the campaign for
SUSTAINABLE Rx PRICING

January 31, 2023

The Honorable Kathy Vidal
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
P.O. Box 1450
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RE: Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights (PTO-P-2022-0025)

The Campaign for Sustainable Rx Pricing (CSRxP) is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers. We are committed to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives.

Prescription drug prices are out of control and continue to grow at unsustainable rates. Twenty-one cents of every health care dollar goes toward prescription drugs – with drugs contributing more to health care costs than any other type of health care service.[1] At the beginning of 2023, drug companies raised prices on at least 350 drugs even though far too many Americans still cannot afford their medications.[2] The price increases to start 2023 follow years of drug makers imposing substantial and unjustifiable price increases on consumers and taxpayers. During the period of July 2021 to July 2022, for example, drug manufacturers raised prices in excess of inflation for 1,216 drugs, with an average price increase of 31.6 percent.[3] The average price increase was nearly $150 per drug (10.0 percent) in January 2022 and was $250 (7.8 percent) in July 2022.[4]

Unsustainably high price increases are not the only significant problem Big Pharma is imposing on patients and taxpayers. Drug companies are setting records for the skyrocketing prices of new drugs at launch. The median annual price among new FDA-approved drugs in 2022 was more than $220,000 – a significant jump even from 2021 when the median launch price was $180,000.[5]

Despite efforts from the pharmaceutical industry to suggest otherwise, drug manufacturers – and drug manufacturers alone – are the drivers of the unsustainable growth in prescription drug prices and the needlessly high spending on drugs that consumers, taxpayers, and businesses face today. Drug makers set high list prices at launch and increase those list prices at rates far above inflation. Spending on high-priced drugs places significant strain on patients, federal health programs, and taxpayers. High-priced

[1] AHIP. "Where Does Your Health Care Dollar Go?" 2021.
[2] Erman M and Steenhuysen J. "Exclusive: Drugmakers to raise prices on at least 350 drugs in U.S. in January." *Reuters*. December 30, 2022.
[3] U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation Office of Health Policy. "Price Increases for Prescription Drugs, 2016 – 2022." September 30, 2022.
[4] *Ibid*.
[5] Beasley, D. "U.S. new drug price exceeds $200,000 median in 2022." *Reuters*. January 5, 2023.

drugs also substantially burden the many small businesses and large employers who seek to offer affordable health insurance to their employees because, as prescription drug expenditures increase, cost-sharing and premium costs also rise.[6] Far too often consumers experience the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients simply should never be presented with such a choice.

Importantly, recently published research strongly suggests that abuse of the U.S patent system by the brand biopharmaceutical industry to undermine competition is particularly contributing to high drug costs and spending. One analysis found that, despite representing less than one percent of U.S. prescriptions, biologics account for nearly half of all drug spending largely because they face less competition from biosimilars due to differences in how the marketplace is regulated and how the brand industry games the patent system to undermine competition.[7] The study's authors estimate that the anti-competitive nature of the U.S. biologic market already has cost patients approximately $5 billion from 2015 through 2020.[8] Without action, the authors estimate patients needlessly will pay an extra $25 billion in excessive drug spending through 2029.[9]

Separately, a report from the House Committee on Oversight and Reform concluded that big pharma's anti-competitive abuses of the intellectual property system have led to significantly higher drug prices and drug spending in Medicare, hurting both Medicare beneficiaries and the taxpayers who fund the cost of the program. Upon reviewing the price histories of 12 of the best-selling drugs in Medicare, the Committee found that brand drug companies raised prices more than 250 times leading to median prices almost 500 percent higher than when they were brought to market.[10] During the period, more than 600 patents were obtained for these 12 drugs to maintain product monopolies and market exclusivity, effectively blocking competition from more affordable alternative therapies for decades.[11] The report determined that the patents already secured for these 12 drugs "could potentially extend their monopoly periods to a combined total of nearly 300 years," noting that delayed biosimilar competition from just one blockbuster selling drug, *Humira,* would cost the U.S. healthcare system at least $19 billion from 2016 to 2023.[12]

