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Senator Richard J. Durbin, Illinois, Chair
United States Senate
Committee on the Judiciary
Washington, DC 20510-6275

June 12, 2024

Dear Chair Durbin,

Thank you again for the opportunity to testify on behalf of PhRMA. Please find our responses to the written questions from Committee members following my testimony on Tuesday, May 21, 2024.

Senator Tillis' Question: a) Given the complexity of the science and manufacturing in the biologics space and the fact that products often need decades to go from groundbreaking research to human interaction, how should we be looking at this question of incremental innovation? b) Is it different in this area, particularly when the development process can involve not just the method of treatment, but also complex manufacturing and patient delivery?

The investment necessary to develop a new medicine can cost an average of $2.6 billion and take 10-15 years, and only 12% of medicines entering clinical trials ever obtain an FDA approval.[1] Manufacturers seek the certainty and predictability provided by intellectual property (IP) protections to make the decades long investments in new technologies, and in building and expanding upon state-of-the-art manufacturing facilities. Strong and reliable IP protections are also critical to fostering public-private partnerships and other forms of collaboration, including investment in emerging innovator companies.

Innovation shouldn't stop once a new drug becomes available to patients, in fact, many advancements for patients are realized through continued investment in R&D after initial approval, known as post-approval R&D. Whether adding a new use in an earlier treatment line or disease stage, or finding new diseases a medicine can treat, patent protections incentivize manufacturers to

[1] DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of health economics*, *47*, 20-33.

continue working to improve their medicines and make them more effective for patients. R&D investment in medicines is an ongoing process that continues long past initial FDA approval, resulting in innovations that improve the lives of patients, including new uses, novel delivery mechanisms and new dosing schedules. These advances can involve significant R&D investments and lengthy and resource-intensive clinical trials, with no guarantees of success. Post-approval R&D can lead to new or improved treatment options for patients that may enable better health, quality of life, or reduce treatment burdens improving treatment adherence and health outcomes.

Post-approval R&D is particularly important in advancing new treatments for cancer patients, as much of the unprecedented progress seen in the fight against cancer over the past decade has been the result of this form of R&D.[2] In fact, the majority of cancer medicines receive approval for more than one indication, with many post-approval indications approved years after the medicine's initial FDA approval. [3,4] In addition to post-approval R&D driving new uses, it also brings greater knowledge on the benefits of medicines. Due to the life-threatening and progressive nature of cancer, long-term follow-up of patients in clinical studies is often needed to evaluate overall survival, which is the length of time that patients with the disease are still alive since beginning treatment. These additional studies conducted after approval are critical to understanding and realizing the full therapeutic value of cancer treatments.[5]

This additional R&D can also be directed to improving methods of manufacturing, developing new manufacturing processes or to developing a more complex form of a medicine. Such manufacturing advances can improve medicines, for example by removing potential impurities. Investment in these innovations similarly is incentivized by IP protections. For R&D

[2] IQVIA Institute. "Global Oncology Trends 2022." https://www. iqvia.com/-/media/iqvia/pdfs/institute-reports/global-oncologytrends-2022/iqvia-institute-global-oncology-trends-2022-forweb.pdf. Published May 26, 2022. Accessed June 11, 2023.
[3] Partnership for Health Analytic Research. "Implications of the Inflation Reduction Act Price Setting Provisions on Post-Approval Indications for Small Molecule Medicines." https://www.pharllc.com/ publication/implications-of-the-ira-price-setting-provisions-on-postapproval-indications-for-small-molecule-medicines/. Published June 2023. Accessed June 11, 2023
[4] Partnership for Health Analytic Research. "Implications of the Inflation Reduction Act on Post-Approval Research & Development of Biopharmaceutical Medicines." https://www.pharllc.com/wp-content/ uploads/2022/11/Clinical-Benefits-of-Post-Authorization-ResearchBrief.pdf. Published November 9, 2022. Accessed June 13, 2023.
[5] National Cancer Institute, NCI Dictionary of Cancer Terms. "Overall Survival." https://www.cancer.gov/publications/dictionaries/cancerterms/def/overall-survival. Accessed June 11, 2023.

intensive industries, the manufacturing process is a key factor in developing new products. That's because in these industries, product and process innovation are often intertwined. Manufacturers justifiably may seek to protect these innovations, while also disclosing their inventions to the public, through patents.

