UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

March 7, 2023

Marc S. Gerber
Skadden, Arps, Slate, Meagher & Flom LLP

Re: AbbVie Inc. (the "Company")
Incoming letter dated December 23, 2022

Dear Marc S. Gerber:

This letter is in response to your correspondence concerning the shareholder proposal (the "Proposal") submitted to the Company by Friends Fiduciary Corporation and co-filers for inclusion in the Company's proxy materials for its upcoming annual meeting of security holders.

The Proposal requests the Company's board of directors 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.

We are unable to concur in your view that the Company may exclude the Proposal under Rule 14a-8(i)(7). In our view, the Proposal raises issues that transcend ordinary business matters and does not micromanage the Company.

Copies of all of the correspondence on which this response is based will be made available on our website at https://www.sec.gov/corpfin/2022-2023-shareholder-proposals-no-action.

Sincerely,

Rule 14a-8 Review Team

cc: Jeffery W. Perkins
Friends Fiduciary Corporation

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
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**BY EMAIL** (shareholderproposals@sec.gov)

December 23, 2022

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Chief Counsel
100 F Street, N.E.
Washington, D.C. 20549

RE: AbbVie Inc. – 2023 Annual Meeting
Omission of Shareholder Proposal of
Friends Fiduciary Corporation and co-filers[1]

Ladies and Gentlemen:

Pursuant to Rule 14a-8(j) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are writing on behalf of our client, AbbVie Inc., a Delaware corporation ("AbbVie"), to request that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") concur with AbbVie's view that, for the reasons stated below, it may

[1] The following shareholders have co-filed the Proposal: Benedictine Sisters of Virginia; Bon Secours Mercy Health, Inc.; CommonSpirit Health; Congregation of Divine Providence; Mercy Investment Services, Inc.; Missionary Oblates of Mary Immaculate–United States Province; Northwest & Ethical Investments L.P. (NEI Investments); Northwest Women Religious Investment Trust; Providence St. Joseph Health; the Sisters of Charity of Saint Elizabeth; the Sisters of Charity of the Blessed Virgin Mary; the Sisters of St. Francis of Philadelphia; Stichting Bewaarder Achmea Beleggingspools; and Trinity Health. The co-filers' submissions and related correspondence are not relevant to this no-action request and have been omitted from the exhibits hereto but may be supplementally provided upon the Staff's request.

exclude the shareholder proposal and supporting statement (the "Proposal") submitted by Friends Fiduciary Corporation ("Friends Fiduciary") and co-filers from the proxy materials to be distributed by AbbVie in connection with its 2023 annual meeting of stockholders (the "2023 proxy materials"). Friends Fiduciary and the co-filers are sometimes collectively referred to as the "Proponents."

In accordance with Section C of Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D"), we are emailing this letter and its attachments to the Staff at shareholderproposals@sec.gov. In accordance with Rule 14a-8(j), we are simultaneously sending a copy of this letter and its attachments to the Proponents as notice of AbbVie's intent to omit the Proposal from the 2023 proxy materials.

Rule 14a-8(k) and Section E of SLB 14D provide that shareholder proponents are required to send companies a copy of any correspondence that the shareholder proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to remind the Proponents that if the Proponents submit correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should concurrently be furnished to AbbVie.

## I. The Proposal

The text of the resolution contained in the Proposal is set forth below:

> **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.

## II. Basis for Exclusion

We hereby respectfully request that the Staff concur with AbbVie's view that the Proposal may be excluded from the 2023 proxy materials pursuant to Rule 14a-8(i)(7) because the Proposal deals with matters relating to AbbVie's ordinary business operations.

## III. Background

AbbVie received the Proposal via email on November 14, 2022, accompanied by a cover letter from Friends Fiduciary, dated November 14, 2022,

and a letter from US Bank NA, dated November 14, 2022, verifying Friends Fiduciary's continuous ownership of at least the requisite amount of stock for at least the requisite period preceding and including the date of submission of the Proposal. Copies of the Proposal and cover letter are attached hereto as Exhibit A.

## IV. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals with Matters Relating to AbbVie's Ordinary Business Operations.

Under Rule 14a-8(i)(7), a shareholder proposal may be excluded from a company's proxy materials if the proposal "deals with matters relating to the company's ordinary business operations." In Exchange Act Release No. 34-40018 (May 21, 1998) (the "1998 Release"), the Commission stated that the policy underlying the ordinary business exclusion rests on two central considerations. The first recognizes that certain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight. The second consideration relates to the degree to which the proposal seeks to "micro-manage" the company by probing too deeply into matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment. As demonstrated below, the Proposal implicates both of these two central considerations.

### *A. The Proposal relates to AbbVie's ordinary business matters.*

The Commission has stated that a proposal requesting the dissemination of a report is excludable under Rule 14a-8(i)(7) if the substance of the proposal involves a matter of ordinary business of the company. *See* Exchange Act Release No. 34-20091 (Aug. 16, 1983) ("[T]he staff will consider whether the subject matter of the special report or the committee involves a matter of ordinary business; where it does, the proposal will be excludable under Rule 14a-8(c)(7)."); *see also Netflix, Inc.* (Mar. 14, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal that requested a report describing how company management identifies, analyzes and oversees reputational risks related to offensive and inaccurate portrayals of Native Americans, American Indians and other indigenous peoples, how it mitigates these risks and how the company incorporates these risk assessment results into company policies and decision-making, noting that the proposal related to the ordinary business matter of the "nature, presentation and content of programming and film production").

