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# United States Senate

WASHINGTON, DC 20510

COMMITTEES
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**VIA ELECTRONIC TRANSMISSION**

January 31, 2022

Mr. Tahir Amin
Co-Founder and Co-Executive Director
Initiative for Medicines, Access & Knowledge (I-MAK)
601 W 26th St
New York, NY

Dear Mr. Amin:

I write you today in my capacity as Ranking Member of the Senate Judiciary Committee Subcommittee on Intellectual Property. As the Ranking Member—and as a Senator from a State with leading biotechnology and pharmaceutical companies—I am keenly aware of the role that strong and effective intellectual property rights play in enabling the development of lifesaving, innovative biopharmaceuticals and other medical treatments.

Specifically, I write regarding your organization's data about the number of patents on pharmaceutical products and the years of exclusivity drugs receive from patents.[1] While I share your goal of lowering drug prices for all Americans, I also believe it is imperative that any proposed solutions are fact-driven, objective, and take into account the many facets of this highly complex issue. Any solutions to this difficult and important issue must ensure that we do not undermine the robust intellectual property protections needed to enable the development of new medicines in the first place.

In order to ensure an objective, measured, and appropriate approach to this issue, it is fundamental that assumptions and premises be based on accurate facts and data from reliable, unbiased sources. Sadly, it has recently come to my attention that several of your studies driving the narrative that patents are to blame for high drug prices do not appear to meet these fundamental criteria. Your organization's research concludes that all of the top-selling drugs are protected by dozens or hundreds of patents that supposedly have the effect of blocking generic competition for an average of 30 to 48 years each.[2]

But according to at least one new analysis that looks more closely at your figures,[3] you do not transparently disclose or explain your underlying data, and the data differs by orders of magnitude from public sources like the US Orange Book and court filings. Although the report's

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[1] For example, I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices* (2018) ("Overpriced Report"); https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/; America's Bestselling Drugs of 2019, https://www.i-mak.org/2019-bestselling/

[2] *See* Overpriced Report, pg. 7.

[3] Mossoff, Adam, *Unreliable Data Have Infected the Policy Debates Over Drug Patents,* Hudson Institute.

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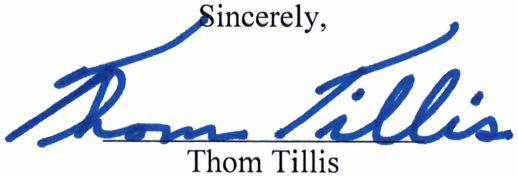
fine print acknowledges that these extreme ranges are hypothetical because they rely on patent applications, there appears to be no attempt to provide numbers based on issued patents that actually would extend exclusivity.[4] It also appears that many of the drugs alleged to be protected by "patent thickets" blocking competition for decades to come have already gone generic, in some cases before the reports making these allegations were even published.

Both drug pricing, and matters of patent law and policy that impact the development of innovative medicines, are too important to this country to rely on sources whose accuracy and reliability are in question. For this reason, I would like to better understand your methodology and how it leads to such substantially different numbers compared with other public sources. I would also like to understand the importance of the future years of calculated exclusivity arising from patents when generic versions of some of these products are already available to patients or when existing patents are unlikely to block or delay generic market entry.

Accordingly, I respectfully ask that you provide my office with a detailed explanation of your methodology for calculating the number of patents on a drug product that could be replicable by other researchers. I also ask that you explain why the numbers differ so dramatically from public sources, and what the significance is of your numbers on years of exclusivity if there are generic products already on the market or anticipated to be on the market.

Thank you for your prompt attention to this matter. I look forward to working with you on this very important matter and to gathering the data needed to make sound public policy decisions that support innovation and access. If you have any questions, please do not hesitate to contact me.

Sincerely,



Thom Tillis
Ranking Member
Subcommittee on Intellectual Property

[4] Overpriced Report, pg. 13.