



**Attention:** The Honourable Lisa R. Barton

Secretary to the Commission  
U.S International Trade Commission  
500 E Street, S.W. Room 112  
Washington, DC 20436

3 January, 2022

Dear Secretary Barton,

**Re: Certain Adalimumab (Humira), Process for Manufacturing or Relating to Same, and Products Containing Same - Investigation No. 337-3585**

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 advocating for health equity in drug development and access. I-MAK does not accept funding from branded, generic or biosimilar pharmaceutical companies. I am 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 around the world, including the U.S, both at the practice and policy level.

Earlier this year, I was invited by the U.S. House of Representatives Committee on Oversight and Reform to testify at the hearing on [Unsustainable Drug Prices \(Part III\)](#), which specifically examined the pricing and business practices of AbbVie Inc in relation to its drug Humira (adalimumab). As an expert witness, I submitted a written testimony.<sup>1</sup> The issues discussed at the Congressional Hearing are relevant to the complaint filed by AbbVie seeking to block Alvotech from importing its adalimumab biosimilar product, AVT02, into the U.S. In particular, an exclusion order barring importation of Alvotech's AVT02 would eliminate the possibility of earlier

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<sup>1</sup> Witness Statement of Tahir Amin  
<https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=112631>

competition against AbbVie's Humira® drug, leading to a further increase in already unaffordable prices for U.S. patients, many of whom are seniors, needing this drug.

As explained at the Congressional Hearing in May 2021, 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. 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. According to the Committee on Oversight and Reform Drug Pricing Investigation Majority Staff Report, in the five year period from 2016 and 2020, pharmaceutical companies raised the price of branded prescription drugs by 36% - almost four times the rate of inflation during that period.<sup>2</sup> These price hikes correspond with a dramatic increase in patenting activity and other gaming of the intellectual property system by the pharmaceutical sector.

AbbVie's manipulation of the intellectual property system, including building patent thickets, for Humira in order to protect its monopoly and ability to keep raising prices without competition is the poster child for this type of business practice that is rampant in today's pharmaceutical sector.<sup>3</sup> Since the first patents for Humira were filed in 1994, AbbVie has filed at least another

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<sup>2</sup> U.S. House of Representatives Committee on Oversight and Reform, Drug Pricing Investigation Majority Staff Report, December 2021 available at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>

<sup>3</sup> Christopher Rolwand, Why the Price of Humira keeps rising despite FDA approval of generic competition, The Washington Post, 8 January 2020 available at <https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-f>

260 patent applications as of 2020. Over 130 of these patent applications have been granted, providing AbbVie with a staggering 39 years of total patent protection on Humira. This amounts to 19 additional years of patent protection beyond the expiry of its main patent in 2016. 90% of these patent applications were filed *after* Humira was approved by the U.S FDA and brought to the market in 2002. Today, AbbVie charges approximately \$77,000 for a year's supply of Humira - 470% more than when the drug was first launched in 2002.<sup>4</sup> Since 2014, AbbVie has increased the price on Humira by more than 100%.

Instead of seeing biosimilar versions of adalimumab enter after AbbVie's main patent on Humira expired in 2016, U.S patients and payers have to wait until January 2023 before they will see any competition and price relief. This is because nine different companies decided it was too costly to litigate through AbbVie's enormous patent thicket and ended up settling for a license instead. Due to a lack of immediate competition, the U.S will have spent an estimated \$77 billion between October 2018 and 2023, when the nine licensed companies that settled can enter the market. Many of these settlements related to Humira have allowed these same companies to launch their product in Europe as early as 2018, while preventing American patients access to lower cost alternatives. In Europe where biosimilars for Humira are readily available, prices have dropped as much as 70%, while in the U.S. AbbVie continues to increase prices.

Through its manipulation of the intellectual property system and relying on the delays and cost related to litigating its patent thicket, AbbVie has successfully blocked the entry of earlier competition. Alvotech remains the only biosimilar company that is challenging AbbVie's patent

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da-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f\_st  
ory.html

<sup>4</sup> U.S House of Representatives Committee on Oversight and Reform, Drug Pricing Investigation Staff Report - Humira and Imbruvica, May 2021 available at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf>

and could launch its product sooner than 2023 if it receives a successful decision from the Northern District of Illinois, which is expected no later than October 2022.

Should this Commission issue an exclusion order barring Alvotech's biosimilar from the U.S import, it would hamper Alvotech's ability to come to market sooner. It would also mean that such a decision directly impacts U.S patients and payers who will have to endure the hurt of higher prices for longer. Considering that AbbVie's Humira franchise in the U.S alone grosses \$16 billion per year, delaying competition from Alvotech is worth approximately an additional \$44 million per day to AbbVie.

AbbVie's complaint to this Commission claims that the issuance of relief in this matter will not adversely impact public health, safety or welfare conditions in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. AbbVie also argues in its complaint that the public interest favours the protection of intellectual property rights in the United States. As my organisation and the recent investigations by the U.S. House of Representatives Committee on Oversight and Reform into AbbVie's manipulation of the intellectual property and patent system show, AbbVie's complaint to this Commission could not be further from the truth or evidence. This complaint is another brazen attempt by AbbVie to prevent competition by wielding the intellectual property system that it has already manipulated for Humira at the considerable expense of American patients and payers.

With so many American patients unable to afford their medicine today, the public interest favours lower drug prices and competition, not an intellectual property system that has been systematically manipulated by AbbVie and others in the pharmaceutical sector in order to extend their monopolies and profits.

This Commission could help alleviate this ongoing misuse of the intellectual property system by rejecting AbbVie's request for relief and instead provide some relief for American patients and payers.

Sincerely,

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

**Tahir Amin**

Co-Executive Director