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VIA ELECTRONIC TRANSMISSION

January 31, 2022

Dr. Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Mr. Drew Hirshfeld
Commissioner for Patents
Performing the functions and duties of the
Undersecretary for Intellectual Property and Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, Virginia 22314

Dear Dr. Woodcock and Mr. Hirshfeld:

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

Unfortunately, I am also aware of the false narrative being advanced by some that patents are being systemically used in ways not contemplated by our patent laws to delay generic drug competition. While I share the important 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 the main sources driving the narrative that patents are to blame for high drug prices do not appear to meet these fundamental criteria. Specifically, I am referring to research from the Initiative for Medicines,

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Access & Knowledge (I-MAK) and a separate project from the University of California (UC) Hastings Law School project called the "Evergreen Drug Patent Search."[1]

I-MAK appears to be a primary source of data regarding the role of patents in drug pricing that is cited during these debates. I-MAK 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 50 years each.[2] But according to at least one new analysis that looks more closely at I-MAK's figures, the organization does not transparently disclose or explain its underlying data, and the data differs by orders of magnitude from public sources like the US Orange Book and court filings.[3] 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.

The "Evergreen Drug Patent Search" database similarly suggests that nearly every FDA-approved drug has amassed unduly large numbers of "protections" that "artificially extend" exclusivity far into the future. As with the I-MAK reports, however, a subsequent analysis of this source has raised concerns about inaccuracy in the underlying data, inadequate transparency, and flawed methodology, and warns that the database risks causing policymakers to be "misled by the statistics."[4] As one illustration, the database apparently contains multiple entries for aspirin and suggests that it is still enjoying exclusivity under an "evergreening" strategy, even though aspirin has been available in generic form for over 100 years.

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 request that your agencies conduct an independent assessment and analysis of the sources and data that are being relied upon by those advocating for patent-based solutions to drug pricing. It is my hope and belief that a clearer and more accurate picture of the underlying facts will help to reveal whether, and to what extent, patent-related issues are really contributing to high drug prices, and help to focus future policymaking in the right areas.

It is my hope that such an independent assessment and study will be completed by no later than December 31, 2022. Having this valuable information before we begin a new Congress will ensure that lawmakers are armed with all the key facts and data needed to make sound public policy decisions regarding drug pricing. Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact me.

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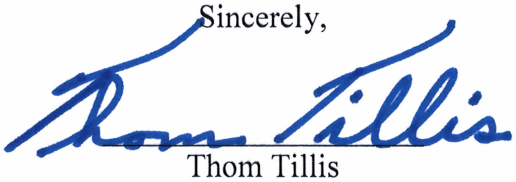
[1] *See* https://sites.uchastings.edu/evergreensearch/about/#.YfbYL-rMKkw

[2] *See, e.g.,* I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices* (2018); https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/ .

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

[4] George Mason University Center for Intellectual Property x Innovation Policy, UC Hastings' Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called "Evergreening."

Sincerely,



Thom Tillis
Ranking Member
Subcommittee on Intellectual Property