RESOLVED, that shareholders of the Gilead Sciences Inc. ("Gilead") 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 Gilead's website.

SUPPORTING STATEMENT: 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.[3] State measures, including drug price transparency legislation, copay caps, and Medicaid purchasing programs, have also been adopted.[4] The House Committee on Oversight and Reform (the "Committee") launched a far-reaching investigation into drug pricing in January 2019.[5]

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

Among the abuses described by the Committee's December 2021 report is construction of a "patent thicket," which consists of many "secondary patents covering the formulations, dosing, or methods of using, administering, or manufacturing a drug"; they are granted after the drug's primary patent, covering its main active ingredient or molecule, has been granted.[6] In June 2022, citing the impact of patent thickets on drug prices, a bipartisan group of Senators urged the U.S. Patent and Trademark Office to "take regulatory steps to . . . eliminate large collections of patents on a single invention."

Gilead markets hepatitis C treatments Sovaldi and Harvoni, whose costs are so high that public payors have had to limit access. Senator Elizabeth Warren publicly criticized Gilead for erecting a thicket of "questionable" patents around these drugs.[7]

In our view, a process that considers the impact of extended exclusivity periods on patient access would ensure that Gilead considers not only whether it can apply for secondary and tertiary patents but also whether it should do so. Gilead's current approach subjects the company to reputational risks and potential regulatory blowback resulting from high drug prices and perceptions regarding abusive patenting practices.

[1] https://www.rand.org/news/press/2021/01/28.html

[2] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

[3] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

[4] https://www.americanprogress.org/article/state-policies-to-address-prescription-drug-affordability-across-the-supply-chain/

[5] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at i.

[6] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 79.

[7] https://www.warren.senate.gov/imo/media/doc/2021.06.04%20Letter%20to%20CEO%20of%20Gilead%20re%20Subcommittee%20Hearing%20.pdf