



**Statement of Tahir Amin
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Knowledge (I-MAK)**

before the

U.S House of Representatives Committee on Oversight and Reform

for a hearing on

Unsustainable Drug Prices (Part III)

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Chairwoman Maloney, Ranking Member Comer, and Members of the Committee. It is my honour to be invited here to share with you my perspectives on the intellectual property system, in particular the role that the patent system plays in driving up the cost of medicines.

I. Introduction and Background

My name is Tahir Amin. I am a Founder and an Executive Director 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 over 25 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 working 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 profit.

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 balance to the 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.

In anticipation of how divided opinions are on the subject of intellectual property, especially patents, I would like to state upfront that this conversation is not about the death knell of innovation. It is about bringing equity to a system that is only working for a few, and about how well this system incentivises genuine invention.

II. The Link Between Patents and Drug Prices

America is in a drug pricing crisis. A 2019 study found that more than 13% of American adults—roughly 34 million people—know at least one friend or family member who died in the past five years because they could not afford treatment. That figure is twice as high for people of colour. The same study found that 58 million Americans had experienced “medication insecurity” (the inability to pay for prescribed medication) at least one time in the past twelve months.¹

Sadly, that’s not surprising. Annual U.S spending on prescription drugs was recently estimated at \$457 billion. Even after adjusting for general inflation, U.S prescription drug spending increased by 76% from 2000 to 2017. Brand name drugs appear to be the primary driver of these rising prices.²

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

Last week, the United States Patent and Trademark Office (USPTO) issued its 11 millionth patent.³ On the surface, this might seem like a milestone to celebrate. However, a deep dive into what’s behind this growth reveals a troubling picture.

It took 155 years for the USPTO to issue its first five million patents in 1991.⁴ 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

¹ <https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx>

² Rand Corporation, International Prescription Drug Price Comparisons, 28 January 2021 available at https://www.rand.org/pubs/research_reports/RR2956.html

³ <https://www.uspto.gov/about-us/news-updates/uspto-issues-patent-number-11000000>

⁴ <https://10millionpatents.uspto.gov/>

patents) and 2015 (3,742 patents).⁵ 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.⁶

For the past four years my organisation, I-MAK, has been analysing the patent portfolios of the top selling drugs in the U.S. These are products which have already been on the market for 15 years.

Our analysis for the top 10 selling drugs in the U.S. in 2019 alone revealed⁷:

- A total of 1,310 patent applications have been filed;
- 692 patents have been granted on these drugs in total;
- On average, that is 131 patent applications filed and nearly 70 patents granted per drug.
- On average, 63% of patents filed on these drugs are *after* the first approval for marketing by the U.S Food and Drug Administration (FDA).
- The average duration of patent protection covering these drugs is a monopoly period of 38 years in total unless contested through litigation. (It should be noted here that U.S patent law gives 20 years of patent protection for an invention, with extensions of up to five years in some circumstances).
- On average there are 2.5 times as many patents filed on these drugs in the U.S. compared to the same drugs in Europe.
- Between 2014-2019, on average we have seen a 71% price increase on these drugs. During this time, some of these drugs should have lost their patent protection, but instead the companies have managed to maintain a monopoly hold because they were able to extend protection through layering on extra patents.

Two of the best-selling drugs on this top ten list belong to AbbVie: Humira and Imbruvica.

Humira

Humira is the best-selling drug of all time. As of June 2020, AbbVie has generated more than \$165.8 billion globally and this single drug still represents almost 60% of the company's sales.⁸ Over half of the sales for Humira come from the U.S.⁹

⁵ <https://nsf.gov/statistics/2018/nsb20181/report/sections/invention-knowledge-transfer-and-innovation/invention-united-states-and-comparative-global-trends#uspto-patenting-activity>

⁶ 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/l5y022>

⁷ <https://www.i-mak.org/2019-best-selling/>

⁸ <https://media.nature.com/original/magazine-assets/d41573-020-00219-5/d41573-020-00219-5.pdf>

⁹ <https://www.axios.com/abbvie-humira-2018-sales-20-billion-e4039176-baeb-44ff-b4fe-1b63005283b9.html>

Humira is a monoclonal antibody. As a result of its mechanism of action, the same antibody can be used to treat a number of different disease indications. Humira has received FDA approval for 11 indications, such as rheumatoid arthritis, psoriatic arthritis and Crohn's disease.