In contrast to patents that cover the composition of a new compound, new uses, new dosage forms, patents that cover new methods of manufacturing can be invented throughout the product lifecycle, and thus patent applications for them can also be filed throughout this lifecycle. For instance, new methods of manufacturing that reduce the potential for immunogenicity are often invented years after a biologic is discovered or has obtained FDA approval. In addition, manufacturers may invent novel methods for purifying proteins that are more efficient or allow for more precise recovery of specific proteins. Such advances in manufacturing methods benefit patients and should be incentivized through robust IP protections.

It is also important to note, IP protection on post-approval advances do not block approval of generic copies or biosimilar versions of an earlier approved version of that medicine. If, as is often alleged, a manufacturer introduced a meaningless change to an existing product, this change would do nothing to delay or prevent FDA from approving a generic or biosimilar of the earlier product. In this way, the patent system continues to reward and incentivize new innovations without extending exclusivity on earlier inventions.

Senator Grassley's Question 1: I'm concerned about the Biden Administration's lack of leadership in protecting intellectual property rights abroad. What's your opinion? How does this impact the industry and the development of new cures?

The Biden Administration has demonstrated limited ambition to further advance, or even maintain, strong intellectual property (IP) policies internationally. Instead, the Administration has departed from longstanding and bipartisan U.S. trade objectives to promote strong IP policies by altogether deprioritizing an agenda to protect American innovation abroad.

U.S. biopharmaceutical innovators face serious IP challenges in foreign markets. As documented in PhRMA's annual Special 301 and National Trade Estimate submissions to the United States Trade Representative (USTR), many foreign governments fail to provide the IP protections

necessary to support biopharmaceutical innovation, despite their commitments under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and U.S. free trade agreements.[6] Unfortunately, the Administration has not adequately enforced trading partners' commitments to protect American innovation, allowing harmful policies and practices in key jurisdictions to go unaddressed. For example, China has not implemented its WTO obligation to provide regulatory data protection for new biopharmaceutical products, and Mexico has not implemented key IP obligations required by the United States-Mexico-Canada Agreement (USMCA).

Worse, the Administration has adopted IP policies that materially harm U.S. innovators. The Administration actively undermined international commitments to protect IP at the WTO's Twelfth Ministerial Conference by agreeing to an unnecessary TRIPS waiver that effectively handed over American COVID-19 vaccine innovations to countries looking to overtake U.S. leadership in biopharmaceutical development. Most recently, Ambassador Tai stated in a press release announcing the 2024 USTR Special 301 Report that the "Administration has continued its policy of declining to call out countries for exercising TRIPS flexibilities, including with respect to compulsory licensing." Despite continued serious concerns, the Report reverses decades of bipartisan precedent and now eliminates all references of compulsory licensing by key trading partners and omits previously included concerns on egregious restrictive patentability practices – further emboldening foreign governments to erode IP protections for American innovators.

Put simply, the Biden Administration's lack of leadership in protecting IP abroad and its unambitious trade agenda is harming America's global competitiveness and patients around the world.

Senator Grassley's Question 2: 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

[6] PhRMA comments on the 2024 National Trade Estimate Report on Foreign Trade Barriers (NTE), available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-2024-NTE-Comments.pdf

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?

Strong and reliable IP protections are critical to fostering public-private partnerships and other forms of collaboration. Congress passed the Bayh-Dole Act in 1980 with bipartisan support to incentivize the private sector to transform discoveries resulting from government-funded early-stage research into useful products in any sector. By allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and right to use those inventions to private sector partners, the Bayh-Dole Act facilitates the development of commercially available medical treatments. Prior to enactment of the Bayh-Dole Act, the government retained the patents on federally-funded inventions – and only 5% of those patents were ever licensed for use in the private sector.[7] Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized Federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit for government-funded research.[8]

