reliability, and peer review? If not, please explain.

There are significant concerns that published articles and reports by academics are infected with basic statistical errors and other fundamental methodological deficiencies similar to those identified about I-MAK's numbers of patents and exclusivity periods. This is important because some government officials, Senators, and academics have relied on and used I-MAK's patent numbers to support claims about drug patents and to support proposed policies and laws.[20]

There are other sources of numbers of patents and exclusivity periods that reflect similar concerns as those raised about the I-MAK numbers, even though these sources are created by academics and even published in academic journals. For example, a recent empirical analysis of Robin Feldman's article, *May Your Drug Price Be Evergreen*,[21] has revealed an important distinction between the underlying data and the dataset used by Professor Feldman in her article (and by others) and made available to other researchers, called the Evergreen Drug Patent Search database.[22] In their 2023 article, *Solutions Still Searching for a Problem: A Call for Relevant Data*

[20] *See, e.g.*, Kevin J. Hickey, Erin H. Ward, & Wen S. Shen, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress* (Congressional Research Service, Apr. 4, 2019), https://fas.org/sgp/crs/misc/R45666.pdf; *Durbin, Cassidy Introduce REMEDY Act To Lower Drug Prices By Curbing Patent Manipulation, Promoting Generic Competition* (Apr. 11, 2019), https://www.durbin.senate.gov/newsroom/press-releases/durbin-cassidy-introduce-remedy-act-to-lower-drug-prices-by-curbing-patent-manipulation-promoting-generic-competition; Michael A. Carrier, Response to Senator Grassley's Questions for the Record: Sen. Jud. Comm. Hearing on "IP and the Price of Prescription Drugs: Balancing Innovation and Competition" (May 28, 2019), https://www.judiciary.senate.gov/imo/media/doc/Carrier%20Responses%20to%20QFRs.pdf.

[21] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590 (2018).

[22] https://sites.uclawsf.edu/evergreensearch/.

to Support "Evergreening" Allegations,[23] Professor Erika Lietzan and Dr. Kristina Acri found the "raw data" to be "largely accurate," but Professor Feldman then converted this raw data into the Evergreen Drug Patent Search database. This is the database that is available online to researchers and has been used by policymakers; the raw data itself is not available for use in the Evergreen Drug Patent Search database. The Evergreen Drug Patent Search database, according to Professor Lietzan and Dr. Acri, "includes metrics that reflect selection, interpretation, and characterization of the data in the raw dataset" that raise questions about its reliability.[24] More specifically, Professor Lietzan and Dr. Acri write that

> we determined that when reporting on the number of unique patents associated with a new drug application, the [Evergreen Drug Patent Search database] consistently counts a patent that has been reissued by the Patent and Trademark Office as two patents—even though the reissued patent replaces the original patent (which has been surrendered) and expires on the same date. *This approach biases their results towards higher patent counts, which supports their claims [about evergreening]*. Again, the database reflects selection, interpretation, and characterization of the data, and policymakers should understand the difference between the raw data and these interpretive metrics.[25]

In sum, the Evergreen Drug Patent Search database inaccurately raises patent counts by counting original and reissued patents as two patents—in patent law and in the real world, all lawyers and businesspersons know that the reissue patent *replaces* the original patent—and I-MAK inaccurately counts abandoned patent applications as issued patents in creating patent numbers covering specific drugs. In both instances, this is not rigorous empirical analysis that reflects the facts of patent law, life sciences research, and the patenting practices of drug innovators.

Academics and others using the unreliable and unverified numbers of patents created by I-MAK and the Evergreen Drug Patent Search database should not be able to claim that publication of their own studies in law journals or peer review journals in healthcare journals are proxies for their veracity. As noted, the problem with these sources of patent numbers—I-MAK and the Evergreen Drug Patent Search database—is that they are not rigorous in accounting for well-known facts of patent law and of patenting practices. The editors and professors operating healthcare journals that publish articles using these unreliable sources of numbers of patents, such as the Journal of the American Medical Association, Health, Science, and others, are not experts in patent law. Thus, these journals lack the expertise, as also their peer reviewers, such as in knowing the legal difference between an original issued patent and a reissue patent. The same can be said for the law students who work as editors and run law journals in which professors have similarly published articles relying on I-MAK or the Evergreen Drug Patent Search numbers of patents.

Thus, peer review and academic publication—traditional scholarly sources that ensure the veracity of data, the rigorousness of the analysis of this data, and ultimately the legitimacy of the claims

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[23] Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 73 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 788 (2023).

[24] *Id.*, at 794.

[25] *Id.*, at 794-95 (emphasis added).

derived from this data—cannot and should not be invoked as a basis for policymakers to rely on numbers of patents used to justify allegations of "evergreening" or "patent thickets." This is not a unique problem in the drug patent policy debates, as there have been media reports of academic publications by highly regard professors and researchers at Harvard University and other universities who committed plagiarism, falsified data, or both. There have been similar problems in other areas of patent policy with "junk science" data relied on by academics and policymakers, such as the infamous claim by two professors at Boston University in 2011 that patent trolls allegedly caused $29 billion in costs to the economy.[26] There is a serious concern in the drug patent policy debates that similar "junk science" data has been created as a matter of policy-based evidence-making, undermining the role of Congress to engage in evidence-based policymaking.

3. What are your thoughts regarding the persistent claim that companies are abusing the patent system to prevent competition far beyond the 20 years Congress intended in the Patent Act? What are the facts behind this debate?

At the hearing on May 21, 2024, and elsewhere, there were many claims of persistent and widespread abuse of the patent system by drug innovators. One example is that drug innovators are receiving more than the statutory 20 years of exclusivity in the patent system. These claims are often supported by reference to I-MAK numbers or numbers derived from the bias Evergreen Drug Patent Search database, or by reference to articles that rely on these studies. The problem is that this rhetoric is not confirmed by the actual patents or rigorous statistical studies.

