U.S. Chamber of Commerce

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May 21, 2024

The Honorable Richard Durbin
Chair
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Lindsay Graham
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Graham:

The U.S. Chamber of Commerce ("the Chamber") appreciates the opportunity to share this statement for the record in advance of your Committee's hearing entitled, "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market." Many of these medicines are only possible because of the tremendous ongoing medical innovation demonstrated by the business community to combat some of the world's most debilitating diseases.

The Chamber supports efforts to help ensure every American has equitable access to life-saving medicines. For that reason, we are concerned about efforts to pursue policies that would lead to fewer life-saving drugs and decrease access to treatments for Americans. The Administration is advancing an agenda that harms innovation, misconstrues the respective roles of public and private funding of science, research, and development, and upends the successful legal frameworks that facilitate public-private partnerships. These counterproductive policies restrict both intellectual property ("IP") commercialization, and the pipeline of new medicines, treatments, and cures.

As will be discussed in more detail, a recent Chamber report demonstrates that these policies may reduce clinical research for new treatment and cures by 75%. The Chamber's concerns with this hearing can be summarized in three main points:

1. Analysis and research demonstrate that market-restrictive, anti-innovation policies such as price controls deter future innovation, inhibit patient access, and ultimately limit patient choice;

2. Efforts by this Administration to use march-in rights would radically alter and undermine America's innovation ecosystem, thwarting American technological leadership and the ability of Americans to access the next generation of innovative technologies and cures; and

3. Policies being considered by the United States Patent and Trademark Office ("USPTO") which target the life-science industry have failed to identify a problem, are not supported by independent, objective, and verifiable facts, and if implemented, would upend current patenting practices that support life-science innovation, economic growth, and patient choice.

The Chamber's concerns are outlined in more detail below.

## I. Market-restrictive, innovation killing policies, such as price controls, have a negative impact on private businesses and result in reduced patient access to new, innovative, and life-saving medications.

Reducing barriers to access has long been a health policy priority and focus for Congress and the business community. The Chamber supports appropriate, effective efforts to help mitigate obstacles that patients might face in accessing and affording life-saving medicines. However, government price setting, when coupled with other anti-innovation policies, will create additional significant access challenges for American patients.

In March 2023, the Chamber released its *Patient Access Report, Phase 1* ("phase 1").[1] The Chamber's Phase 1 Report cautions that the IRA's drug pricing will harm patients by causing them to forfeit early and extensive access to the best life-saving medications. The Report's methodology shows that in other Organization for Economic Cooperation and Development ("OECD") countries which have implemented price controls, patients see fewer overall biopharmaceutical product launches, including biologics and oncology products, and have delayed access to medicines.[2]

For example, prior to the enactment of the Inflation Reduction Act's ("IRA") price controls, out of 104 new oncology products released globally, 80% were US Food and Drug Administration ("FDA") approved and made available in the U.S., while only 58% of those new medicines were similarly available in Europe. Unlike the United States, in several benchmark countries, patients often wait up to several hundred days to receive access to life-saving treatments, waiting an average of 133 days (about 4 and a half months) in Germany and up to 500 days (about 1 and a half years) in Spain. This work highlighted how the IRA threatens market availability of and patient access to these new medicines.

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[1] *See GIPC 2023 Patient Access Report*, March 21, 2023, available at https://www.uschamber.com/intellectual-property/patient-access-report.

[2] The report found that fewer biopharmaceutical products overall launched in Canada, Japan, South Korea, Australia, and European Union member states than in the United States over the past 20 years.

The second phase of the Chamber's *Patient Access Report*, which was released on February 1st, further confirms the adverse impact that price controls will have on the ability of American patients to access new medications. Phase 2 suggests that the IRA will have a highly negative impact on the number of products developed and/or launched in the US—in the range of 29% to 44% fewer products, some of which could be life-saving scientific advances for rare diseases and cancers, among other disease areas. Significantly, these estimates are in line with other research conducted on the potential impact of the IRA on life sciences research and development ("R&D").

For example, in June 2023, the health economics research consultancy Vital Transformation estimated that the IRA could, over a 10-year period, result in a reduction of 40% in approvals from the FDA. Similarly, a 2021 University of Chicago research paper estimating the impact of HR 5376—the draft bill that became the IRA—found that life sciences R&D spending was likely to fall by 18.5% and that this cut in investment would result in 135 fewer new medicines being developed.