The Biden Administration's National Institute of Standards and Technology (NIST) recently issued a Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("the Draft Framework").[9] Far from a "careful" approach that would provide a "gentle nudge" to address drug pricing, the Draft Framework misinterprets the Bayh-Dole Act of 1980 and uses a vague approach that is already causing uncertainty. The Draft Framework ignores the intent of the law, as stated by the bill's sponsors,[10] as well as decades of policy precedent by encouraging federal agencies to explicitly consider the price of a product incorporating federally funded inventions when evaluating the statutory march-in

[7] Government Accountability Office (GAO). Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions, 2009. Available at: www.gao.gov/products/GAO-09-742.
[8] Wendy H. Schacht, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship*, Report RL32324 (Congressional Research Service), November 30, 2012.
[9] 88 Fed. Reg. 85593–605 (Dec. 8, 2023).
[10] *See* Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002 (Bayh-Dole did not intend that the government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government.")

criteria. If finalized in its present form, NIST's proposal would create an environment of uncertainty in Bayh-Dole's technology transfer scheme that could discourage companies from investing funds in the already highly risky endeavor of drug development as well as the development of other important technologies.

When companies first license a new technology, they often don't know whether a finished product will even be viable, let alone how much it will cost to develop and what pricing will be viable in the highly competitive biopharmaceutical market. As such, march-in is a particularly blunt tool, and if wielded, a company could be stripped of all its economic interest in a product and risk a near total loss of its investment. Worse, the Administration's plan gives no clear guidance as to what price could trigger this loss. Faced with this uncertainty, companies may well conclude that reliance on government funding is too risky. As a result, NIST's march-in proposal could send the U.S. innovation ecosystem back to a time before Bayh-Dole when government-funded research sat on a shelf, undeveloped and unused. The significant negative consequences that may flow from this uncertainty, and from fundamentally undercutting the very purpose of Bayh-Dole, are offset by no measurable, practical, or realistic gain for the American people or the U.S. innovation ecosystem.

Senator Grassley's Question 3: In Dr. Feldman's written and oral testimony, he suggests that the Committee consider 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 as ways to address the high cost of drugs? Why or why not?

Please find our response to the 5 specific proposals Dr. Feldman outlined in his testimony that the Committee should consider below:

1. *Grant the FDA the authority and resources to evaluate all patents submitted for listing in the Orange Book to determine eligibility for inclusion as well as direct the FDA to provide additional guidance on the types of patents that should be listed.*

The industry does not support the listing of inappropriate patents in the Orange Book. Instead, the industry seeks to comply with the statutory Orange Book listing requirements implemented by the FDA. PhRMA therefore agrees with Dr. Feldman that Congress should direct FDA to provide additional guidance on whether certain types of patents should be listed, and

furthermore PhRMA believes that the FDA already has adequate authority to provide clarification on types of patents and the resources to do so. FDA has not, however, provided clear guidance on device-related patents that should be listed, even though PhRMA and companies have for years requested guidance from FDA concerning whether such patents must be listed. FDA already has the authority to provide clarification on the listing of various patents and should do so.[11]

Generally, the patent listing system has operated effectively over the almost 40 years since enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman). There have been times when FDA has clarified types of patents required to be listed, including changing its regulations in 2003 with respect to, for example, patents on intermediates. There also are existing mechanisms for challenges to listings. FDA has not, however, provided clear guidance on device-related patents that should be listed, even though PhRMA and companies have requested guidance from FDA over many years concerning listing of these patents. FDA already has the authority to provide clarification on types of patents and should do so. There is no need for FDA to take on the significant resource burdens of substantively evaluating all patents submitted for listing in the Orange Book when providing requested clarity on listing would address concerns.