Given today's prescription drug pricing crisis and the significant role that patent abuse plays in this crisis, CSRxP applauds and welcomes actions from the U.S. Patent and Trademark Office (USPTO) to thwart anti-competitive gaming actions by Big Pharma that restrict competition and keep prices high. We thus appreciate the opportunity to comment on "Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights" (PTO-P-2022-0025). In our comments, we express particular support for USPTO actions that can stop brand drug companies from unfairly extending product monopolies and driving up prices through development of patent thickets and estates, obviousness-type double patenting, product hopping, and evergreening, as described below:

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[6] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.
[7] Roy, Avik. "The Growing Power of Biotech Monopolies Threatens Affordable Care." Foundation for Research on Equal Opportunity. September 15, 2020.
[8] *Ibid*.
[9] *Ibid*.
[10] House Committee on Oversight and Reform Majority Staff Report. "Drug Pricing Investigation." December 2021.
[11] *Ibid*.
[12] *Ibid*.

- ***Patent Thickets and Estates:*** Brand drug makers construct patent estates and thickets to prolong market exclusivity for their products well beyond initial exclusivity periods. The blockbuster biologic *Humira*, for instance, generated more than $20 billion in global sales in 2021.[13] Two hundred forty-seven (247) patents have been filed on *Humira* in the U.S. with the goal of delaying competition by 39 years.[14] Eighty-nine percent of those patents of were filed after *Humira* was already on the market, with nearly half of the others filed after the first *Humira* patent expired in 2014—more than 20 years after the initial *Humira* patents were filed in 1994.[15] *Humira's* patent estate has had significant cost consequences for Medicare and Medicaid, with spending on *Humira* in these programs increasing by 266 percent from 2012 to 2016.[16] *Humira's* patent estate also has imposed enormous costs on patients, with average *Humira* spending per person more than doubling from $16,000 to $33,000 between 2012 and 2016.[17] Notably, more than three times as many patent applications have been filed for *Humira* in the USPTO than in the European Patent Office, thereby in large part enabling biosimilar competition for *Humira* to enter Europe four years earlier than in the U.S. **The four additional years of market exclusivity for *Humira* in the U.S. compared to Europe is projected to needlessly cost American patients, payers, and taxpayers an excess of $14.4 billion.[18]**

  The *Humira* case is demonstrative of a broad anti-competitive trend by big pharma of building patent estates and thickets to extend periods of market exclusivity for brand drugs and raise prices. One recent study found, for example, that the one-year cost from delayed competition for five specific drugs with patent thickets (*Enbrel*, *Eylea*, *Humira*, *Imbruvica*, and *Opdivo*) ranges from $1.8 billion to $7.7.6 billion.[19] A separate study on 21 patent infringement lawsuits pursued by drug companies under the Biologics Price Competition and Innovation Act (BPCIA) on biologic drugs covering a total of 179 patents found that just six percent of patent filings were for active ingredients or new molecules; the vast majority were for secondary uses – and in many cases for much less critical changes to the biologic treatments or their manufacturing processes with little to no actual innovation leading to improved clinical value for patients.[20] Moreover, the majority of brand pharmaceutical companies' patent filings in the study came late in the terms of the brand biologics' exclusivity periods – on an average a decade after initial approval – suggesting that brand drug makers file patents late in product lifecycles to extend their market exclusivities and generate additional revenues from market monopolies.[21] Additionally, one-fifth of the patents examined in the study lacked equivalent patents in the European Union, Canada, or Japan, indicating that brand drug makers particularly game the U.S. patent system to prolong exclusivity and boost profits.[22] Additional research reached a similar conclusion: **of the roughly 100 best-selling drugs between 2005 and 2015, on average 78 percent of the drugs associated with new patents in Food and Drug Administration (FDA) records were not for new drugs**

