Statement of Tahir Amin
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before the

U.S Senate Committee on Health, Education, Labor and Pensions

for a hearing on

"Why does the United States pay, by far, the highest prices in the world for prescription drugs?"

8 February 2024

Chairman Sanders, Ranking Member Cassidy, and Members of the Committee. It is my honour to be invited here to share with you a root cause of why the U.S pays, by far, the highest prices in the world for prescriptions drugs. That root cause is how the pharmaceutical industry manipulates the patent system to lengthen patent protection and its market monopoly in order to block competition, all while increasing prices.

I. Introduction and Background

My name is Tahir Amin. I am a Founder and Chief Executive Officer of the Initiative for Medicines, Access & Knowledge, also known as I-MAK, a non-profit organisation working to address structural inequities in how medicines are developed and distributed. We do not accept funding from branded or generic pharmaceutical companies.

I qualified as a U.K attorney and have nearly 30 years of experience in the field of intellectual property. I have experience working with the intellectual property and patent systems of several countries in the world, including the U.S, both at the practice and policy level.

I spent the first decade of my legal career practising as an attorney at international law firms and multinational companies securing and protecting intellectual property. Many of my clients were American companies, as was one of my employers during this time. Through this work, I learned both the legal and business side of intellectual property and its importance to inventors, investors and companies. I also learned how to use loopholes to game the system. These loopholes enabled me to "invent" intellectual property rights so companies could obtain and maintain a monopoly in the market, while continuing to extract maximum profits.

After a decade in private practice seeing how intellectual property rights—and especially patents—are often misused for commercial gain, I co-founded I-MAK to help restore integrity and to the patent system. For the past 15 years, I have worked alongside patients and advocates to remove unmerited patent rights that stand in the way of generic and biosimilar competition and keep life-saving medicines out of reach of the patients who need them.

I speak to you today as someone who has seen both sides of this issue.

II. The Link Between Patents and Drug Prices

America is in a drug pricing crisis. More than one-third of Americans say they have not filled a prescription for medication because of its cost.[1] Black Americans are most heavily impacted as they are more likely to require medication for chronic conditions, such as high blood pressure or diabetes, while having median incomes of nearly $30,000 less than white households.[2]

Prescription drug spending on retail and non-retail drugs is poised to grow 63% this decade, reaching $917 billion dollars.[3] This increase is fuelled by spending on patent-protected branded drugs. While branded drugs make up just 8% of prescriptions versus 92% for generics, they account for 84% of all drug spending in the U.S.[4] Even after adjusting for general inflation, U.S prescription drug spending increased by 76% from 2000 to 2017.

These price hikes correspond with a dramatic increase in patenting activity in the pharmaceutical sector.

It took 155 years for the USPTO to issue its first five million patents in 1991.[5] It has taken less than one fifth of that time for the USPTO to issue its next 6 million. This would suggest that over half of all inventions in the history of the U.S. patent system occurred in the last 30 years. But have we really become more inventive in the last 30 years, or have we just become better at "inventing" patents because our patent system is no longer stringent enough?

A similar picture emerges when we drill down into pharmaceutical patents specifically. The number of pharmaceutical patents granted in the U.S. more than doubled between 2005 (1,580 patents) and 2015 (3,742 patents).[6] But nearly 80 percent of the drugs—products based on small molecules—associated with new patents during this time were not for new drugs, but for existing ones.[7]

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[1] YouGov, More than one-third of Americans have not filled a prescription because of cost, 10 March 2023, available at https://today.yougov.com/health/articles/45388-americans-have-not-filled-prescription-price-poll

[2] Protect Our Care, How High Drug Prices Hurt Black Americans, July 2021 available at https://www.protectourcare.org/wp-content/uploads/2021/07/POC-Report-How-High-Drug-Prices-Hurt-Black-Americans-.pdf

[3] Charles Roehrig and Ani Turner, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report, Altarum, July 2022.