2. *Require that patents submitted to the FDA for listing in the Orange Book are also submitted to the USPTO for re-examination.*

PhRMA disagrees with this proposal, which would slow down the Hatch-Waxman process and create uncertainty for innovators. Patents in any sector have a presumption of validity, and requiring all listed patents to be submitted for reexamination suggests there is a particular validity or patent quality problem in the pharmaceutical sector that is not borne out by data. The proposal would also create a huge resource burden for U.S. Patent and Trademark Office (USPTO) given the number of patents listed in the Orange Book. The proposal also appears to be based on the mistaken premise that listing a patent in the Orange Book is somehow suspect. Patents are legally

[11] Indeed, case law in this area has demonstrated that the patent listing requirements require further clarification by FDA, as the decisions in these cases have led to further confusion including regarding the meaning of "claim." *See, e.g., In re Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1 (1st Cir. 2020); Opinion & Order, *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, Civ. No. 23-20964 (SRC) (D.N.J. June 10, 2024) ; *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997); *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, 60 F.4th 1373 (Fed. Cir. 2023).

required to be listed in the Orange Book, and this listing process provides generic manufacturers with clarity about the patents covering the reference product that are relevant to generic entry. Generic manufacturers also are able to challenge Orange Book listed patents before launch of their products to resolve patent issues without the risk of incurring damages from selling an infringing product. Using the reexamination process for every Orange Book listed patent would drain USPTO resources without clear benefit, given the existing mechanisms for challenging patent listing and patent validity.

3. *Limit the number of patents that brand-name manufacturers can assert to one patent per family when suing for infringement, for example based on the presence of terminal disclaimers.*

PhRMA disagrees with this proposal. Aside from the impact on property rights by prohibiting enforcement of valid patent rights, the proposal fails to recognize the reality of the patent system. Terminal disclaimers reduce the term for an entire patent, even if it is used to address an issue with a particular claim in a patent. This proposal would eliminate patent rights in valid claims to distinct inventions. Terminal disclaimers are also addressed below in the response to Question 4.

4. *Grant the FDA more resources and flexibility to approve generic drug-device combinations that differ slightly from brand-name reference products (while still containing the same active ingredients) and require the FDA to ensure that postmarketing surveillance studies are conducted to confirm similar outcomes for patients receiving generic and brand-name versions.*

FDA already has authority to approve these generic drug-device combination products, but we support clarifying FDA's authority to do so. However, any legislation on this should be appropriately tailored to this objective. Per FDA's Legislative Proposal, the agency aims to clarify "that differences in labeling between the [reference listed drug] (RLD) and the proposed generic as a result of permissible differences in the device are also permissible." Although this clarification would seem appropriate, there is no need for the legislation to go further. Any legislation should simply clarify that labeling changes are a result of differences in a device for use with the generic drug are allowed, in line with FDA's objective.

5. *Increase the 180-day exclusivity periods for the first generic firms to file paragraph IV certifications on complex products like drug-device combinations and decrease the 30-month stays awarded to brand-name firms that sue for infringement.*

PhRMA disagrees with decreasing the 30-month stay. The 30-month stay is an integral part of the Hatch-Waxman framework that allows for resolution of patent disputes prior to generics entering the market. After generics enter the market, the patent litigation becomes more complex given the potential for damages and an injunction. The 30-month stay is already a balanced provision, and the 30-month length was crafted to provide sufficient time to allow the court to rule in the patent infringement suit. If a generic wins in the district court prior to the end of 30 months, the stay ends. In addition, if innovators obtain and list patents after a generic application has been submitted, there is no separate 30-month stay for litigation over such patents.

PhRMA does not have a position on increasing the 180-day exclusivity periods for the first filing generics on complex products.

Senator Grassley's Question 4: Do you agree with the various proposals to address issues with terminal disclaimers and obviousness-type double patenting? Please explain.

PhRMA disagrees with the recent proposals to "address issues with terminal disclaimers and obviousness-type double patenting." Terminal disclaimers (TD) require the applicant to agree to a common expiration date and common ownership of "disclaimed" patents of obvious variants. TDs were designed to overcome the judicial doctrine of obviousness-type double patenting (OTDP), which was established when patent terms were 17 years from issuance, and later issued patents would always last longer.[12] TDs provide a straightforward solution to address concerns about patents that were seen to claim obvious variants from being enforced by multiple assignees and from providing extended patent term. They have been an integral part of the U.S. patent system across industries and technologies.

[12] This has profoundly changed. On June 8, 1995, the Uruguay Round Agreements Act (URAA) took effect. Patents with effective filing dates after that date are entitled to a term that lasts 20 years from the relevant filing date, regardless of when they issue.

