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## Report: Hundreds of Patents on America's Top Selling Drugs are Triggering Price Hikes and Blocking Competition

An inside look at pharmaceutical patent abuses on America's best-selling medicines exposes the root of the drug pricing crisis

NEW YORK—A new <u>report</u> examining the top selling prescription drugs in America reveals how aggressive and exploitative patenting strategies have enabled drugmakers to regularly increase drug prices while extending monopolies in an attempt to delay competition from more affordable generic alternatives. Issued by a team of legal, science and health experts at the non-profit I-MAK (Initiative for Medicines, Access and Knowledge), the report highlights the role of patent abuse as one of the leading causes of high drug prices today and comes as pressure mounts from <u>voters</u> and policymakers to address America's drug pricing crisis.

"Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices" finds that the twelve highest-grossing drugs in the U.S. average 38 years of attempted patent protection—nearly double the twenty-years <u>intended under U.S. patent law</u>—and that since 2012 the prices on these drugs have increased by an average of 68%, with only one drug dropping in price. The average best selling drug has 125 patent applications filed and 71 granted.

Spanning twelve drugmakers and a range of conditions such as cancer, arthritis, stroke, and diabetes, the study captures an industry-wide trend of pharmaceuticals "evergreening" their products with excessive patents so they can artificially extend monopolies and boost profits—at the expense of American families and the budgets of public and private payers around the country.

"The trend of drugmakers extending patent monopolies without any meaningful new science or invention is raising drug prices and exacting a heavy toll on American payers and households," said **Tahir Amin, co-founder and co-executive director at I-MAK.** "Contrary to what the law intends, drugmakers have transformed the patent system into a defensive business strategy to avoid competition and earn outsized profits. Abuse of the patent system is causing undue economic hardship and keeping lifesaving medicines out of the hands of people who need them."

Currently <u>one in four families reports difficulty</u> in paying for their prescriptions. A staggering nineteen million Americans, or eight percent of the population, are purchasing their medicines overseas due to high drug prices. With overall prescription drug spending <u>poised to nearly double</u> in the next decade, *Overpatented, Overpriced* shows that in 2017 alone, the twelve highest-grossing drugs in America cost \$96 billion to health insurers, government payers, and consumers. These soaring prices are directly linked to the excessive patenting strategies of drugmakers. For example:

• AbbVie, which markets the world's number one selling drug, Humira (\$18bn in global sales in 2017), is also the worst patent offender with 247 patent applications.

- Herceptin, a cancer drug sold by Roche/Genentech, had patents first filed in 1985 and has current patent applications pending that could extend patent exclusivity until 2033—a 48-year potential monopoly span.
- Four of the top twelve drugs have already been on the market for 20 years and have pending patent applications seeking to extend patent life to 2033: (Herceptin, Genentech), 2030 (Rituxan, Biogen/Genentech), 2029 (Enbrel, Amgen), and 2025 (Remicade, Janssen).
- Just since 2012, one third of these drugs had price hikes of more than 100%: Lyrica (163%), Enbrel (155%), Humira (144%), and Lantus (114%).

Since drugmakers often continue to increase the prices of medicines once or twice a year—even after the product has already been on the market for many years—revenues may continue to grow for these medicines until there is generic competition. The top grossing drugs examined in the report have already been on the U.S. market for an average of 15 years.

"The situation is increasingly untenable, and a growing number of American families are calling on decision makers at the state and federal level for meaningful change," said **Priti Krishtel, co-founder and co-executive director at I-MAK.** "Unfortunately, policy makers have not yet put enough effort into accelerating generic competition, or at minimum ensuring that drugmakers do not extend monopolies beyond the twenty years intended under U.S. patent law. More must be done to limit the power of the pharmaceutical industry to abuse the patent system and reverse the drug industry's dramatic expansion of patent monopolies."

While the patent system can provide an incentive to encourage drugmakers to develop new medicines for which there is robust commercial demand, the monopolies granted under U.S. patent law are meant to be limited in duration, and only for new and non-obvious inventions.

Lyrica, one of Pfizer's top-selling drugs used to treat neuropathic pain, is a prime example of overpatenting based on trivial inventions that is often used to artificially extend commercial exclusivity. With a first patent filed in 1995, and the drug on the market for the past fourteen years, Lyrica has been a major source of revenue for Pfizer—grossing over \$5 billion in global sales last year. Although the drug was set to go off-patent at the end of 2018, Pfizer filed and was issued patents for an additional twenty year period on a controlled-release formulation of the product (Lyrica CR)—meaning that patients would simply be able to take a single pill instead of two or three pills daily.

Generic competition, with two or more generic suppliers competing to reduce the price of a medicine, consistently lowers prescription drug prices by more than half. A <u>separate study</u> has shown that on average, the pricing for a variety of oral prescription drugs decreases by 66% in the first 12 months and by 74% in the first 24 months following generic entry.

## 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; it has won over 80 percent of its challenges to unmerited patents worldwide. 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 <u>here</u> for more on I-MAK's impact around the world.