



Andrei Iancu, Co-Chair
David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
Frank Cullen, Executive Director

May 20, 2024

The Honorable Dick Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Graham:

On behalf of the Council for Innovation Promotion (C4IP), we write in advance of your Tuesday, May 21, 2024, hearing on drug prices to dispel common myths about pharmaceutical patents that remain pervasive on Capitol Hill.

C4IP is a bipartisan organization chaired by two former directors of the U.S. Patent and Trademark Office, who respectively served under Presidents Obama and Trump. We aim to foster strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.¹

We recognize the need for Congress to implement reforms that expand access to life-saving medicines. Unfortunately, some Members of Congress mistakenly believe they can lower drug prices by undermining the patent protections responsible for creating those medicines in the first place. These lawmakers are often misled by activists who accuse biotech companies of abusing intellectual property law through practices like "patent thicketing" and "evergreening."

Proponents of the "patent thicket" myth contend that biopharma companies file superfluous patents on the same drug to construct an impenetrable legal barrier that prevents generic drug manufacturers from introducing cheaper competitors.

The practice of securing numerous patents on a single drug may sound scandalous,

¹ Council for Innovation Promotion, *About C4IP*, <https://c4ip.org/about/>.

but it is not. Many highly complex inventions, from cell phones to medicines, combine multiple different technologies, discoveries, and insights into a single product. The original iPhone, for instance, had roughly 200 patents protecting all its different components and capabilities.²

Similarly, it is common for a single medicine to be protected by basic composition of matter patents, method of manufacture patents, method of formulation patents, and so on. Each of these represent individual, yet related, insights and discoveries.

Activists also accuse drug companies of "evergreening," the practice of supposedly filing new patents on existing drugs or trivial variations of them to extend the life of the original patent.

These accusations are false, and fundamentally misrepresent how the patent system works. The USPTO only grants patents to inventions that are novel, useful, and non-obvious. "New" patents covering old inventions are rejected, as are such patents covering trivial variations.

Definitionally, any newly granted patents are for genuine improvements to existing therapies.³ An updated drug incorporating inventions that allow for greater dosing flexibility or include a time-release function that reduces the risk of an adverse reaction *should* be patentable, and Congress absolutely should ensure companies investing in creating such innovations are encouraged and rewarded with strong patent protection.

And new patents for improved versions of medicines have *no effect whatsoever* on the expiration date of the original patents. Generic competitors are entirely free to produce the original medicine once the original patents expire, the existence of an updated version of such medicine notwithstanding.

Contrary to what activists claim, the current patent system is not unduly deterring generic competition. In fact, the United States has the highest generic penetration rate in the developed world. Nine in 10 U.S. prescriptions are filled with generics.⁴

² *Apple's iPhone Well Protected by Patents*, MacDailyNews (May 25, 2007), <https://macdailynews.com/2007/05/25/apples-iphone-well-protected-by-patents/comment-page-3/>.

³ 35 U.S.C. §§ 102, 203; see also *Patents: Make Sure Your Idea Is Useful, Novel, and Non-Obvious*, FindLaw (Aug. 9, 2023), <https://www.findlaw.com/smallbusiness/intellectual-property/idea-must-be-useful-novel-or-non-obvious.html>.

⁴ FDA, *Generic Drugs*, <https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs#:~:text=In%20the%20United%20States%2C%209,to%20healthcare%20for%20more%20patients> (last visited May 20, 2024).

"Evergreening" and "patent thicketing" aren't keeping cheaper generics out of patients' hands.

But this evidence hasn't dissuaded some lawmakers from advocating for policies that would undermine IP protections on life-saving medicines -- and violate federal law.

At the urging of several Members of Congress, the Biden administration could soon try misusing the Bayh-Dole Act of 1980 to "march in," confiscate patents and licenses, and forcibly relicense patents on drugs developed by private companies based on upstream scientific research conducted with even minuscule amounts of federal funding. This plan would do nothing to lower drug prices -- in fact, only around 1% of drugs would be legally eligible for march-in at all.⁵

Others have urged the administration to misuse a statute called Section 1498, which allows the federal government to make and use a product protected by patents without a license from the owner, provided that the product is utilized *by or for the United States itself*.⁶ For decades, legal scholars have almost uniformly agreed that Section 1498 authorizes the government to infringe only on patented technology it uses directly, such as for military purposes.⁷ Under no honest reading could one conclude it applies to sales to consumers in private markets of drugs covered by active patents.

Rather than making drugs more accessible, these proposals would rob patients of future treatments by kneecapping research and development. It costs an average of \$2.6 billion to bring a single new drug to market.⁸ Shorn of patent protections, biotech companies and investors will have no ability to protect their inventions from copycats or recoup their enormous upfront expenses. Many will pull out of pharmaceutical development altogether.

⁵ *March-in Rights Under the Bayh-Dole Act & NIH Contributions to Pharmaceutical Patents*, Vital Transformation, <https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/> (last visited May 20, 2024).

⁶ Amy Kapczynski, Professor of Law, Yale School of Law, *et al.*, Letter to Sen. Warren 1 (Apr. 20, 2022), <https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf>.

⁷ Jonathan M. Barnett, Professor, Gould School of Law, University of Southern California, *et al.*, Letter to Chairman Sanders and Ranking Member Cassidy, Senate Committee on Health, Education, Labor and Pensions; Chairman Smith and Ranking Member Neal, House Committee on Ways and Means 10 (Sept. 28, 2023), <https://s3.amazonaws.com/media.hudson.org/Letter+to+Congress+-+Bayh-Dole+and+1498+Not+Basis+for+Price+Controls+on+Drugs.pdf>.

⁸ *What's the Average Time to Bring a Drug to Market in 2022?* N-Side, <https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022#:~:text=How%20much%20does%20it%20cost,high%20as%20%242.6%20billion%20USD> (last visited May 20, 2024).

There are other, more constructive ways to help those consumers who struggle to pay the cost of their drugs, like insurance reforms. As you consider potential drug pricing legislation, we urge you to defend the patent protections that make groundbreaking medical innovation possible.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Cullen', is positioned below the word 'Sincerely,'.

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

Sen. Alex Padilla, Member, Senate Committee on the Judiciary
Sen. Amy Klobuchar, Member, Senate Committee on the Judiciary
Sen. Chris Coons, Member, Senate Committee on the Judiciary
Sen. Chuck Grassley, Member, Senate Committee on the Judiciary
Sen. Cory Booker, Member, Senate Committee on the Judiciary
Sen. John Cornyn, Member, Senate Committee on the Judiciary
Sen. John Kennedy, Member, Senate Committee on the Judiciary
Sen. Jon Ossoff, Member, Senate Committee on the Judiciary
Sen. Josh Hawley, Member, Senate Committee on the Judiciary
Sen. Laphonza Butler, Member, Senate Committee on the Judiciary
Sen. Marsha Blackburn, Member, Senate Committee on the Judiciary
Sen. Mazie Hirono, Member, Senate Committee on the Judiciary
Sen. Mike Lee, Member, Senate Committee on the Judiciary
Sen. Peter Welch, Member, Senate Committee on the Judiciary
Sen. Richard Blumenthal, Member, Senate Committee on the Judiciary
Sen. Sheldon Whitehouse, Member, Senate Committee on the Judiciary
Sen. Ted Cruz, Member, Senate Committee on the Judiciary
Sen. Thom Tillis, Member, Senate Committee on the Judiciary
Sen. Tom Cotton, Member, Senate Committee on the Judiciary