The adverse impact of price controls on life-science innovation isn't just limited to the ability of patients to access new medicines but might halt scientific advances altogether. Research from the Chamber also shows that price controls decimate clinical research, particularly clinical research in cutting edge therapies. The Chamber's research, *From Groundbreaking Innovation to the Emergence of Research Deserts* ("Research Deserts"), shows that the IRA's price controls and the potential threat of march-in rights could reduce clinical research for some treatments and cures by as much as 75%.[3]

The Research Deserts report compares levels of clinical research between the United States and a sample of developed, major OECD economies that have historically imposed varying degrees of national price controls and other artificial cost-containment measures on the biopharmaceutical sector. Notwithstanding their comparable scientific and technological strengths, rates of clinical research and life science innovation in these economies have consistently lagged behind the United States. As the report demonstrates, the IRA's imposition of price controls will threaten U.S. leadership in clinical research and development turning our life science innovation oasis into a proverbial research desert.

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[3] *From Innovation Oasis to Research Desert How Price Controls Imperil American Medical Innovation and the Search for Cures*, December 11, 2023, available at https://www.uschamber.com/intellectual-property/new-study-forecasts-devastating-impact-on-patients-and-medical-science-from-government-price-controls.

Specifically, the Research Deserts report demonstrates that over time, the IRA is likely to both directly and indirectly reduce the number of clinical trials by thousands across all categories of research examined. By therapeutic field, the Chamber's research shows this reduction could amount to 12.25% for cardiovascular diseases to 68.94% for obesity research. Clinical trials related to future early-phase research risk being reduced by close to 50% or more with, for example, research related to biologics and cancer reduced by 59.41% and 54.13%, respectively. Early-phase research related to obesity could be reduced by more than 75%.

The Chamber's research isn't just hypothetical or academic: anecdotal statements made by America's most innovative companies since the IRA's enactment also serve as evidence that the development of new cures and treatments will suffer. Several life-science innovators have ended product research and development programs, citing the new price controls. For example, Novartis warned that the new law could discourage research in its most promising areas of study: RNA and radioligands. And Alnylam has stopped the development of a treatment for a rare eye disease due to the need "to evaluate impact of the Inflation Reduction Act." These are but a few of the most prominent examples of the innovative, life-saving products whose realization, availability and ultimately access are ironically threatened by the IRA's price controls that are intended to improve access.

As the Chamber's research details, and as anecdotal evidence since the IRA's enactment proves, the United States has been the global leader in all types of clinical research with particular strengths in areas of cutting-edge, early-phase trials and research related to cancer, Alzheimer's disease, diabetes, obesity, cardiovascular disease, and biologics. Additionally, American patients have also consistently benefited from having both earlier access to medications and more medications to choose from in treating their conditions. The IRA and other price controls jeopardize much of our research leadership and the ability of American patients to have choices. In addition, the IRA's price control regime is marred by fundamental legal flaws, as the Chamber has explained in the briefs that it has filed in litigation challenging the regime as unconstitutional. Surely this outcome—fewer cures, fewer choices, and longer wait times—isn't one that any member of this Committee supports.

The Chamber urges members of this Committee to recognize the valuable role the private sector plays in delivering new cures to patients and to reject efforts to augment harmful policies, like the misguided price controls in the IRA, which would undermine the healthcare of American patients. If anything, instead of focusing on policies which further expand price controls and harm the development of life-saving cures, this Committee should instead consider the facts, research, and evidence, including the statements by life science innovators, and repeal the IRA's existing price controls and seek to enact policies that promote free enterprise and further patient access to life-saving medications.

## II. If implemented, recently proposed interagency guidance on march-in rights ("proposed guidance") would radically alter America's innovation ecosystem, leading to fewer new products and technologies and seriously damaging America's global leadership, national security, and economic competitiveness.

