Initiative for Medicines, Access & Knowledge

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Report Finds 89% of Total U.S. Patent Applications on Humira Were Filed After FDA Approval – Pointing to a Deliberate Strategy to Delay Competition

I-MAK's latest study finds AbbVie's exploitation of the US patent system could cost American taxpayers more than 14.4 billion dollars before competition arrives in 2023

New York— An investigative study that exposes the patenting practices that have led to the skyrocketing price increases for the most popular drug in the U.S. was released today by the Initiative for Medicine, Access & Knowledge (I-MAK). Finding that AbbVie, the patent holder of Humira – a drug used by those suffering from arthritis and other inflammations – filed 89% of its 247 patent applications after the drug was first approved and on the market in 2002. Nearly half of the 247 patent applications were filed since 2014, indicating an aggressive evergreening strategy to delay competition.

Despite litigation by competitors, biosimilar versions of Humira are not expected to enter the U.S. until 2023. In comparison, competing biosimilar versions will be entering the European market as early as October 2018. I-MAK's study finds that compared to AbbVie's U.S. patent estate, far fewer patent applications on Humira were filed in the European Patent Office (76) and Japan (63). I-MAK calculates that because of the extended patent monopoly in the U.S. and the delayed 2023 entry of biosimilars, the estimated cost to American payers and taxpayers will be in excess of $14.4 billion dollars.

"Overpriced medicines not only limit access to the patients who need them, but strain the healthcare systems all Americans rely on," said **Tahir Amin, co-founder and co-executive director at I-MAK**. "AbbVie's egregious patenting practices, which allow it to maintain a monopoly and continue to hike prices, strain the budgets of America's public health care agencies, as well as those of individuals and families throughout the country."

All Americans feel the impact of drug monopolies. Funded by U.S. taxpayers, Medicare and Medicaid help ensure that vulnerable Americans have access to health care. As drug costs rise, spending by these programs does as well. Total spending by Medicare and Medicaid increased 266% on Humira between 2012 and 2016, and the average spending on Humira per person more than doubled from $16,000 to $33,000. In 2016, the $3.3 billion spent on the drug by Medicare and Medicaid accounted for 31 cents of every dollar spent on Humira in the U.S.

Still, more than 4 in 10 American adults over age 50 are concerned about their ability to afford their medications.

"According to Medicare, I receive too much Social Security to qualify for payment assistance for my Humira prescription," said Sue Lee, a Humira patient in Crestwood, Kentucky. "I refuse to almost empty my savings and give my drug company almost $10,000 a year. There is no cure for plaque psoriasis, so

this will not go away, but Humira would drain what little savings I have left. I am keeping it under control right now, but just this week I got 4 new sores on left leg," Lee said.

"Americans in their sixties consume three times as many specialty prescriptions as patients in their twenties," said **Priti Krishtel, co-founder and co-executive director at I-MAK.** "As this population grows in size, the price of drugs they most often use has tripled since 2006. When drugmakers, like AbbVie, significantly raise prices and abuse the patent system to maintain its monopoly, it makes drugs unnecessarily expensive, leading to decreased access to critical, sometimes life-saving, medication.

I-MAK is calling for the U.S Patent and Trademark Office (USPTO) to hold hearings and invite public comments on pharmaceutical patenting practices and their impact on drug prices for public and private payers, and households across America. And, flagging the need to include non-profits and public interest organizations on the Public Patent Advisory Committee. Congress also should hold hearings to assess how pharmaceutical patenting practices affect federal health care programs and households, while taking effective oversight of the USPTO and other federal agencies that have the authority to address the overpatenting problem.

ABOUT I-MAK

Since 2006, I-MAK has been working to increase access to medicines around the world. I-MAK has challenged patents in 49 countries, spanning 8 diseases and 20 therapies and won high-impact cases on HIV drugs saving health programs worldwide over $1 billion. In order to stay independent and exclusively represent the interests of patients and consumers, I-MAK does not accept funding from branded or generic pharmaceutical companies. Click here for more on I-MAK's impact around the world.

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