[4] The Use of Medicines in the U.S 2022, The IQVIA Institute, 21 April 2022

[5] https://10millionpatents.uspto.gov/

[6] Report - S&E indicators 2018 | NSF - national science foundation. Science & Engineering Indicators 2018 Report. Accessed Oct. 31, 2023. https://www.nsf.gov/statistics/2018/ nsb20181/report/sections/invention-knowledge-transfer-and-innovation/invention-united-states-and-comparative-global-trends#uspto-patenting-activity

[7] R Feldman. May your drug prices be evergreen. Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, https://doi.org/10.1093/jlb/lsy022

For the past 8 years my organisation, I-MAK, has been analysing the patent portfolios of the top selling drugs in the U.S.

Our analysis for the top 10 selling drugs in the U.S. in 2021 alone revealed[8]:

- A total of 1,429 patent applications have been filed as of 2022;
- 741 patents have been granted on these drugs in total;
- On average, that is more than 140 patent applications filed per drug, and 74 patents granted per drug.
- On average, 66% of patents filed on these drugs are *after* the first approval for marketing by the U.S Food and Drug Administration (FDA).
- On average 55% of the granted patents for these drugs were filed after FDA approval.
- Over four times as many patents were granted on these top 10 selling drugs in 2021 when compared to Europe.
- Keytruda (Merck), Eliquis (Bristol-Myers Squibb (BMS)/Pfizer), Stelara (Johnson & Johnson) and Imbruvica (AbbVie/Johnson & Johnson) were 4 of the top selling drugs in 2021. As of June 2022, these four drugs alone have had at least 494 patent applications filed on them, of which 235 were granted patents.
- Most of the patent applications (305) for these four drugs were filed after FDA approval.

A closer look at some of these best-selling drugs reveals the following.

Keytruda (Merck)

Merck's Keytruda belongs to a class of drugs known as immune checkpoint inhibitors used for cancer immunotherapy. It was first approved in September 2014. At the last count in July 2023, it has received an additional 35 FDA approvals across 16 different types of cancer.

Keytruda is projected to become the best-selling drug ever, taking over AbbVie's Humira. Its worldwide sales are forecasted to be $27.19 billion in 2024. In 2023, global sales for Keytruda were $25 billion, with $15 billion in the U.S alone. Keytruda represented 47% of Merck's total pharmaceutical revenue in 2023.

As of June 2022, there are at least 180 patent applications and 78 granted patents covering Keytruda and its various indications. 61% of the 180 patent applications were filed after the first FDA approval for Keytruda in 2014.[9]

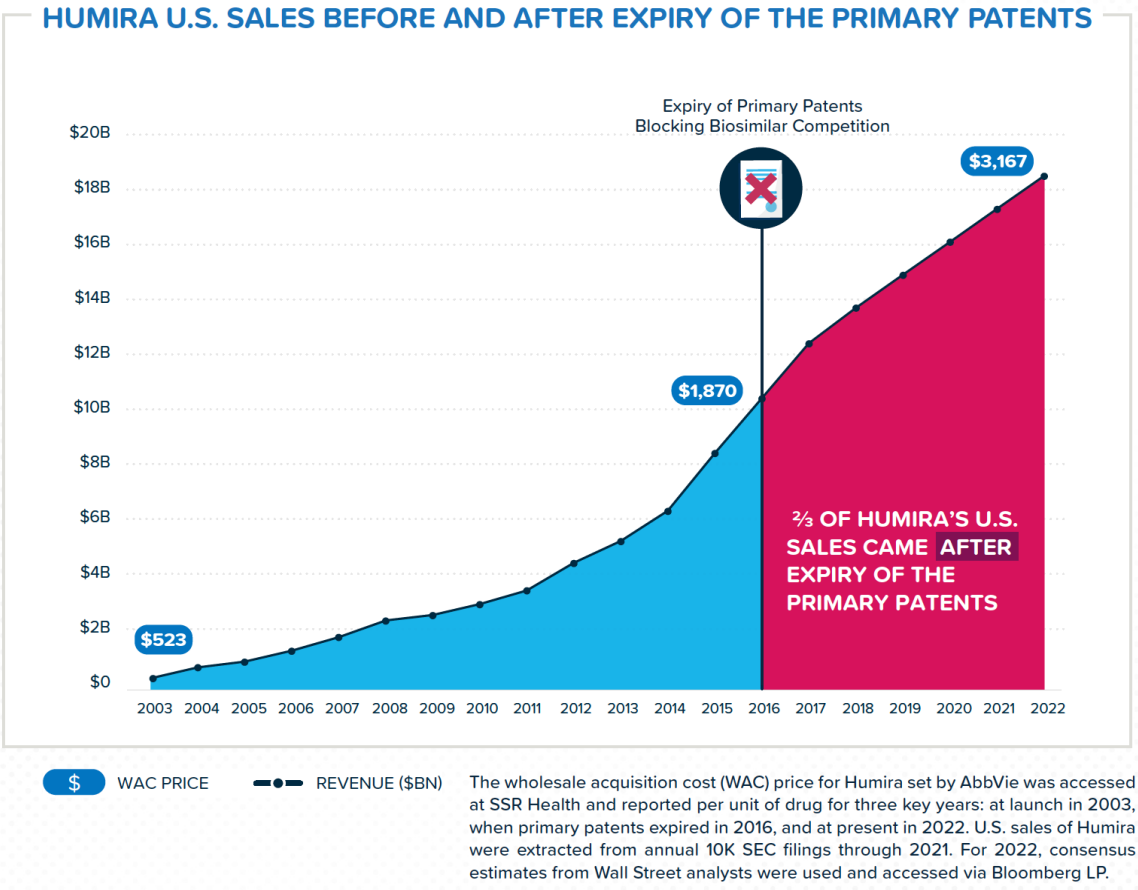
The first patent filed in relation to Keytruda was 2002. Based on our findings, the latest expiring patent for Keytruda will be in 2039, which will be eleven years after the key patents covering the drug are set expire (2028). In total, Merck currently has 37 years of patent protection for Keytruda (it is worth noting that patents are granted for 20 years for an invention). This protection includes