We are deeply concerned that, if implemented, the recently proposed guidance from the Department of Commerce and NIST related to march-in rights could seriously undermine American innovation. The Bayh-Dole Act has been, since its passage, a foundational element in America's success in research and development. The Bayh-Dole Act enables public-private collaborations and expands access to new, life-changing innovations that help make the U.S. the global innovation leader.[4]

By any measure, the Bayh-Dole Act has been extraordinarily successful. According to some estimates, since its passage, the Bayh-Dole Act has contributed $1.9 trillion to the U.S. economy, supported 6.5 million jobs, and helped lead to more than 15,000 start-up companies.[5] In addition, the Bayh-Dole Act has enabled thousands of commercial products stemming from university research to be introduced to the public.[6] As The Economist put it, the Bayh-Dole Act "unlocked all the inventions and discoveries that had been made in laboratories throughout the United States...."[7]

Under the Bayh-Dole Act, Congress intended that inventions with some Federal support be developed and commercialized on an equal footing with other inventions. This part of the law also took steps to address concerns that private sector firms might fail to take reasonable steps to ***commercialize*** a partially taxpayer-funded innovation.[8] Accordingly, Congress included a ***very limited*** march-in provision, which allows the government to force the patent owner to grant additional licenses if, for example, good faith efforts are not being made to bring the product to market.[9]

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[4] Tom Wilbur, *IP Explained: Four things to know about the Bayh-Dole Act*, September 13, 2019 ("Adopted by Congress in 1980, the bipartisan Bayh-Dole Act allows institutions and grant recipients, such as universities, to hold the title to patents on inventions stemming from government-funded research and to license the rights to those inventions to private sector partners who further develop them for commercialization. These private sector partners, including biopharmaceutical companies, assume the full risk of developing and commercializing the technologies that may eventually prove to be viable products. This can generate royalties for the research institution, paid by the commercial developer, once a product is brought to market."); *see also* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-sciences Innovation System*, ITIF, March 2019, available at https://www2.itif.org/2019-bayh-dole-exec-summary.pdf; *THE BAYH-DOLE ACT: Spurring American Biopharmaceutical Innovation,* PhRMA, available at PhRMA-Bayh-Dole-Factsheet-v7.pdf.

[5] Home - The Bayh-Dole Coalition (bayhdolecoalition.org).

[6] *See* https://autm.net/surveys-and-tools/databases/statt.

[7] *Innovation's golden goose*, The Economist, December 14, 2002 (Describing how the Bayh-Dole Act was perhaps the most inspired piece of legislation enacted in the last half century.).

[8] *See Issue Brief: March-In Rights Under the Bayh-Dole Act*, Bayh-Dole Coalition, February 2023.

[9] *Id.*

Unfortunately, in recent years, some advocates that seek to weaken intellectual property rights have advanced a false theory that march-in rights can be used as a form of market intervention and price control. [10] The proponents of this theory wrongly claim that the government has the legal authority to "march-in" and override exclusive patent licenses at any time, for any reason, if it decides a product is too expensive. The government could then simply grant additional licenses to the patent to companies that promise to sell the product at a reduced cost.

This theory is without basis and contrary to the Bayh-Dole Act. The late Senators Birch Bayh and Bob Dole—the lead sponsors and negotiators of the Act—both confirmed march-in rights were never intended to be a mechanism to control prices. Senators Bayh and Dole noted that nothing in the text or legislative history supports such an assertion.[11] Senators Thom Tillis and Marsha Blackburn – two Members of Congress heavily engaged on issues of intellectual property law and technology transfer – have also affirmed that using march-in rights to set strict price controls "contradicts the purpose and the function of the Bayh-Dole Act."[12] And as recently as three weeks ago, a bipartisan group of lawmakers led by Senator Coons made abundantly clear that considering the price of a product is "contrary to the language and intent of the Bayh-Dole Act."[13]

Each Administration since the law's enactment, including the Biden Administration as recently as last year, have recognized that the law is clear, confirming that price has no role to play in determining whether to exercise march-in rights. Perplexingly, the proposed guidance would cast a pallor of uncertainty over public-private collaborations. Federally supported inventions would once again be encumbered with legal risk and unpredictability, making it more difficult for universities and private sector inventors to attract the partners and capital needed to develop nascent inventions. We believe the draft guidelines are inappropriate, illegal, and should be immediately withdrawn.

