PATIENTS FOR AFFORDABLE DRUGS NOW™

September 11, 2024

The Honorable Dick Durbin
Chairman
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Lindsey Graham
Ranking Member
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Durbin and Ranking Member Graham:

I am writing on behalf of Patients For Affordable Drugs Now to express our opposition to S. 2220, the PREVAIL Act, and S. 2140, the Patent Eligibility Restoration Act. These bills will make it harder for patients – including those like myself – to afford the medications we need by making it easier for drug companies to obtain undeserved patents and by taking away our rights to challenge patents that should never have been granted through Inter Partes Review (IPR.)

Americans already pay between three and eight times what people in other wealthy nations pay for the exact same brand-name drugs.[1] Meanwhile, about three in ten Americans report having difficulty affording their medications.[2] When their prescription drug prices are too high, Americans face challenges affording other expenses, such as food and housing. One survey found that over 20 percent of people took on debt or declared bankruptcy because of their medications.[3]

When a drug company makes a truly innovative discovery, it should be rewarded with a patent and receive a fair return for the risk and investment it undertook. However, drug corporations abuse the patent and exclusivity system to undermine free-market competition and prevent affordable generic and biosimilar drugs from coming to market. In fact, gaming of the patent system to extend monopolies beyond the time intended under law inhibits true innovation that patients need. Between 2005 and 2015, 74 percent of the new drug patents issued were for drugs already on the market.[4] A second study of the ten top-selling drugs in 2021 corroborated that number. Of the roughly 100 best-selling drugs in another study, nearly 80 percent obtained an additional patent to extend their monopoly period.[5] If big drug companies can block competition and raise prices on old

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[1] Mulcahy, A., Schwam, D., and Lovejoy, S. (2024, February). International Prescription Drug Price Comparisons: Estimates Using 2022 Data. *RAND Corporation.* https://www.rand.org/pubs/research_reports/RRA788-3.html

[2] Kirzinger, A., Montero, A., Sparks, G., Valdes, I., Hamel, L. (2023, August). Public Opinion on Prescription Drugs and Their Prices. *KFF.* https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

[3] Nguyen, A. (2021, March). Survey: Americans Struggle to Afford Medications as COVID-19 Hits Savings and Insurance Coverage. *GoodRx*. https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/

[4] Koons, C. (2017, November). Most New Drug Patents Are for Old Remedies, Research Shows. *Bloomberg.* https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows

[5] Feldman, R. (2018, December). May your drug price be evergreen. *Journal of Law and the Biosciences*. https://academic.oup.com/jlb/article/5/3/590/5232981?login=true

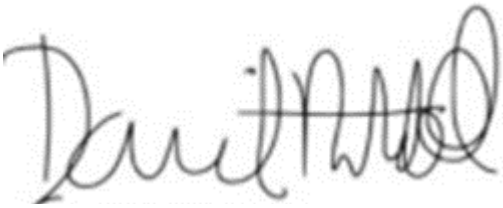
drugs at will, they have far less incentive to invest in research and development (R&D) to develop innovative new drugs that could save lives.

S. 2220, the PREVAIL Act, would undermine current mechanisms to reduce drug prices by limiting the ability of individuals and groups to request review of patents and would make it more difficult for judges to invalidate wrongly granted patents. Specifically, S. 2220 would exclude patients from IPR proceedings, which enable any member of the public to ask the Patent Trial and Appeal Board (PTAB) to review patents and cancel any that are erroneously issued. In doing so, IPR proceedings increase competition and research that was stalled by wrongly granted patents. Moreover, the IPR process is an important pathway for patients to challenge patents, as the only other pathway available is federal court from which they are excluded. Recent studies[6] have shown that IPR proceedings have successfully lowered prescription drug prices, such as one example where there was a 97% decrease in the price of treatment for cardiovascular disease (prasugrel) following IPR proceedings.

S. 2140, the Patent Eligibility Restoration Act, allows any invention or discovery to be patent-eligible with very few exceptions, further expanding the ability of drug corporations to game the patent system and keep prices high. S. 2140 would eliminate nearly all judicial exceptions to patent eligibility and make any invention that is claimed as "useful" or a "useful improvement" eligible, significantly lowering the bar for patent protection and disregarding other meaningful considerations, such as whether an element of the invention was already invented or how it was made. S. 2140 would allow patents for non-innovative drugs that have been merely tweaked to ensure the price would increase.

We urge you to vote against S. 2220 and S. 2140, as both would undermine free-market competition, encourage extended monopoly pricing, and make it harder for patients to afford the drugs they need. We look forward to working with you to make drugs more affordable for everyone. These bills take us in the exact opposite direction.

Sincerely,



David Mitchell
President and Co-Founder
Patients for Affordable Drugs NOW

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[6] Charles Duan, *On the Appeal of Drug Patent Challenges*, 2 Am. U. L. Rev. 1177, 1203–04 (2023), available at: http://dx.doi.org/10.2139/ssrn.4406404.
Van de Wiele, V.L., Kesselheim, A.S. & Tu, S.S. Biologic patent challenges under the America Invents Act. *Nat Biotechnol* 42, 374–377 (2024), https://doi.org/10.1038/s41587-024-02156-9.