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:

In advance of the Senate Judiciary Committee's May 21 hearing - *Ensuring Affordable & Accessible Medications: Examining Competition in the Presciption Drug Market*, I write to offer some insights on behalf of the Alliance of U.S. Startups and Inventors for Jobs (USIJ), a group of inventors, startup companies, venture capitalists, incubators, and research institutions representing diverse industries from software to biotech.[1]

Our members depend on a reliable patent system to attract investment necessary to bring new and disruptive products to the market. In the case of startups in the life sciences sector this often means hundreds of millions of dollars of venture investment before a product is even commercially viable. This entire process can also often take up to a decade and the likelihood of failure is much greater than success. But American inventors, entrepreneurs and investors still take these risks to a greater extent than in any other country, and from 2016-2020, nearly two thirds of new drugs originated at small companies.[2] This is due to a number of factors, but a predictable and secure patent system is chief among them.

We realize there is tension between the unique protections afforded by the U.S. patent system and the desire to increase patient access to life-saving drugs. The relationship between the patent system and the unprecedented advancement of life saving medicine in the U.S. deserves your careful consideration, but we believe there are a number of myths driven more by misleading

[1] https://www.usij.org/about

[2] https://www.pharmavoice.com/news/2020-01-pharma-innovation/612330/

efforts to weaken the patent system than by an objective assessment of market realities and sound policy.

One such myth is that of "evergreening," the alleged practice of delaying patent expiration by securing additional, minor patents on a particular drug. However, experts in the field of drug development tell a much different story regarding the constant and very beneficial incremental innovations that require significant research, safety evaluation, time and resources. The motivation of researchers and those involved in product development is to constantly improve the health impact and quality of life for patients. If we limit patent protections to only radical new discoveries, we will stifle the countless new ways in which existing (formerly radical) science can be deployed to make improvements that may seem less dramatic but will have profound impacts. It is also often true that incremental improvements within therapeutic drugs can reduce the long-term cost of treatment, particularly if these improvements result in lower rates of adverse effects, improved efficacy, and more sustainable and predictable dosage options for patients.

Vilifying an entire category of patents and health care advancement as “evergreening” will ultimately dissuade investment and development that stands to benefit patients.

Another related concern revolves around "patent thickets," or inter-related patents that some claim serve only to extend patent protection on a drug and prevent generic competition. It is important to note in the first instance that every U.S. patent that is granted must show that the underlying invention is novel and non-obvious. And while many classes of drugs and biologics do have a number of valid patents associated with them, it is also true that the number of patents correlated to a specific product is, by no means, unique to life sciences. The construction of patent families in complex areas like life sciences and consumer electronics does not automatically reflect a desire to hinder competition as stated by some, but it is often the result of significant R&D investments, hundreds of clinical trials, and thousands of hours of research made over years, if not decades. It is also uniquely true in disciplines such as biologics that genetically engineered proteins are extremely difficult to formulate and manufacture. These processes improve over time and result in patentable breakthroughs that often also lead to the ability to treat additional diseases.

Because of these widespread misperceptions, many activists and some policymakers believe that weakening patent protections would make drugs more accessible to patients. This could not be further from the truth. Without strong patents, innovative startups and small companies would have difficulty obtaining funding and have little ability to pursue expensive and risky new projects -- such as developing novel medicines.

In addition to perpetuating harmful myths, some have also proposed misusing two long-standing and well-understood statutes to weaken patent protection in the name of lowering drug prices.

A proposal from the Biden administration would misuse the Bayh-Dole Act's "march-in" rights to relicense the patents on drugs developed with the help of federal funding purely based on market price. This is not only completely at odds with the statutory language and intent of the Bayh-Dole Act, it would also be highly ineffective -- just 1% of new drugs approved from 2011-

2020 would be plausibly subject to march-in petitions. This proposal would, however, apply to all federally supported research, as well as programs such as Small Business Innovation Research (SBIR) and would chill investment in many industries, not just biotech.[3]

In the wake of the proposal, USIJ surveyed a large venture capital firm and found that nearly 40% of its health care investments, worth nearly $2 billion in total, rely on patent licenses facilitated by the Bayh-Dole Act.[4] Those startups could see their funding sources dry up if this law is rewritten.

Some have also urged the misuse of Section 1498 of Title 28 of the U.S. Code, a wartime statute allowing the U.S. government to appropriate patents for its own direct use, as another means to control drug prices. This interpretation contradicts the conclusions of numerous legal scholars and would likewise damage the patent protections that small innovators rely on.[5] [6]

Patients need innovative new drugs. And the development of those new drugs depends heavily on secure intellectual property protections. During your deliberations, we urge you to keep in mind the critical importance of these protections.

Best regards,

Chris Israel
Executive Director
Alliance of U.S. Startups and Inventors for Jobs

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[3] https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/

[4] https://static1.squarespace.com/static/5746149f86db43995675b6bb/t/65c291d0e5eee76544e7ef38/1707250128589/USIJ+Response+to+NIST+Bayh+Dole+Guidance+RFI+.pdf

[5] https://s3.amazonaws.com/media.hudson.org/Letter+to+Congress+-+Bayh-Dole+and+1498+Not+Basis+for+Price+Controls+on+Drugs.pdf

[6] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4348499