



Senator Thom Tillis  
North Carolina  
113 Dirksen Senate Office Building  
Washington, DC 20510

**Via Electronic Transmission**

9 March, 2022

Dear Senator Tillis,

Thank you for your letter of 31 January, 2022.

I welcome the opportunity to discuss the impact patent thickets have on drug prices and the data my organisation (I-MAK) has published on the top selling pharmaceutical products in the United States (U.S.).

I-MAK stands by the underlying data, facts and findings we published to educate the public about how pharmaceutical companies are gaming the patent system at the expense of patients. The system has deliberately been kept opaque by the pharmaceutical industry and its well-funded supporters over the years.

**Background to I-MAK**

I-MAK's team comprises former private sector practising intellectual property and health attorneys, market analysts and scientists that have worked in the branded and generic/biosimilar pharmaceutical industry. We are committed to evidence-based – not industry-based – policymaking that will benefit American families and help lower drug prices. It is why we have never taken funding from the pharmaceutical industry, whether branded, generic, or biosimilar.

Since its inception in 2006, I-MAK has advised and worked with leading international organisations such as the World Health Organization, Unitaid, GAVI, Clinton Health Access Initiative, the European Patent Office, and World Intellectual Property Organization on databases, informatics and methodologies for patent landscaping to help bring more transparency and evidence-based policy around pharmaceutical patents in order to improve competition and more affordable access to medicines for patients.<sup>1</sup> Our patent research and data has appeared in peer

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<sup>1</sup> Tahir Amin, *How to Conduct Patent Searches for Medicines: A Step-by-Step Guide*, World Health Organization Regional Office for South East Asia, 2010 available at <https://apps.who.int/iris/handle/10665/205312>

reviewed journals and cited on several occasions.<sup>2 3</sup> We are regularly asked by leading peer review journals, consulted by academics and the private sector to review their methodologies and analysis of patent data.

In response to the specific concerns raised in your letter about the reliability of our data around the numbers of patents and period of protection for the top-selling drugs, we would like to respond as follows.

### **Evidence from industry's own documents shows how they develop patent strategies to delay competition**

I-MAK is not alone in identifying how pharmaceutical companies are systematically using the patent system to file dozens or hundreds of patents to stall competition and keep drug prices high. Internal strategy documents and correspondence from pharmaceutical companies obtained by the House Committee on Oversight and Reform provide first-hand evidence of how companies stockpile patents in an attempt to stall competition and maintain high drug prices.<sup>4</sup> We have simply helped to illuminate that this practice is not one bad actor or a few, but an endemic problem across the industry. This is especially the case where it concerns the best-selling drugs.

For example, Celgene obtained or applied for 29 patents covering different chemical structures and uses of the active ingredient used in its product Revlimid. These patents alone have helped to extend Celgene's patent protection on Revlimid until 2028, nine years beyond its main patent that expired in 2019.<sup>5</sup> Many of these patents and patents covering other subject matter that add to these 29 patents and extend the protection period further are not listed on the US FDA Orange Book. As it stands, multiple generic competitors will not enter the U.S market until 2026 due to settlements made by companies as a result of Celgene's patent thicket strategy. Had multiple generics entered in 2020, it could have saved an estimated \$46 billion dollars.<sup>6</sup>

Similarly, strategy documents obtained by the House Committee on Oversight and Reform show how AbbVie has built its patent thicket to thwart competition in the U.S. against its best-selling biologic drug Humira.<sup>7</sup> As a result of over 100 granted patents, AbbVie has managed to delay

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<sup>2</sup> Tahir Amin and Aaron S Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, Health Affairs, Vol 31, No. 19, October 2012 available at <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2012.0107>

<sup>3</sup> S. Chandrasekharan, T. Amin et al., *Intellectual Property Rights and Challenges for Development of Affordable Human Papillomavirus, Rotavirus and Pneumococcal Vaccines: Patent Landscaping and Perspectives of Developing Country Vaccine Manufacturers*, Vaccine, 17;33 (46):6366-70, November 2015 available at <https://pubmed.ncbi.nlm.nih.gov/26368398/>