[13] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2021 Financial Results." February 2, 2022.
[14] I-MAK. "Overpatented, Overpriced Special Edition: Humira." Revised September 2021.
[15] *Ibid*.
[16] *Ibid*.
[17] *Ibid*.
[18] *Ibid*.
[19] Brill A and Robinson C. "Patent Thickets and Lost Drug Savings." Matrix Advisors. January 2023.
[20] Van de Wiele V, Beall R, Kesselheim A, Sarpatwari A. "The characteristics of patents impacting availability of biosimilars." Nature Biotechnology. 40, 22-25(2022). January 18, 2022.
[21] *Ibid*.
[22] *Ibid*.

coming on the market, but rather for existing drugs – again suggesting that brand drug makers abuse the patent system to obtain additional patents that prolong market exclusivity and increase profitability.[23]

- ***Obviousness-Type Double Patenting:*** A primary way that big pharma constructs patent thickets and estates is through "obviousness-type double patenting." Under existing USPTO rules, a patent owner of a brand biologic therapy can obtain multiple duplicative (non-patently distinct) patents covering the same invention – known as "obviousness-type double patenting" – so long as the patent holder agrees to a "terminal disclaimer." With a "terminal disclaimer," the patent holder agrees that the new patent claims are obvious and not novel compared to the existing patent already owned by the brand patent holder. Despite the fact that the new patent claims are obvious and not innovative, the "terminal disclaimer" allows USPTO to still issue an additional duplicative patent to the patent holder of the brand biologic. This anti-competitive practice of "obviousness-type double patenting" essentially enables the brand patent holder to amass more and more patents for its brand product, creating an even "thicker" patent thicket for the brand. As the patent thicket for the brand grows, the brand company creates more and more barriers for potential biosimilar developers to enter the market and offer cost-saving therapies to patients. Notably, no countries other than the U.S. permit use of "terminal disclaimers" in their patent systems.

  Published research demonstrates that "obviousness-type double patenting" seems to lead to significant delays in biosimilar competition for high-priced biologics – and thus needlessly increases costs for consumers and taxpayers. Data show, for example, that the USPTO granted 73 patents for the "core" patent estate (excluding manufacturing patents) for the blockbuster biologic *Humira.*[24] The 73 *Humira* core patents cover only 14 actual novel and non-obvious inventions; the remaining 59 patents for *Humira* are obvious and duplicative and have been added to the *Humira* patent portfolio primarily through the granting of "terminal disclaimers."[25] In other words, **80 percent of the core *Humira* patents (59 of 73 total patents) in the U.S. are duplicative and not patently distinct from existing patents due to the patent owner's use of "terminal disclaimers" for purposes of "obviousness-type double patenting."** The use of "terminal disclaimers" has effectively enabled *Humira* to build an extensive patent thicket that has fended off competition for years beyond its initial period of market exclusivity. In sharp contrast, the use of "terminal disclaimers" is not permitted outside the U.S. and, to that end, only a total of eight *Humira* patents have been granted to the brand patent holder in Europe.[26] While the researchers state that the practice of "obvious-type double patenting" did not directly cause the delay in *Humira* biosimilar competition in the U.S., they importantly underscore that **biosimilar competition for *Humira* in Europe began in October 2018 whereas such competition will not occur in the U.S. until 2023.**[27] As noted previously, **the additional years of market**

[23] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 48.
[24] Goode R and Chao B. "Biological patent thickets and delayed access to biosimilars, an American problem." J Law Biosci. 2022. Sept 1;9(2):lsac022. Doi: 10.1093/jlb/lsac022. eCollection 2022 Jul-Dec.
[25] *Ibid*.
[26] *Ibid*.
[27] *Ibid*.

exclusivity for *Humira* are projected to egregiously cost American payers and taxpayers an excess of $14.4 billion.[28]

- ***Evergreening and Product Hopping:*** Through a separate set of abusive tactics known as "evergreening" and "product hopping," drug manufacturers lengthen monopolies and market exclusivity periods by seeking approval of "new" products that are essentially the same as original brand products but with patents covering relatively minor changes, such as extended-release formulations or combination therapies that combine two existing drugs into one pill. These reformulated and combination therapies can effectively delay meaningful generic competition and extend periods of relative brand market dominance that drive up drug costs for patients and taxpayers.