A Senate bill (S.3583) is targeted specifically to the pharmaceutical industry and only permits companies to assert one patent per "Patent Group," which are patents linked by a terminal disclaimer, against a party with a copied product.[13] The bill's stated purpose is "to address patent thickets," which allegedly "come at a high cost to the American people."[14] The bill impacts patents linked by a TD and the underlying suggestion is that these are bad, low quality, invalid patents. But in fact, these patents all have the same expiration date, so they do not prolong the patent term, and pharmaceutical patents are not broadly invalid. PhRMA does not support the currently pending proposals addressing obviousness-type double patenting and TDs because they undermine the values of our intellectual property system in promoting innovation and incentivize gamesmanship. Further, the rhetoric that terminal disclaimers are increasing drug costs has been built on seriously flawed data including those from I-MAK and the Hastings database.[15] Academics have repeatedly criticized these sources for the "serious questions of reliability and accuracy" they raise.[16]

Despite the strong rhetoric around so-called patent thickets, data shows that the number of patents covering a pharmaceutical product is not a general concern across the industry. Pharmaceutical products (i.e. drugs) are covered by ***fewer*** patents per product than other products such as golf balls/clubs and cell phones.[17] Pharmaceutical patents are not "bad patents" either. Instead, they are upheld at higher rates in district courts and PTAB than other types of patents.[18]

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[13] "S.3583 - A bill to address patent thickets" was introduced in the Senate on Jan 11, 2024. *See* https://www.congress.gov/bill/118th-congress/senate-bill/3583.

[14] Statement of Purpose of the "One invention one patent" act, which was a predecessor of S.3583.

[15] *See*, I-MAK, *Overpatented, Overpriced: Curbing patent abuse: Tackling the root of the drug pricing crisis*, (Sept. 2022); Evergreen Drug Patent Database.

[16] *See,* Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents* (Jan. 2022); Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 FORDHAM INTELL. PROP., MEDIA & ENT. L.J. 788, 788 (2023).

[17] *See, e.g.*, Titleist Patent Marking (last visited June 4, 2024) (noting, for example, 24 patents covering the 2023 Pro V1 golf balls, 40 patents covering the 2021 Pro V1x golf balls, and 90 patents covering "irons" golf clubs); Building a Better Golf Ball, Popular Science (Nov. 24, 2008) (noting that a golf ball may contain as many as 70 separate inventions); TaylorMade Golf Patent Marking (listing over 100 patents for certain golf clubs); Apple-Samsung Case Shows Smartphones as Legal Magnet, New York Times (August 25, 2012) ("By one estimate, as many as 250,000 patents can be used to claim ownership of some technical or design element in a smartphone."); LG Patent Marking (last visited June 4, 2024) (listening hundreds of patents as covering LG's smartphones); Alison Noon, *Puma Must Face Nike's Flyknit Patent Infringement Claims*, Law360 (Oct. 10, 2018) ("Nike claimed to have acquired more than 300 utility patents to protect the knit-upper shoe trend it launched in 2012.").

[18] Tu & Lemley, *What litigators can teach the Patent Office about pharmaceutical patents*, Wash Law Rev. 2022; 99:1673, 1692. The article looked at so-called "secondary patents" but acknowledged based on its own data that "even the numbers for secondary patents involve a much higher win rate than for non-pharmaceutical patents."

Additionally, multiple studies failed to demonstrate that the number of existing pharmaceutical patents impacts competition.[19]

Further, the patent system already has a carefully crafted framework to challenge the validity of pharmaceutical patents that balances the need to incentivize research and development in important new drugs, while also allowing lower cost generic drug entry. Under the framework created by the Hatch-Waxman Act, litigation typically resolves validity disputes within two years to ensure the issues are addressed before the end of the 30-month regulatory stay.[20] Given this quick timeline, courts already have mechanisms to limit the number of claims litigated,[21] and judges often require the parties to limit the number of litigated patents and claims.