<sup>4</sup> Majority Staff Report, *Drug Pricing Investigation*, Committee on Oversight and Reform, U.S House of Representatives, December 2021 (Majority Staff Report) available at <https://oversight.house.gov/news/press-releases/chairwoman-maloney-releases-comprehensive-staff-report-culminating-the-committee>

<sup>5</sup> See Majority Staff Report pg.85

<sup>6</sup> I-MAK Blueprint for Reform, *Strengthening a Competitive Market for Prescription Drugs Through Patent and Drug Regulatory Reform*, February 2022 (Strengthening Competition for Prescription Drugs) available at <https://www.i-mak.org/strengthening-competition-blueprint/>

<sup>7</sup> See Majority Staff Report, pg 83 and Committee on Oversight and Reform Investigation into McKinsey & Company's Consulting Practices, Conflicts of Interest - AbbVie documents available at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/AbbVie.pdf>

competition in the U.S. through settlement agreements until 2023. Meanwhile, biosimilar versions of Humira became available to Europeans in 2018, with prices dropping by 70% within 6 months. The U.S. will spend an estimated \$77 billion on branded Humira from October 2018 until 2023 when biosimilars are supposed to enter. Moreover, the several companies that have settled will be paying royalties to AbbVie because of the large volume of patents it holds and which were too costly to litigate through.<sup>8</sup> Americans will bear the costs of such delay and the royalties that biosimilar competitors will have to pay to AbbVie because of its patent thicket strategy.

### **Public sources like the FDA Orange Book or court filings do not show all patents a company may have on a drug**

The contention that I-MAK's patent data differs by orders of magnitude from public sources like the U.S. FDA and court filings and is, therefore, unreliable is an inaccurate narrative. It is inaccurate, because it fails to take into account the hidden real-world workings of the industry when it comes to patents. It is widely known in the field of pharmaceutical patents that publicly available databases like the U.S. FDA Orange Book or patents asserted in court filings do not disclose the real universe of patent applications and granted patents that pharmaceutical companies stockpile to deter or delay competition.

Competitors have to conduct extensive and costly patent landscaping exercises that are not just confined to the U.S. FDA Orange Book, or the very limited data available on the Purple Book for biologic drugs, prior to making a decision to enter the market. These unseen transaction costs related to patent searching and "freedom-to-operate" exercises even before entering litigation are significant for many reasons. For example, while developing a generic or biosimilar version, a competitor will be attempting to find an alternative way to make a product that avoids infringing the mass thicket of patents a company may hold. That thicket pre-emptively fences off many of the possible routes available to a generic and biosimilar competitor. Even if the patent holder may never eventually list all those patents on the U.S. FDA Orange Book or assert them in litigation, they essentially serve as landmines that competitors have to avoid. Indeed, these patent thickets could potentially deter some generics or biosimilar companies from ever entering the market.

This problem is even more pronounced when it comes to competition in biologic drugs (eight of the drugs in our report). Unlike small molecule generic drugs, biosimilar drugs are not identical copies of the branded version. As a result, patent holders can deploy a variety of patents they hold against different competitors depending on the biosimilar version that is coming to market.<sup>9</sup> Indeed, the number of patents a company may initially assert during the "patent dance" phase of litigation is not known because these proceedings are not transparent. Therefore, it is not an accurate methodology to simply rely on comparing patent numbers to only those listed on public databases and asserted in court filings. Current policy has failed to address this gaping hole in

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<sup>8</sup> See

<https://news.abbvie.com/news/abbvie-announces-humira-adalimumab-global-patent-license-with-momenta.htm>

<sup>9</sup> Stacie Ropka et al, *Opinion: Purple Book Listings Are Only A First Step*, AJMC, The Center for Biosimilars, 8 May 2021 available at <https://www.centerforbiosimilars.com/view/opinion-purple-book-patent-listings-are-only-a-first-step>

transparency from the pharmaceutical industry, so it has been left to researchers and public interest groups like ours concerned about drug prices to shed light on pharmaceutical patenting practises.