[8] I-MAK, Overpatented, Overpriced, September 2022 available at https://www.i-mak.org/overpatented/ and https://drugpatentbook.i-mak.org/

[9] https://drugpatentbook.i-mak.org/

a subcutaneous delivery formulation for the drug, which could replace the current intravenous infusion if approved. It could also lengthen Merck's market monopoly on the drug by switching to the subcutaneous form.

Market and media analysts are currently reporting that we could see biosimilar competition for Keytruda when the key patents on the drug expire in 2028 (often referred to as the patent cliff). Given the patent thicket that Merck has accumulated around Keytruda, I think that is wishful thinking. If we have learned any lessons from how AbbVie was able to extend its market monopoly on Humira for an additional seven years beyond its key patent and generate $102 billion in revenue alone in that period (which included continued price increases) because of its patent thicketing strategy (see Figure below[10]), then we can expect Merck to do the same. Based on an analysis of all Keytruda's patents, after all the patent litigation and settlements are done, we will be fortunate if we see biosimilars for Keytruda enter before 2034 – roughly 6 years after the key patents expire. I also predict, as AbbVie did with Humira, that Merck will continue to increase prices for its branded Keytruda during the additional market monopoly period because of its extended patent protection. I do not see Merck leaving some $100 billion plus on the table, they will use whatever patents they have to litigate for every cent of it.



[10] I-MAK, Overpatented, Overpriced, September 2022

Imbruvica (AbbVie/Johnson & Johnson)

Imbruvica is a drug used to treat a variety of B cell cancers, including leukemia and lymphoma. It was first approved in 2013 and is approved by the FDA for several different indications.

The price of Imbruvica has increased by 108% in the U.S since it was introduced in 2013, compared to a 30% general inflation increase in the same period.[11] Imbruvica's list price has increased nearly 32 % in the U.S in the past 5 years, from $431 in 2019 to $567 per capsule (70mg).

As of June 2022, AbbVie has filed 195 patent applications, of which 96 have been granted to date. That roughly works out to over one patent filed every month for the last 14 years. Over half of these patent applications were filed after Imbruvica received its first FDA approval. Currently, granted patents for Imbruvica give AbbVie patent protection for 29 years, until 2036—nine additional years beyond its original 20 years of patent protection.

Despite generic companies litigating AbbVie's patents, we have already seen six companies enter into patent settlement agreements. As a result of these agreements, competitors will delay introduction of generic versions of Imbruvica until 2032 and 2033. These 5 additional years of market monopoly because of extended patent protection could help AbbVie and Johnson & Johnson secure over $7 billion dollars in revenue.

