Testimony Submitted for the Record

U.S. Senate Committee on Judiciary, Subcommittee on Intellectual Property

Hearing: "The Patent Trial and Appeal Board: Examining Proposals to Address Predictability, Certainty, and Fairness"

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Chairman Leahy, Ranking Member Tillis, and members of the Senate Committee on the Judiciary Subcommittee on Intellectual Property, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record in support of improvements to the U.S. Patent and Trademark Office Patent Trial and Appeals Board (USPTO PTAB), which will thwart abuses of the patent system by brand drug makers that limit competition and inappropriately extend product monopolies. We commend your leadership and strongly support bipartisan efforts to implement changes that promote competition and prevent pharmaceutical companies from gaming the U.S. intellectual property system in order to keep drug prices needlessly high for U.S. patients and taxpayers.

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] Many big pharma companies implemented traditional start-of-year price hikes yet again in January 2022 even though approximately 18 million American adults could not afford to fill prescriptions for at least one prescribed medication in 2021.[2] [3]

And despite efforts from the pharmaceutical industry to suggest otherwise, drug manufacturers – and drug manufacturers alone – are the drivers of the high and unsustainable growth in prescription drug prices and spending that consumers, taxpayers, and businesses needlessly 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 not only places significant strain on federal health programs and taxpayers, but also on the many small businesses and large employers who seek to offer affordable health insurance coverage to their employees because as prescription drug expenditures increase, cost-sharing and premium costs rise.[4]

[1] AHIP. "Where Does Your Health Care Dollar Go?" 2021.
[2] Marsh, Tori. "Live Updates: January 2022 Drug Price Increases." GoodRx Health. January 6, 2022.
[3] Witters, Dan. "In U.S., an Estimated 18 Million Can't Pay for Needed Drugs." *Gallup*. September 21, 2021.
[4] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.

Importantly, recently published research strongly suggests that the brand biopharmaceutical industry's abuse of the patent system to undermine brand biologic and biosimilar competition particularly is 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.[5] 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.[6] Without action, the authors estimate patients needlessly will pay an extra $25 billion in excessive drug spending through 2029.[7]

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 spending in Medicare, hurting both Medicare beneficiaries and 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.[8] 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.[9] 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.[10]

To keep drug prices and spending excessively high, the pharmaceutical industry employs a variety of anti-competitive tactics to game the intellectual property system and prevent competition from lower cost generic and biosimilar therapies such as the development of patent "thickets" and "estates," "product hopping," and "evergreening."

- **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.[11] Two hundred forty-seven (247) patents have been filed on *Humira* in the U.S. with the goal of delaying competition by 39 years.[12] 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.[13] *Humira's* patent "estate" has had significant cost consequences for Medicare and

[5] Roy, Avik. "The Growing Power of Biotech Monopolies Threatens Affordable Care." Foundation for Research on Equal Opportunity. September 15, 2020.
[6] *Ibid*.
[7] *Ibid*.
[8] House Committee on Oversight and Reform Majority Staff Report. "Drug Pricing Investigation." December 2021.
[9] *Ibid*.
[10] *Ibid*.
[11] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2021 Financial Results." February 2, 2022.
[12] I-MAK. "Overpatented, Overpriced Special Edition: Humira." Revised September 2021.
[13] *Ibid*.

Medicaid, with spending on *Humira* in these programs increasing by 266 percent from 2012 to 2016. *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.[14] 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. Consequently, the four additional years of market exclusivity for *Humira* in the U.S. resulting from the biologic's extensive patent "estate" or "thicket" is projected to needlessly cost American payers and taxpayers an excess of $14.4 billion.[15]

The *Humira* case is demonstrative of a broader anti-competitive trend by big pharma of building patent "estates" and "thickets" to extend periods of market exclusivity for brand drugs and raise prices. For example, a recent 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.[16] 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 biopharmaceutical companies file patents late in product lifecycles to extend their market exclusivities and generate additional revenues from market monopolies.[17] Additionally, one-fifth of the patents examined in the study lacked equivalent patents in the European Union, Canada, or Japan, clearly demonstrating that brand drug makers particularly game the U.S. patent system to prolong exclusivity and boost profits.[18] A separate study 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 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.[19]

- **"Evergreening" and "Product Hopping":** Under a different set of abusive regulatory tactics, 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 – practices often referred to as "evergreening" or "product hopping." 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.

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[14] *Ibid*.
[15] *Ibid*.
[16] 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.
[17] *Ibid*.
[18] *Ibid*.
[19] Feldman, Robin et al. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 48.

One analysis determined, for example, that consumers can lose up to $2 billion per year per each anti-competitive product reformulation.[20] 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.[21] 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."[22]

Thus, put simply, the brand biopharmaceutical industry is engaging in a variety of anti-competitive practices that abuse the U.S. patent system to inappropriately prolong market monopolies for costly brand drugs. These practices needlessly raise drug costs for consumers and taxpayers and significantly contribute to the overall unsustainable growth in prescription drug prices and spending that exists today. **Given today's critical prescription drug pricing crisis and the significant contribution that intellectual property system abuse by big pharma plays in this crisis, CSRxP welcomes actions from the Subcommittee and the Congress to thwart anti-competitive abuses of the patent system by brand drug makers that restrict competition and keep prices high.**

To that end, CSRxP supports the bipartisan Stop Significant and Time-Wasting Abuse Limiting Legitimate Innovation of New Generics (STALLING) Act, which targets big pharma's abuse of the FDA citizen petition process to delay generic drug applications. CSRxP also supports the bipartisan Affordable Prescription Drugs for Patients Act of 2021, which curbs abusive "product hopping" and "patent thicketing" tactics by brand drug makers to game the patent system and unfairly extend product monopolies. Further, CSRxP urges the Congress to enact legislation that will:

1. **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. The Congress should require 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.

[20] Shadowen, Steve et. al. "Anticompetitive Product Changes in the Pharmaceutical Industry." Rutgers Law Journal, Vol. 41, No. 1-2, Fall/Winter 2009.
[21] 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.
[22] *Ibid*.

2. **Expand access to the USPTO 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. The Congress should direct the USPTO to 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.

3. **Require the USPTO 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. The Congress should direct the USPTO 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.

4. **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. The Congress should require the USPTO to implement higher standards for new formulation patents or require demonstration of greater clinical benefit by the new formulation.

5. **Raise patent standards for additional uses of existing compounds.** Drug makers in certain cases have filed new patents for additional uses of existing compounds. The Congress should direct USPTO to increase standards for patent approval for additional uses of existing compounds in order to avoid unfair extensions of market monopolies.

6. **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.** The Congress should direct 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.

7. **Require the FDA to apply increased scrutiny to listed patents.** 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."[23] Therefore, the Congress should direct the FDA to apply increased scrutiny to listed patents to help limit the number of listed invalid patents or valid patents inappropriately applied.

8. **Require the FDA to impose heightened scrutiny to patent "use codes.**" 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.[24] 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.[25] 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 code more than doubled from 63 to 173.[26] The Congress should direct 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 wishes to thank you for your leadership in aiming to make innovative treatments available to patients while at the same time protecting the U.S. patent and intellectual property system from abuse by brand drug makers. We look forward to our continued work with the Subcommittee and the Congress 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. Please find further information on the drug pricing problem and ways to rein in high drug prices at our website (www.csrxp.org).

[23] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 11.
[24] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017, page 14.
[25] *Ibid*., page 14.
[26] *Ibid*., pages 39 – 40.