It is also commonly known in the field that the U.S. FDA Orange book does not require branded drugmakers to list all of their patents in relation to a product.<sup>10</sup> For example, patents covering the process or intermediate compound for making a drug are not required to be listed. Patents covering the substance resulting from the product of metabolism (metabolites) are also not required to be listed. These types of patents, while not appearing on the U.S. FDA Orange Book can still be asserted in litigation or present hurdles for competitors.<sup>11</sup> Branded companies are also known to assert other types of patents they have in their thicket that are not listed on the U.S. FDA Orange Book, but which a competitor may be accused of infringing. For example, Celgene sued Sun Pharma for infringing three additional patents it holds covering different chemical structures (polymorphs) that are not listed in the U.S. FDA Orange Book for its product Revlimid.<sup>12</sup>

### **I-MAK's Methodology and defining true competition**

As you have noted, in the methodology section of I-MAK's report, we explain how we have calculated the periods of patent protection on the products studied and their impact on generic and biosimilar competition.<sup>13</sup> It is important to note here that throughout the report we clearly state that the number of years of patent protection for each drug studied is the drugmakers' *attempt* or *potential* to extend its monopoly period that could block competition. We included granted patents and patent applications in this calculation.<sup>14</sup> Patent applications can also serve as deterrents or barriers that generic and biosimilar companies have to navigate and watch out for. Accordingly, we believe this is a reasonable basis for evaluating the potential period of patent protection on a drug. Nevertheless, even including patent applications in our dataset, we found that for most of the drugs studied it was granted patents that represent the actual number of years of attempted protection.

Regarding the methods we used to identify all the patents in our study, the steps are clearly explained in the Methodology section of our report.<sup>15</sup> We believe those familiar with patent searching techniques would be able to replicate these steps and arrive at the same or very similar

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<sup>10</sup> Federal Food, Drug and Cosmetic Act 21 USC §355 (b)(1)

<sup>11</sup> Gilead Sciences Inc has asserted U.S Patent No. 7,429,572 (relating to a metabolite) which is not listed on the US FDA Orange Book for its product Sovaldi in litigation against generic competitor Teva Pharmaceuticals, see <https://www.jdsupra.com/legalnews/anda-litigation-settlements-76667/>. See also Aaron Barkoff, *Editorial: The Orange Book Should Include Process Patents or Be Eliminated*, Patently-O, May 4, 2006 available at [https://patentlyo.com/patent/2006/05/editorial\\_the\\_o.html](https://patentlyo.com/patent/2006/05/editorial_the_o.html)

<sup>12</sup> See *Celgene Corporation v Sun Pharma Global FZE et al.* Civil Action No. 19-10099

<sup>13</sup> I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*, 2018 (Overpatented, Overpriced), pg 13 available at <https://www.i-mak.org/overpatented/>.

<sup>14</sup> See *Overpatented, Overpriced*, pg. 7

<sup>15</sup> See *Overpatented, Overpriced*, pg. 13

dataset to what we found.<sup>16</sup> As patent searching is an iterative process, the final results of a patent landscape may have a small degree of variance depending on the search terms used and how the claims of the patents identified are analysed. It is why most professional patent search services will always offer a disclaimer for their findings acknowledging that they may not have identified all relevant patents on a product. Indeed, it is very possible that there are actually *more* patents related to the products in our report than we have identified.

With respect to your point about ‘many’ of the drugs having generic or biosimilar competition before our report was published, this is also not accurate for a few reasons. At the time of writing in 2018, 11 out of the 12 drugs studied did not have any generic or biosimilar competition in the United States. Even the drug that did have competition (Remicade) at the time of writing was limited to only one competitor.