Eliquis (Bristol Myers Squibb (BMS)/Pfizer)

Eliquis is an anticoagulant medication used to treat and prevent blood clots.

Sales for Eliquis in the U.S increased by 10% to $8.6 billion in 2023. Eliquis accounts for 27% of BMS's sales in the U.S. The price of Eliquis has increased by 124% since its introduction in 2012 as compared to 31% general inflation increase during the same period.[12] In January this year, the list price for Eliquis increased by 6% from the year before. This increase outpaced inflation and the annual price increases of the top 50 best selling drugs.

As of June 2022, BMS/Pfizer have filed at least 43 patent applications for the drug, of which 22 are granted. Sixteen of these patent applications were filed after FDA approval. There are 2.4 times more granted patents in the U.S than in Europe. Generic versions of Eliquis entered some European countries in 2022 after several patents that would have extended the market monopoly period were found invalid.[13] However, in the U.S these same patents were held valid after litigation and generic versions are not expected to enter until 2028. As a result of extended patent protection, generic versions will have entered Europe almost 6 years earlier than in the U.S. By

[11] Noah Tong, Here are 25 Medicare Part D drugs that have skyrocketed in Price, Fierce Healthcare, 10 August 2023, available at //www.fiercehealthcare.com/payers/here-are-25-medicare-part-d-drugs-have-skyrocketed-price

[12] *Ibid*

[13] Amy Sandys, Court of Appeal confirms invalidity of Bristol-Myers Squibb apixaban patent, 9 May 2023, available at https://www.juve-patent.com/cases/court-of-appeal-confirms-invalidity-of-bristol-myers-squibb-apixaban-patent/

our estimate, BMS/Pfizer will make $48 billion in revenue during this extended market monopoly period.[14]

III. Solutions to the Patent and Drug Pricing Problem

This Committee should recognise that the use of patent thickets to extend the market monopoly period on a product is not a case of a few bad actors. This is an endemic problem across the pharmaceutical industry.

If we want to get to the heart of addressing our national drug pricing crisis, **the first and most important thing Congress can do to solve this problem is raise the bar for what classifies as an invention that deserves a patent.** Over the last 30 years, more and more patents have been sought and granted for things that are not new inventions given what we know in the pharmaceutical sciences today.

For example, no reasonable researcher would call combining two existing drugs or switching dosages novel science by today's standards. And yet, drugmakers regularly get 20 years of patent protection for this commonly practiced knowledge.

In 1962, Senator Estes Kefauver of Tennessee said:

"If you want to tweak a drug, and you want to get another patent on it, the modified version has to be significantly better, therapeutically, for patients."[15]

A patent puts enormous monopoly power into the hands of a single drugmaker. That power should only be granted if the invention is original and materially better than what already exists. We cannot rely on the market and litigation to resolve these problems; they need to be addressed before a patent monopoly is granted in the first place.

IV. Conclusion

The Constitution grants Congress the power to "promote the progress of science and useful arts by securing *for limited times* to authors and inventors the exclusive right to their respective writings and discoveries."

But patenting activity today goes well beyond the time limited monopoly intended by the Constitution. Today's patent system has become less an engine for real invention than a tool for companies and their lawyers to exploit using sophisticated legal and marketing Jedi tricks under

[14] I-MAK, Overpatented, Overpriced, September 2022

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4101807/

the guise of “innovation.” This *might* be tolerable if the stakes were not so high. The quest for ever longer monopolies too often comes at an incalculable cost: the cost of people’s lives.

This is not an indictment of the pharmaceutical industry. Drugmakers and their armies of patent lawyers—people like me in my former life—are simply doing what the system incentivises them to do, and what they are bound by their shareholders and clients to do.

But it is in Congress's power to end this perversion and restore integrity to the patent system. Instead of incentivising investment in minor modifications for the purposes of extending patent protection, we need a system that incentivises bold research—breakthroughs that are therapeutically better than existing alternatives and fill a real market need, not low-hanging fruit designed to maximise profits. Congress has the ability to return the patent system to what it was always intended to be: not a vehicle for unprecedented profits, but an engine for inventions that are truly original and unprecedented.