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New Report: Ending Drug Patent Abuse Critical Next Step in Taming Soaring Drug Costs

I-MAK Findings Reveal Pharma Securing Excessive Patents on Top Drugs to Extend Monopolies and Delay Low-Cost Competition

NEW YORK – As more than 1 in 4 Americans struggle to afford high-cost prescription medicines, a new report examining America's blockbuster drugs reveals that pervasive abuse of the U.S. drug patent system is at the root of the drug pricing crisis. The *Overpatented, Overpriced: 2022* report analyzes the ten top selling drugs and exposes the scale of the patent abuse problem and its impact on U.S. prescription drug spending, which exceeds $400 billion today. While the Inflation Reduction Act's drug pricing provisions will give Medicare the power to lower some drug costs for seniors, the report highlights the urgency of long-overdue patent system reform to curb drugmakers' monopolies on top selling drugs as a critical next step in the national effort to rein in soaring drug costs for all.

Overpatented, Overpriced: 2022, the latest in a series examining America's drug patent practices by the nonprofit, nonpartisan public education group I-MAK (Initiative for Medicines, Access, & Knowledge), details how drug companies are gaming a broken drug patent system by securing excessive patents to extend their market monopolies, block low-cost competition, and prevent patients from accessing affordable generic alternatives. As the nation's drug spending is poised to reach nearly a trillion dollars by 2030, the study highlights excessive patenting practices on blockbuster drugs, such as Revlimid, Humira and Enbrel, which cover a range of conditions including cancer and arthritis.

Overpatented, Overpriced: 2022 key findings include:

- On average, there are **74 granted patents on each of America's ten top selling drugs**, providing major drugmakers substantial advantage to keep generic and biosimilar competitors off the market.
- Drugmakers filed more than 140 patent applications on average per drug; and, on average, **66% of patent applications were filed after the FDA approved the drug** to be on the market.
- Nearly one-third of Revlimid's cumulative sales in the U.S. have occurred after its primary patents expired, and **over two-thirds of Humira's U.S. sales have come after the expiration of its primary patents**.
- On average, **four times** as many patents are granted on the top ten drugs in the U.S. compared to Europe.
- Lower-cost generic and biosimilar versions of three top selling drugs - Humira, Eliquis, and Enbrel - launched in Europe an average of 7.7 years earlier than their expected U.S. entry. During this time, without generic or biosimilar competition Americans will spend an estimated **$167 Billion** on branded versions of just these three drugs. To date, these drugs still do not have generic or biosimilar competition in the U.S.

"We cannot get to the root of the drug pricing crisis without fixing America's broken patent system. When drug companies are given legal cover to block competition at the expense of American lives, it's time to

sound the alarm," says Tahir Amin, Co-Founder, and Co-Executive Director at I-MAK. "There is growing acknowledgment that these manipulative, anti-competitive tactics are unfair and need correction. It is time to reclaim the patent system: not as a vehicle for unprecedented profits, but as an engine for discoveries that are truly unprecedented."

The *Overpatented, Overpriced: 2022* report highlights how primary patents on 7 out of 10 of America's top selling drugs are set to expire this decade, incentivizing drug companies to prepare for these expirations by filing for or securing hundreds of patents ("patent thickets"). This strategy serves to extend drugmakers' monopoly power far beyond the 20 years of patent protection intended by law and allows them to extract settlements in litigation from generic or biosimilar companies to delay or block lower-cost drugs from entering the market.

The report spotlights three top selling drugs that are facing current or near-term loss of exclusivity - Humira, Revlimid, and Eylea – as they offer instructive examples of how patent related delay tactics protect the revenue and earnings for blockbuster medicines. An average of 124 patents have been granted on these three drugs, which generate an outsized percentage of their company's revenues and earnings, currently ranging from 30 to 48% of the company's U.S. drug sales.

Humira

- 165 patents secured, 92% of patent applications filed after FDA approval
- $17.3 billion in annual sales and 40% of company's U.S. pharma revenue (2021)
- 19.7 years on the market (FDA approved in 2002)
- The first biosimilar for Humira is poised to enter the market in 2023
- By the time Humira faces biosimilar competition in the first quarter of 2023, it is estimated to have garnered nearly $100 billion in sales after the expiration of its primary patent

Revlimid

- 117 patents secured, 74% of patent applications filed after FDA approval
- $8.7 billion in annual sales and 30% of company's U.S. pharma revenue (2021)
- 16.7 years on the market (FDA approved in 2005)
- After delays due to litigation and settlements, Revlimid now has volume-restricted generics on the market but will not see fully unrestricted competition until 2026

Eylea

- 91 patents secured, 66% of patent applications filed after FDA approval
- $5.8 billion in annual sales and 48% of company's U.S. pharma revenue (2021)
- 10.8 years on the market (FDA approved in 2011)

"This study is about what's really at stake: the lives and financial security of American families," says Priti Krishtel, Co-Founder, and Co-Executive Director at I-MAK. "Today, we have an unprecedented opportunity and growing alignment in Congress to transform the patent system to reduce drug prices and increase access to lifesaving medications for all Americans. We can do this by raising the bar for what gets a patent and ensuring the U.S. Patent and Trademark Office better serves the public."

The report also highlights a growing bipartisan acknowledgment and movement at the Congressional, federal agency, and Administration levels to tackle patent abuse by drugmakers, noting a recent letter by a bipartisan group of U.S. senators to U.S. Patent and Trademark Office Director Kathi Vidal stating, "The Patent Act envisions a single patent per invention, not a large portfolio based on one creation."

"The patent system games that drugmakers are playing to boost their profits are leaving patients behind," says Dr. Reshma Ramachandran, MD, chair of Doctors for America's FDA Taskforce. "As a clinician, I am seeing first-hand how families are struggling to afford lifesaving medicines. Patients must come before

profits – and that won't happen until we reform America's outdated, ineffective patent system."

METHODOLOGY

A more detailed patent methodology for each drug, including specific search criteria used, can be found here. The source data for every patent identified by I-MAK in relation to the ten top selling drugs are housed in The Drug Patent Book, available here. This database, created by I-MAK, is the first-of-its-kind publicly accessible, user-friendly blueprint for comprehensive drug patent data on top ten selling drugs. Additionally, all market-related methods and sources are available in the report and here.

ABOUT I-MAK

The Initiative for Medicines, Access, and Knowledge (or I-MAK) is a 501(c)(3) organization with a mission to build a more just and equitable medicines system for all. Our framework integrates deep analytical research to influence policy, education to activate change, and partnerships to drive solutions. We bring decades of private-sector expertise and an evidence-based approach to this mission. Our work spans 50 countries and includes engagement with patients, drug manufacturers, patent offices, community leaders, public health professionals, policymakers, scientists, economists, and more.