The facts as they stand today are as follows:

- Six of the 12 drugs studied still do not have competition on the market (Enbrel, Humira, Revlimid, Eliquis, Xarelto and Eylea) as a result of patent settlements and litigation, costing Americans billions of dollars and causing immeasurable hardship.
- Out of the six drugs that now do have competing products on the market, four do not have multiple competitors (Avastin, Lantus, Remicade, Rituxan). It is well accepted that for there to be true competition in the market that will achieve the greatest reduction in prices (between 79-95%), there needs to be between 4-6 competitors.<sup>17</sup>
- Only Herceptin and Lyrica now have more than 4 generic or biosimilar competitors on the market. However, in the case of Lyrica, Pfizer used the tried and tested strategy of switching patients to a different formulation of the drug that is still under patent protection in order to maintain its market share as generic competition entered.<sup>18</sup>

The evidence and facts are clear that patents are being used by pharmaceutical companies to delay or block generic and biosimilar products from reaching Americans in a timely fashion.

### **It is long past time to address the drug patent problem to lower drug costs**

As I have mentioned at the outset of this letter, I-MAK stands by its findings and that relying on public sources and court filings is not an accurate methodology for identifying *all* patents on a drug. These public sources only tell a fraction of the real story. The essential question our analysis raises and which we would welcome your response on is: why do pharmaceutical companies

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<sup>16</sup> Thomas E. Wolff, *Freedom-to Operate: My Six Basic Rules*, Searcher, May 2008 available at [https://www.wolffinfo.com/docs/FTO\\_Patent\\_Searching\\_Wolff\\_in\\_Searcher\\_Magazine.pdf](https://www.wolffinfo.com/docs/FTO_Patent_Searching_Wolff_in_Searcher_Magazine.pdf)

<sup>17</sup> Aislinn Antrim, *Competition Lowers drug Prices, FDA Says*, Pharmacy Time, April 2020 available at <https://www.pharmacytimes.com/view/competition-lowers-drug-prices-fda-says>

<sup>18</sup> Eric Sagonowsky, *With a year left before generics hit, Pfizer nabs FDA approval for new-and-improved Lyrica*, Fiercepharma, October 12, 2017 available at <https://www.fiercepharma.com/regulatory/pfizer-wins-lyrica-extended-release-approval-could-it-be-prepping-patient-switch-push> See also National Prescription Coverage Coalition, *Act Now-Block Lyrica CR* available at <https://nationalprescriptioncoveragecoalition.com/act-now-block-lyrica-cr/>

have so many patents and patent applications in the first place that could potentially give them extended periods of protection to delay competitors unless they are successfully removed as barriers through litigation? Given skyrocketing drug prices, the American public can ill-afford to be dependent on the patent litigation games and settlements between pharmaceutical companies to determine the length of patent protection on a drug and when robust competition can enter. The patent system should be curbing these patent excesses at the examination stage to ensure only the highest quality patents are granted.

We believe the concerns raised in your letter regarding our study could be easily addressed if Congress required full transparency from the pharmaceutical industry. For example, Congress could request the companies to provide a list of *all* the patents held on a drug to the U.S. Patent and Trademark Office and FDA, irrespective of whether it would be asserted in litigation. Congress could also make it a policy that patents asserted in the “patent dance” phase of biologic- biosimilar litigation be made publicly available. We would be more than happy to assist with such efforts, including meeting with you and your staff to review policy solutions contained in our Blueprint for Reform that can help lower prescription drug costs for Americans<sup>19</sup>.

We thank you for your letter sharing our concern about lowering prescription drug costs. This is a moment of opportunity to help shine light on how pharmaceutical companies are abusing the patent system and the harm it is causing to Americans.

Please do not hesitate to reach out if you have further questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tahir Amin', with a stylized flourish at the end.

Tahir Amin  
Co-Executive Director  
Initiative for Medicines, Access & Knowledge (I-MAK), Inc

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<sup>19</sup> See Strengthening Competition for Prescription Drugs