The first patents on Humira were filed in 1994. As of 2020, there are at least 257 patent applications that have been filed for Humira. 90% of these patent applications were filed after Humira was approved and brought to market in 2002. AbbVie has amassed 130 granted patents for Humira—a record—giving it a staggering 39 years of patent protection.¹⁰

One of the arguments AbbVie uses to justify this wall of patents is that the drug treats 11 different disease indications. But importantly, the original patents on the antibody filed as early as 1996, and which expired in 2016, already provided protection for many of these indications.¹¹ AbbVie recycled these claims—again, claims they had already reported in their original patent filing—in patent applications over a decade later. The only difference was that the later claims provided more details about dosing or combining Humira with existing drugs. Why did AbbVie do this? Because by reinventing old claims they were able to add 6-11 additional years to their monopoly period.¹² In comparison, a number of the same patents filed in Europe were either withdrawn or revoked after being initially granted and then opposed.¹³

Despite litigation by 9 different companies, patent settlement agreements have allowed AbbVie to maintain its patent wall around Humira and keep competitors out of the U.S market until 2023. Due to a lack of immediate competition, the U.S will have spent an estimated \$77 billion between October 2018 and 2023, when competition can enter the market. As part of their settlement agreements, competitors will also have to pay royalties to AbbVie on U.S patents on Humira that will still be in force after 2023. That's a win-win for AbbVie, but a loss for patients. The cost of these royalties will likely be passed on to consumers.

Meanwhile, across the pond, competing biosimilar versions of Humira have already entered the European market, with prices dropping as much as 70%. However, it should be noted that as part of its settlement agreements in the U.S., AbbVie traded the European market to keep its U.S. monopoly.

Imbruvica

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 currently approved by the FDA for 11 indications.

The current annual list price for Imbruvica is \$174,000. The price for Imbruvica has increased over 57% in the five years since the drug was launched. In the month of January 2020, its price

¹⁰ <https://www.i-mak.org/humira/>

¹¹ For example, see U.S Patent No. 6509015

¹² For example, see U.S Patent No. 8,926,975 and U.S Patent No 9,546,212.

¹³ For example, see EP140665B1 and EP1944322B1

increased 7%. Based on current projections, Imbruvica is set to become the fourth highest grossing drug in the U.S., with annual revenues of nearly \$9 billion.¹⁴

As of 2020, AbbVie has filed 165 patent applications, of which 88 have been granted to date. Over half of these patent applications were filed after Imbruvica received its first FDA approval. Currently, granted patents for Imbruvica give AbbVie a patent monopoly of 29 years, until 2036—nine years beyond its original 20 years of patent protection. It is estimated that Americans will spend \$41 billion for branded Imbruvica during these additional nine years.¹⁵

As with Humira, AbbVie has employed what I call a “drip-feed” patent strategy for Imbruvica. The initial patent filings for Imbruvica in 2006 sought protection for the treatment of two specific cancers, but they also disclosed that the drug could be used for over 100 other indications.¹⁶ These initial patents are set to expire in 2026. However, AbbVie has filed dozens of new patent applications for many of these additional indications, with only slightly more specificity than what appeared in the original patents.¹⁷ These new patents have given AbbVie an extra 9 years of monopoly protection on Imbruvica.

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. This is six to seven years after AbbVie’s initial patents expire on Imbruvica. These additional years will cost Americans billions more dollars on branded Imbruvica.

III. Solutions to the Overpatenting Problem

The patent games I have just described are not an AbbVie problem, nor are they a case of a few bad actors. These are systemic failures that pharmaceutical companies are exploiting because they can; abusive patent practices are permitted by law, and they go far beyond these two drugs made by AbbVie.