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[10] Ltr. from Senator Warren et. al. to Secretary Xavier Becerra, February 18, 2022.
[11] Bayh-Dole Coalition *Issue Brief*, supra note 19.
[12] Ltr. from Senators Thom Tillis and Marsha Blackburn to Secretary Xavier Becerra, February 24, 2022 ("Stripping intellectual property rights for private actors simply because they are commercializing their applied research on terms opponents dislike contradicts the very purpose and function of the Bayh-Dole Act. March-in rights were never intended to function as price controls nor does the statute allow it. The authors of the statute – Senators Bayh and Dole – have said as much. Every Republican and Democratic Administration dating back to President Clinton has agreed. The statute clearly doesn't sanction marching in to control prices of successfully commercialized products.").
[13] *See* Ltr. from Senators Chris Coons and Thom Tillis, and Representatives Issa and Auchincloss to Gene L. Dodaro, Comptroller General of the United States, May 1, 2024.

## III. Certain policies being considered by the USPTO, if implemented, would upend current patenting practices that support life-science innovation, economic growth, and patient choice.

The Chamber's broad and diverse membership includes many companies which have legitimate concerns around patent examination quality in their art areas. That is why the Chamber has supported increased funding for USPTO to hire and train more patent examiners and facilitate information technology improvements at the Office. Nevertheless, the comments below reflect the Chamber's strong impression that current proposed changes at the USPTO are politically and practically directed at the life sciences industry only, and the views expressed here reflect that context.[14]

As a threshold matter, the Chamber also notes that while some of the proposals being considered by USPTO are broadly framed and, in theory, technologically neutral, the reality is the questions raised and agency actions contemplated are targeted solely towards the life science technology sectors.[15] It is unwise for the agency to consider changes to examination practices, which will, under well-established US and international law, apply to all art units and technology sectors, simply to address a ***perceived*** problem in life science patent examinations.

However, with that in mind, the Chamber believes that in the context of patenting practices in the life-science sector, such practices support innovation, economic growth, patient choice, and promote public health and well-being. The Chamber rejects the false and misleading narrative that so-called "patent thickets"[16] are responsible for high drug prices and do not represent true innovation. Scholars have demonstrated that the idea of biopharmaceutical patent thickets are mostly a myth.[17]

The Chamber understands from member companies and practitioners that there is no evidence that any federal court has ever insisted that a competitor adjudicate at trial each claim in every patent in an alleged "thicket" to enter the market. Instead, under the rigorous and specially designed Hatch-Waxman and BPCIA

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[14] With respect to the recent Noticed of Proposed Rule Making on Terminal Disclaimer Practice published on May 10, 2024, the Chamber is still soliciting the views of its members and has not yet formed a viewpoint in relation to the specific questions raised by that request for comment.

[15] *See Id.*

[16] Individuals and organizations variously define a patent thicket in this context as the process of a branded company obtaining purportedly obvious variants of the same patent with the sole purpose of delaying the entry of a generic competitor. *See* Osenga, *infra* note 17.

[17] *Adam Mossoff, Unreliable Data Have Infected the Policy Debates Over Drug Patents, The Hudson Institute, January 2022; Erika Lietzan & Kristina M.L. Acri née Lybecker, Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations, Fordham Intellectual Property, Media & Entertainment Law Journal, Vol. 33, Sep. 26, 2022; Ltr. from Senator Thom Tillis, Ranking Member, Senate Judiciary Committee Subcommittee on Intellectual Property to Tahir Amin, January 31, 2022; Professor Kristen Osenga, Are "patent thickets" to blame for high drug prices, Richmond-Times Dispatch, Nov. 30, 2022.*

frameworks, most litigation is resolved after litigating only a limited number of representative claims, providing legal certainty for innovator and generic, alike. The public record of litigation under these frameworks shows that in nearly every case, multiple generic or biosimilar challengers per product are using the existing process to efficiently adjudicate patent disputes and are not deterred or blocked from doing so by "impenetrable thickets" as alleged.

