RESOLVED, that shareholders of AbbVie Inc. ("AbbVie") ask the Board of Directors to establish and report on a process by which the impact of extended patent exclusivities on product access would be considered in deciding whether to apply for secondary and tertiary patents. Secondary and tertiary patents are patents applied for after the main active ingredient/molecule patent(s) and which relate to the product. The report on the process should be prepared at reasonable cost, omitting confidential and proprietary information, and published on AbbVie’s website.

Supporting Statement

Intellectual property protections on branded drugs play an important role in maintaining high prices and impeding access. When patent protection on a drug ends, generic manufacturers can enter the market, reducing prices. But branded drug manufacturers may delay generic competition by extending their exclusivity periods.

Access to medicines, especially costly specialty drugs, is the subject of consistent and widespread public debate in the U.S. A 2021 Rand Corporation analysis concluded that U.S. prices for branded drugs were nearly 3.5 times higher than prices in 32 OECD member countries.\(^1\) The Kaiser Family Foundation has “consistently found prescription drug costs to be an important health policy area of public interest and public concern.”\(^2\)

This high level of concern has driven policy responses. The Inflation Reduction Act empowers the federal government to negotiate some drug prices, and in fact some have argued it enacts significant patent reform, specifically around the issue this proposal seeks to understand. This comes from one important provision stating that the only drugs that can be considered for price negotiations are those with no generic competition, thus discouraging extended patent exclusivities.

Additionally, five Senate bipartisan bills aim to speed access to generics:

1. Ensuring Timely Access to Generics Act of 2023 (S. 1067)
2. Expanding Access to Low-Cost Generics Act of 2023 (S. 1114)
3. Increasing Transparency in Generic Drug Applications Act of 2023 (S. 775)
4. Preserve Access to Affordable Generics and Biosimilars Act of 2023 (S. 142)
5. Stop STALLING Act of 2023 (S. 148)

AbbVie also faces potential significant legal risk as one of several companies the Federal Trade Commission has issued letters to claiming the Company “improperly listed patents in the Food and Drug Administration’s ‘Orange Book’ in order to block generic rivals.”\(^3\)

AbbVie has raised the price of Humira, its top-selling drug, 27 times since its launch. One hundred and thirty patents, most of them secondary patents, have been granted on Humira, extending its exclusivity period by 19 years.\(^4\) AbbVie touted to investors in a 2015 presentation that challenging any of Humira’s patents in litigation would take four to five years.\(^5\)

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\(^2\) https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
\(^3\) https://pharmaphorum.com/news/ftc-challenges-dozens-improper-us-drug-patents
\(^5\) https://investors.abbvie.com/static-files/af79eef2-5901-4b62-9354-982d2d95404e, slide 16
In our view, a more thoughtful process that considers the impact of extended exclusivity periods on patient access could bolster AbbVie’s reputation and help avoid regulatory blowback resulting from high drug prices and perceptions regarding abusive patenting practices.