Keytruda, a drug marketed by Merck which treats various cancers, is set to become the new Humira. It is poised to be the top grossing drug in the world in 2024, with estimated annual global revenues of \$26 billion. It is expected to account for half of Merck’s revenue.

¹⁴ <https://www.i-mak.org/imbruvica/>

¹⁵ <https://www.i-mak.org/imbruvica/>

¹⁶ See U.S Patent No. 7,514,444 and 8,497,2777

¹⁷ For example, see U.S Patent Nos. 9,125,889, 9,801,881 and 9,655,857

Using tactics similar to those used by AbbVie, Merck has been able to extend its monopoly on Keytruda by eight years. By my organisation's calculations, these additional years of monopoly protection could cost Americans an estimated \$137 billion.¹⁸

This manipulation of the system will continue unless Congress exercises its oversight power to protect the patent system—and the American public—from abuse. Today, we are talking about Humira and Imbruvica but, if Congress fails to act, we will be here tomorrow talking about Keytruda, and then a new drug, and then another one after that.

If we want to get to the heart of addressing our national drug pricing crisis, there are three things we need to do:

The first and most important thing Congress can do to solve this problem is raise the bar for what gets patented. Over the last 30 years, more and more patents have been sought and granted for things that aren't 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."¹⁹

A patent puts enormous monopoly power into the hands of a single drugmaker. That power should only be granted if the invention is genuinely new and materially better than what already exists.

The second thing Congress can do is change the financial incentives and culture at the USPTO. The majority of the USPTO's revenue comes from fees paid only if a patent is granted, which means the agency's revenue is directly linked to the number of patents it grants. This creates a financial incentive to grant as many patents as possible, even if the claims to inventiveness are weak.

Studies have shown that the USPTO grants patents at higher rates when revenue is strained, suggesting that patent decisions are being influenced by factors other than inventiveness.²⁰ The push to grant ever-more patents puts a strain on patent examiners, given the average patent

¹⁸ For example, see U.S Patent Nos. 9,125,889, 9,801,881 and 9,655,857

¹⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4101807/>

²⁰ https://www.hamiltonproject.org/assets/files/decreasing_patent_office_incentives_grant_invalid_patents.pdf

review time at the USPTO is just 19 hours — that is roughly only 2 working days.²¹ This is hardly enough time to evaluate whether something is genuinely inventive, and whether it warrants the creation of a monopoly worth billions of dollars. Indeed, research shows that for small molecule pharmaceutical products, two thirds of secondary patents (patents filed after the original product patent) are invalidated when litigated to the end without a settlement.²² We cannot rely on litigation to resolve these problems; they need to be addressed before a patent monopoly is granted in the first place.

Alongside changing the financial incentives, we also need a culture change at the USPTO. One that centres equity at the heart of the agency’s mission and redefines its customer base to include not just those who are directly applying for patents and trademarks, but those whose lives stand to be fundamentally altered by these decisions. The next USPTO director should be someone who will be willing to equally prioritise the public interest and have experience working with diverse communities outside of the small world of usual “customers” and lawyers.

Thirdly, Congress should reduce the cost of patent challenges. These costs discourage even the most meritorious patent challenges and allow poor quality patents to stand, often at the expense of patients. In the U.S, patent challenges are prohibitively expensive, with filing fees alone costing upward of \$41,500 per patent. This is far higher than in Europe and Australia.²³

IV. Conclusion

American ingenuity is rightly a source of pride and, because of that, it’s tempting to lionise the patent system.

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 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.

²¹ https://www.oecd.org/site/stipatents/5_4_Frakes_Wasserman.pdf

²² CS Hemphill and B Sampat. Drug patents at the Supreme Court. *Science*. Vol 339, Issue 6126, 1386-1387. 22 Mar 2013.

Available: <https://science.sciencemag.org/content/339/6126/1386>.

²³ http://archive.epo.org/epo/pubs/oj010/03_10/03_sup10.pdf

But it is in Congress's power to end this perversion of the patent system. Instead of incentivising investment in minor modifications for the purposes of extending a patent, 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 discoveries that are truly unprecedented.