  One analysis determined, for example, that **consumers can lose up to $2 billion per year per each anti-competitive product reformulation.** [29] Similarly, a study in *JAMA Health Forum* concluded that: (1) of "206 brand-name drugs approved in tablet or capsule form by the U.S. Food and Drug Administration between 1995 and 2010, approval of new formulations was four times more likely among blockbluster drugs," defined as prescription drugs with annual sales of $1 billion or great; and (2) drug makers sought to pursue new formulations "less frequently once generic competitors entered the market.[30] The results led the authors to argue that "revenue is a substantial driver of whether and when a manufacturer secures FDA approval of the first new formulation of existing drugs, reinforcing concerns that manufacturers are using evergreening strategies to maintain revenue and avoid generic competition."[31]

Recognizing how brand drug companies use patent thickets and estates, obviousness-type double patenting, evergreening, and product hopping to extend market exclusivity for brand drugs, CSRxP again wishes to express our appreciation and support for actions from USPTO to combat anti-competitive intellectual property abuses by big pharma. In particular, we support the following USPTO efforts to strengthen the robustness and reliability of U.S. patents enumerated in the RFC, as well as offer additional recommended administrative actions to reform the patent system in a manner that both promotes competition and fosters innovation for patients.

USPTO Initiatives in the RFC to Strengthen U.S. Patents and Curb IP Abuse

CSRxP particularly supports the following policies described in the RFC that will improve the robustness and reliability of patents issued by the USPTO.

2a: Extend patent examination time. CSRxP supports giving patent examiners more time during the patent examination period to examine patents. With additional time, patent examiners will be able to better evaluate whether applicants are seeking patents that are novel and non-

[28] I-MAK. "Overpatented, Overpriced Special Edition: Humira." Revised September 2021.
[29] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009.
[30] Gupta R, Morten C, Zhu A et al. "Approvals and Timing of New Formulations of Novel Drugs Approved by the US Food and Drug Administration Between 1995 and 2010 and Followed Through 2021." *JAMA Health Forum*. May 20, 2022.
[31] *Ibid*.

obvious versus merely duplicative and obvious. Additional time may be particularly useful for cases with several continuations (large family cases) and cases with evidence submitted in support of patentability, as USPTO suggests in the RFC.[32]

2b: Provide enhanced training and resources for patent examiners. CSRxP supports the provision of additional training and resources for patent examiners. We applaud the new collaboration between the USPTO and FDA to improve the robustness and reliability of drug and biological patents and particularly urge USPTO examiners to work with FDA officials to better distinguish between patents for drugs and biologics that are unique, novel, and non-obvious versus those that are duplicative and obvious. Any administrative efforts that can improve understand to reduce the number of patents covered by a single drug or biologic will help to remove the anti-competitive patent thickets and estates that brand drug makers use to shield their products from competition.

2c: Improve communication between patent examiners and the PTAB. CSRxP supports initiatives to enable enhanced communication between patent examiners and the Patent Trial and Appeal Board (PTAB). With improved information sharing, patent examiners and members of the PTAB should be able to more efficiently and appropriately implement processes that lead to the issuance of patents that are truly innovative and non-obvious and limit brand manufacturers from using the PTAB to delay the introduction of generic and biosimilar competition into the marketplace.

2e: Apply enhanced scrutiny to continuation patents. CSRxP urges USPTO to implement procedures that apply greater scrutiny to continuation patents particularly in large patent families. Continuation patents in large families especially can enable brand patent holders to develop even more extensive patent thickets and estates for their brand products, enabling them to delay competition from lower cost biosimilar therapies.