In terms of specific patents and drugs, the claim of *decades* of market exclusivity is contradicted by the facts. For example, in its 2018 *Overpatented, Overpriced* white paper, I-MAK asserts that Pfizer, the owner of the patents covering Lyrica, will have exclusive rights over Lyrica in the healthcare marketplace until 2038—a whopping 20 years from the publication date of I-MAK's white paper in 2018 and 11 years after the expiration date in 2027 of the patents listed in the Orange Book for Lyrica CR.[27]

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[26] *See* Adam Mossoff, *Repetition of Junk Science and Epithets Does Not Make Them True*, IPWATCHDOG (Nov. 19, 2015), https://ipwatchdog.com/2015/11/19/repetition-of-make-them-true/id=63302/; Adam Mossoff, *The SHIELD Act: When Bad Economic Studies Make Bad Laws*, TRUTH ON THE MARKET (Mar. 15, 2013), https://truthonthemarket.com/2013/03/15/the-shield-act-when-bad-studies-make-bad-laws/. *See also* David L. Schwartz & Jay Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425 (2014).

[27] *See* Mossoff, *supra* note 3, at 3.

Despite I-MAK's claims, the patent covering Lyrica's active ingredient expired in December 2018, the same year that I-MAK published its claim that Pfizer would have market exclusivity over this drug until 2038. In fact, the FDA approved *nine generic versions* of Lyrica the next year in 2019. Generic drug competition against Lyrica began that very same year: the generic drug company, Amneal Pharmaceuticals, announced in July 2019 that it had "received approval for, and launched, its generic version of Lyrica."[28] One media outlet reported in July 2019 that, for Pfizer's Lyrica, "its patent cliff is here."[29] Yet, according to I-MAK's 2018 white paper, none of this would happen for another 19 years. The facts flatly contradict I-MAK's assertions of vast periods of market exclusivity on top-selling drugs.

This has been further confirmed by *multiple* statistical studies of drug patents published over a period of more than a decade. These studies have consistently reported average market exclusivity periods of approximately 11-13 years, not the 2-4 decades asserted by I-MAK or suggested by Professor Feldman and others. It is notable that this is almost *one-half less* than the total 20-year patent term that drug innovators should receive under the patent laws. In *Solutions Still Searching for a Problem,* Professor Lietzan and Dr. Acri studied 224 New Drug Applications, and they found an average length of time before generic entry for each of these original drugs of 11.3 years.[30] Another study by Professor Lietzan and Dr. Acri of 227 new drugs that had received patent term extensions under the patent laws between 1984 and 2018 had an average period of market exclusivity of only 12.62 years.[31] A separate study in 2021 by Professor Charu Gupta found an average period of market exclusivity of only 13.3 years before market entry of a competitor generic drug for a set of 370 new drugs.[32] Another study published in 2019 by several other scholars of 170 top-selling drugs found an average period of market exclusivity of only 13.75 years for drugs that had received patent term extensions, and only 10 years of market exclusivity for drugs that were ineligible for patent term extensions.[33] Another study published in 2015 found an average period of market exclusivity of only 12.5 years for 175 new drugs.[34] Lastly, a study by Professor Scott Hemphill and Dr. Bhaven Sampat found an average period of market exclusivity of 12.1

[28] Amneal Announces Launch of Generic Lyrica® (July 22, 2019), https://investors.amneal.com/news/press-releases/press-release-details/2019/Amneal-Announces-Launch-of-Generic-Lyrica/default.aspx.

[29] Eric Sagonowsky, *Lyrica generics roll: Pfizer blockbuster finally hits patent cliff*, Fierce Pharma (July 22, 2019), https://www.fiercepharma.com/pharma/lyrica-generics-roll-pfizer-finally-hits-patent-cliff-for-nerve-pain-and-fibromyalgia.

[30] Lietzan & Acri, *supra* note 23, at 840.

[31] The statute authorizing patent term extensions is 35 U.S.C. § 156. Their study is Erika Lietzan & Kristina Acri, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1326-29 (2020).

[32] *See* Charu Gupta, *One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry* (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3748158.

[33] *See* Reed F. Beall et al., *Patent Term Restoration for Top-Selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20, 20 (2019).

[34] *See* B. Wang et al., *Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 JAMA INTERN MED. 635 (2015).

years before generic entry for a set of 119 drugs that were approved by the FDA between 2001-2010.[35]

In sum, there is no evidence of systemic manipulation of the patent system by drug innovators—they are not engaging in "product hopping" or "evergreening" to wrongly extend periods of exclusivity beyond the 20-year paten term. Claims about "product hopping" and "evergreening" are policy rhetoric employed by activists like I-MAK and some academics to create a moral panic in Congress and agencies about alleged abuse of the patent system. They do this to reduce a complex set of legal, regulatory, and economic determinants of drug prices down to an overly simplistic, sound-bite boogeyman: the patent system.

If Congress follows the principle of good governance in evidence-based policymaking, then it should recognize that numerous, multiple studies by different scholars engaging in over a decade of research consistently found average market exclusivity periods for new drugs ranging between 11-13 years. This is far less than the total period of 20 years of exclusivity promised to all innovators by the patent system. More important, it directly contradicts I-MAK's unverified and unreliable claims in its own white papers that there are 2-4 decades of market exclusivity. These published studies all follow rigorous statistical and other empirical methods of analysis, they are transparent in their analytical methods in the articles reporting their results, and their underlying data is clearly available for replication analyses. None of this can be said about I-MAK's numbers.

[35] *See* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012).