If anything, both practice and reality suggest that more patents in a family support innovation and economic growth, patient choice, and the public good. Innovation is not a one-off, siloed process. Often, when a life sciences innovator files an initial patent claim they do so in the early stages of research and development, years before an intended product reaches the market and all aspects of its applications and treatments have been clinically tested. Extensive clinical trials and investments in research and development are required to discover subsequent health conditions that may be treated by the initial product. From delivery efficacy and patient compliance to dosages, mitigation of side effects, extended-release formulations, and entirely new treatments, so-called follow-on innovations deliver invaluable benefits to patients and consumers. [18]

For example, when Botox was originally approved it was to treat eye disorders. Today, there are more than 11 approved treatments, including for cerebral palsy.[19] Similarly, AZT was originally developed as failed attempt at cancer treatment.[20] It was only years after its failed application as a cancer treatment—and untold investments in clinical trials and research—that its potential in the fight against HIV/AIDS was discovered.[21] Without the ability to engage in follow on innovation and secure patent protections, it is questionable whether the new treatments for either of these life science innovations would be available. Current continuation and terminal disclaimer practices help ensure that such investments are able to be protected.

Each stage of innovation requires new investment and risk, which is made possible by incentives like the potential for patent protection. According to one study, the median cost of getting a new life science innovation to market was $985 million, with an average overall cost of $1.3 billion[22] Other studies estimate the cost, based on

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[18] *Osenga, supra* note 17 ("It's no secret that drug manufacturers regularly continue to innovate drugs long after they're originally proven safe and effective. There are countless legitimate reasons to do so. Sometimes, post-market research suggests that a particular dosage or delivery method could be superior to the original.").
[19] *Id.*
[20] Christopher M. Holman, Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, IP-Watch, Sep. 21, 2018, available at https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/.
[21] *Id.*
[22] *See generally* Wouters OJ, McKee M, Luyten J, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 2009-2018, JAMA, March 3, 2020

the amount of research and clinical trials required, could be as high as $2.8 billion.[23] The reality is that cutting-edge medical treatment, and the hope it gives to patients with previously uncurable diseases and illnesses, is costly.

To justify these substantial costs and investments, many of which never materialize or become profitable, innovators must have access to potential patent protection for innovation that arise later in the product's development lifecycle. Simply put, given the significant costs associated with bringing any iteration of a product to market, without continuations to facilitate claiming of previously disclosed embodiments, or without the ability to secure full scope of protection through use of terminal disclaimers, and additional protections for follow on innovations, life science companies will not invest in new or improved versions of their medicines.

For the Chamber, the life sciences innovation ecosystem, and the patent system that supports it, are working. Follow-on innovation, and the patent practices which facilitate it, provide innumerable benefits to patients, giving them better, more effective medicines, and allow public access to more data, which can and will spur future innovations.

Moreover, current continuation practice and related practice concerning terminal disclaimers are crucial to the flourishing of life-science innovation – and are a foundational element of the US system that has promoted American innovation and continues to be a draw for investment in the pharmaceutical sector even when compared to other advanced economies. While continuation practice may cause issues in other industries, within life sciences, continuations provide the flexibility to pursue protection for different inventions described in the initial patent description without fear that deserving inventions would lose protection solely due to decisions to pursue a different embodiment at an earlier time.

This not only promotes innovation, but also facilitates efficient and higher-quality patent examination by dividing claim sets into more manageable pieces, and, perhaps more importantly, provides incentives to accelerate disclosure of information to the public as inventors will have no fear that they would lose protection if an invention were disclosed early but is not claimed at that time. A restrictive approach to these applications or limits on terminal disclaimer practice – which allows for the grant of patents on obvious variants to ensure full scope of infringement protection for previously-disclosed innovations, without the patent owner obtaining any additional patent term – would be counter to these policy goals.

Too much is at risk—from patient benefits to economic growth and consumer choice—for the USPTO to proceed with some of the policy changes under consideration.

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[23] Robert Zirkelbach, *The Cost of Innovation*, PhRMA, November 19, 2014.

## IV. Conclusion

The Chamber appreciates the opportunity to share these comments for the record. We remain ready and willing to work with Congress to promote free-market solutions that ensure equitable access to life-saving medication. However, policies that have been enacted and are being considered, including the confiscation of the property of American businesses, will not help patients but instead will simply delay the development of new treatments and cures. The Chamber, therefore, is committed to stopping implementation of these harmful policies.

Sincerely,

Tom Quaadman
Executive Vice President
Global Innovation Policy Center
U.S. Chamber of Commerce

cc: Members of the Committee on the Judiciary