2f: Prohibit obviousness-type double patenting. As detailed above, obviousness-type double patenting arises through use of "terminal disclaimers" in the patent issuance process. Under existing USPTO regulations, brand drug companies agree to "terminal disclaimers" in order to add duplicative and non-innovative patents to their patent estates, making those estates for brand products even more extensive and creating higher barriers for biosimilar developers to enter the market and compete. *Humira* stands out as a particularly egregious example of this practice, having only 14 actual novel and non-obvious patents in its "core" patent estate of 78 patents.[33] Given this abuse of the patent system and its adverse impact on consumers and taxpayers, CSRxP urges USPTO to update regulations to reform the "terminal disclaimer" process and prohibit obviousness-type double patenting. To do so, CSRxP urges USPTO to either: (1) eliminate terminal disclaimers all together as part of the patent issuance process; or (2) require that filing of a terminal disclaimer be a binding admission of obviousness-type patenting, effectively making patents tied through terminal disclaimers stand and fall together when their validity is challenged.

[32] 87 FR 60130

[33] Goode R and Chao B. "Biological patent thickets and delayed access to biosimilars, an American problem." J Law Biosci. 2022. Sept 1;9(2):lsac022. Doi: 10.1093/jlb/lsac022. eCollection 2022 Jul-Dec.

2h: Conduct a comparative analysis of patent examination and issuance. CSRxP strongly supports efforts by the USPTO to conduct a comparative analysis of the examination and issuance of pharmaceutical and biological patents in the U.S. patent system compared to the intellectual property systems of other countries. Lessons learned from other countries will help USPTO and other policymakers implement bipartisan solutions that combat abuses of the intellectual property system by big pharma, which drive up costs for consumers and taxpayers.

Additional Recommended Administrative Actions to Combat Patent Abuse

In addition to the policies enumerated in the RFC, CSRxP respectfully urges the USPTO to pursue the following additional actions to thwart anti-competitive practices undertaken by brand drug companies to extend their product monopolies and increase costs.

6. **Return to the "broadest reasonable interpretation" (BRI) standard within the USPTO PTAB *inter partes review* (IPR) process to foster increased generic and biosimilar competition in the drug market.** The American Invents Act of 2011 established the IPR process with the goals of improving patent quality and serving as a quicker and less expensive alternative to district court patent litigation. Patent owners, including the brand biopharmaceutical industry, criticized the IPR's use of the BRI, asserting that the process has a lower burden of proof and different standards for determining the meaning of a patent claim than district courts, which makes it easier to invalidate a patent. In the prior administration, the USPTO issued a final rule eliminating use of the BRI standard in IPR cases – rather than the "ordinary and customary meaning" approach used in federal district courts. CSRxP respectfully urges the USPTO to issue an updated rule that restores use of the BRI to the IPR process as an important means to promote greater generic and biosimilar competition.

7. **Expand access to the PTAB IPR process by extending the timeframe to file an IPR and lowering the cost of the process to filers in order to give generic and biosimilar manufacturers more opportunities to compete in the market.** Currently, the USPTO's IPR process permits up to nine months for a generic or biosimilar/interchangeable biologic manufacturer to determine the relevance of a patent. CSRxP suggests that the USPTO extend the timeframe to determine the relevance of a patent, which will give generic and biosimilar innovators more time to assess and potentially engage in the IPR process.

8. **Implement automatic review of secondary patents in order to limit inappropriate patent thickets and estates that inappropriately extend market exclusivity for brand products.** Rather than only securing a patent for a drug's active ingredient or a biologic's composition of complex molecules, brand biopharmaceutical manufacturers typically obtain secondary patents for manufacturing, methods of delivery (e.g. self-injectors, inhalers, etc.), or other aspects of a product to help improperly extend monopolies for brand products by adding to patent thickets or estates. CSRxP suggests that USPTO require patent examiners to automatically review all secondary patents when such patents are provided to the FDA. The FDA then should scrutinize "use codes" to determine if these applications are overly broad, inaccurate, or indicative of an attempt by a manufacturer to create barriers to competition for their product.