The quick timing of Hatch Waxman litigation also impacts PTAB proceedings. Within the one-year time bar under 35 U.S.C. §315(b), defendants often already have a narrowed list of the patents and claims that will be litigated, and they can target those claims in any post-grant petitions. Further, if the patents linked by terminal disclaimer are truly similar to each other, then the arguments and expert testimony should be similar across the patents. Thus, the increased cost for multiple patents should be minimal since the inter partes review (IPR) costs are largely in preparing the papers and arguments with experts, not in the filing fees. And if the petitions require different arguments and experts, which increases the cost, this also indicates that the patents have unique validity positions and emphasizes that their validity should be considered independently of one another.

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[19] *See* Jonathan M. Barnett, Are There Really Patent Thickets?, 39 Regulation 14, 15 (Winter 2016-2017); *see also* Erika Lietzan & Kristina Acri née Lybecker, Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations, 33 Fordham Intell. Prop., Media & Ent. L.J. 788, 789 (noting that the U.C. Hastings Evergreen Drug Patent Database did not accurately capture when generic drugs enter the market, and "generic competition launched on average eighty-four months (seven years) before the Hastings Database implied it would"); Global Biosimilars Market Growing to Exhibit a Noteworthy CAGR of 22.9% by 2033, Key Drivers, Growth and Opportunity Analysis - Research Nester, Global News Wire (Oct. 12, 2022); The Global Biologics Market Is Projected to Grow at a CAGR of 8.82% By 2032: Visiongain Reports Ltd, Global News Wire (Aug. 9, 2022) (finding that approval of biosimilars and interchangeable biologics have contributed to growth in the biologics and biosimilar market, which is projected to continue).

[20] ANDA cases reaching trial between 2016 and 2017 did so at a median time of 759 days, and many ANDA cases were terminated before reaching trial. *See,* Lex Machina, Hatch-Waxman ANDA Litigation Report 2018, at 10.

[21] *See, e.g.,* https://www.txed.uscourts.gov/sites/default/files/forms/ModelPatentOrder.pdf (Eastern District of Texas) and https://www.ded.uscourts.gov/sites/ded/files/chambers/Scheduling%20Order%20for%20Hatch-Waxman%20Patent%20Infringement%20Cases.pdf (District of Delaware).

Instead of providing a more efficient system, S.3583 creates an incentive for gamesmanship. In Hatch-Waxman litigation the patent owner plaintiff rarely knows the details of the generic product before filing the complaint. If the plaintiff is forced to select only one patent per "Patent Group" for assertion, generic companies could be incentivized to hide the specifics of their product in a paragraph IV letter and not address infringement at all, and then only reveal product details and non-infringement theories after the patent has been selected.[22] This could neuter pharmaceutical patents and does not serve the policy objective.[23]

Additionally, the bill is problematic because it would *de facto* also take away a patent owner's rights in asserting patently *distinct* inventions. A "Patent Group" is defined in the bill as two or more commonly owned patents that are linked by a "terminal disclaimer." Under current OTDP/TD practice, even if only a single claim in a patent application is subject to an OTDP rejection, the applicant is required to file a terminal disclaimer that applies to the *entire patent*. Therefore, by allowing the assertion of only one patent in a "Patent Group," the bill forces a choice not only between the patentably indistinct claims, but also between patentably *distinct* claims embodying *separate* inventions that are completely unrelated to the original OTDP rejection.

In short, PhRMA does not support the currently pending legislative proposal addressing obviousness-type double patenting and terminal disclaimers because it undermines support for innovation and promotes gamesmanship.

The USPTO also issued a proposed rule that would make a patent subject to a TD unenforceable should the patent it is linked to by TD be found unpatentable or invalid as anticipated or obvious.[24] PhRMA will be submitting comments in response to this proposed rule.

Thank you for the opportunity to respond to the Committee's questions. I can be reached at julrich@phrma.org with any additional questions.

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[22] A generic drug company must address non-infringement and offer confidential access to its ANDA in its paragraph IV letter only to preserve the ability to seek a declaratory judgment. See 21 C.F.R. 314.95(c)(8).
[23] A similar dynamic could also occur with respect to patent litigation over biosimilars.
[24] *See* Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 80 Fed. Reg. 40439 (proposed May 10, 2024).