9. **Require drug manufacturers to demonstrate greater clinical benefit, or other higher standards, to receive new formulation patents to limit anti-competitive "evergreening" and "product hopping" practices.** Manufacturers obtain additional patents that cover new formulations of their existing brand products as means to effectively extend market exclusivity of their brands. CSRxP respectfully urges the USPTO to implement higher standards for new formulation patents or require demonstration of greater clinical benefit by the new formulation.

10. **Raise patent standards for additional uses of existing compounds.** Drug makers in certain cases have filed new patents for additional uses of existing compounds. CSRxP respectfully urges the USPTO to increase standards for patent approval for additional uses of existing compounds in order to avoid unfair extensions of market monopolies.

11. **Limit the number of continuing patent applications that can be filed for the same invention to restrict the ability of brand drug makers to prolong market exclusivity periods.** CSRxP suggests that the USPTO to place a limit on the number of continuing patent applications that can be filed for the same invention in order to prevent brand manufacturers from maintaining product monopolies in perpetuity.

12. **Collaborate with the FDA to apply increased scrutiny to listed patents for drugs in the "Orange Book."** Drug manufacturers list patents in FDA's "Orange Book" for small molecules within 30 days of product approval. While in many cases patents are appropriately listed, in other cases patents may be of either questionable validity or perfectly valid but applied inappropriately. According to researchers, "FDA does not scrutinize the company's representations…but merely records whatever the company submits in what is known as the 'Orange Book.' Thereafter, a competitor seeking approval of a generic drug must battle every patent listed in the Orange Book in relation to the drug. Thus, simply listing a patent in the Orange Book can operate to block or delay competition, even if the patent does not cover the drug."[34] Therefore, CSRxP suggests that the USPTO work with the FDA to apply increased scrutiny to listed patents to help limit the number of listed invalid patents or valid patents inappropriately applied.

13. **Collaborate with the FDA to impose heightened scrutiny to patent "use codes" in the "Orange Book."** The FDA requires manufacturers to submit a short statement describing the approved use(s) claimed by the patent, which the agency then lists in the "Orange Book" as a "use code." The FDA assumes the "use code" is an accurate description of the patent scope and does not further scrutinize the description.[35] Research has shown that manufacturers have submitted "use codes" that are overbroad or inaccurate in describing the actual content of the patent, potentially as a way to delay or block generic competition.[36] One analysis found that, of the roughly 100 best-selling drugs from 2005 to 2015, the number of "use codes" added to the "Orange Book" rose from 115 in 2005 to 364 in 2015 and the number of drugs that added a use

[34] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 11.
[35] *Ibid*., page 14.
[36] *Ibid*., page 14.

code more than doubled from 63 to 173.[37] As such, CSRxP suggests that the USPTO work with the FDA to apply heightened scrutiny to patent "use codes" to ensure the descriptions are accurate and within the patent scope so they cannot effective block or delay generic competition.

Conclusion

In conclusion, CSRxP again commends the USPTO for undertaking initiatives to improve the robustness and reliability of U.S. patents so that only those inventions that are truly novel and innovative obtain patents. By taking steps to limit the issuance of obvious and duplicative patents, the USPTO will help significantly to thwart the anti-competitive abuses of the intellectual property system by big pharma that delay competition and keep drug prices egregiously high. CSRxP looks forward to our continued work with the Administration to adopt and implement bipartisan, market-based solutions that will slow the unsustainable growth in prescription drug prices for U.S. consumers and taxpayers without imperiling the discovery of innovative breakthrough therapies that can improve the health and well-being of patients.

Sincerely,

Lauren Aronson
Executive Director
Campaign for Sustainable Rx Pricing

[37] *Ibid*., pages 39 – 40.