In accordance with the policy considerations underlying the ordinary business exclusion, the Staff has consistently permitted exclusion under Rule 14a-8(i)(7) of shareholder proposals relating to the products and services offered for sale by a company. *See, e.g., Wells Fargo & Co.* (Jan. 28, 2013, *recon. denied* Mar. 4, 2013) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company prepare a report discussing the adequacy of the company's policies in

addressing the social and financial impacts of its direct deposit advance lending service as relating to the ordinary business matter of "products and services offered for sale by the company," stating in particular that "[p]roposals concerning the sale of particular products and services are generally excludable under rule 14a-8(i)(7)"); *Pfizer Inc.* (Mar. 1, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report describing the steps the company has taken to prevent the sale of its medicines to prisons for the purpose of aiding executions, noting that the proposal "relates to the sale or distribution of [the company's] products"); *The Walt Disney Co.* (Nov. 23, 2015) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company's board of directors approve the release of a specific film on Blu-ray, noting that the proposal "relates to the products and services offered for sale by the company"); *FMC Corp.* (Feb. 25, 2011, *recon. denied* Mar. 16, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal seeking, among other things, an immediate moratorium on sales and a withdrawal from the market of a specific pesticide, as well as other certain pesticides, noting that the proposal "relates to the products offered for sale by the company"); *JPMorgan Chase & Co.* (Mar. 16, 2010) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board implement a policy mandating that the company cease its current practice of issuing refund anticipation loans, noting that the proposal related to the company's "decision to issue refund anticipation loans" and that "[p]roposals concerning the sale of particular services are generally excludable under rule 14a-8(i)(7)").

More specifically, under those same policy considerations underlying the ordinary business exclusion, the Staff has recognized that decisions regarding intellectual property matters are fundamental to a company's day-to-day operations and cannot, as a practical matter, be subject to direct shareholder oversight. In *International Business Machines Corporation* (Jan. 22, 2009), for example, the proposal requested that the company take steps to further the advancement of open source software, which the company noted allows recipients to "freely copy, modify and distribute the program source code without paying a royalty fee." In permitting exclusion under Rule 14a-8(i)(7), the Staff noted that the proposal related to the company's "ordinary business operations (i.e., the design, development and licensing of [the company's] software products)."

In this instance, the Proposal focuses primarily on how AbbVie decides to safeguard and protect the investments in its innovative medicines via patent rights, which is an ordinary business matter. Specifically, the Proposal's resolved clause asks AbbVie's board of directors (the "Board") to establish and report on a process by which AbbVie would consider the impact of extended patent exclusivities on one particular factor—product access—in deciding whether to apply for secondary and tertiary patents. The Proposal's supporting statement then goes into detail on aspects of AbbVie's intellectual property strategy, including the quantity of patents the company has acquired. Read together, the Proposal's resolved clause and supporting

statement clearly articulate a concern with the ordinary business matter of how AbbVie decides to pursue specific patents associated with the products that it develops and sells.

AbbVie has approximately 75 pipeline programs in mid- and late-stage development, more than 220 research partnerships and a research and development footprint in approximately 20 countries. Decisions with respect to whether, how and when AbbVie applies for patent protection across this broad spectrum of patient-focused scientific discovery are so fundamental to its day-to-day operations that they cannot, as a practical matter, be subject to direct shareholder oversight. These decisions involve numerous scientific considerations, along with the balancing of complex legal factors such as: whether patents meet the recognized standards of novelty, inventive step and utility; laws and regulations relating to effective and fair competition in the many jurisdictions in which AbbVie applies for patent rights; and economic incentives to continue to innovate and develop new treatments, cures and vaccines. In determining whether to apply for a patent and what types of patents to pursue, AbbVie also must consider the timeframe, since obtaining a patent often takes several years and requires passing through a robust and thorough process that involves extensive review by patent examiners and substantive responses by the patent applicant. Balancing these numerous and complex factors is plainly within the ambit of management's operations of AbbVie's ordinary business. Moreover, these decisions are inherently based on confidential, competitively sensitive and proprietary information, underscoring that these decisions are fundamental to management's ability to run the company on a day-to-day basis. Therefore, the Proposal may be excluded under Rule 14a-8(i)(7) as relating to AbbVie's ordinary business operations.

We note that a proposal may not be excluded under Rule 14a-8(i)(7) if it is determined to focus on a significant policy issue. The fact that a proposal may touch upon a significant policy issue, however, does not preclude exclusion under Rule 14a-8(i)(7). Instead, the question is whether the proposal focuses primarily on a matter of broad public policy versus matters related to the company's ordinary business operations. *See* 1998 Release; Staff Legal Bulletin No. 14E (Oct. 27, 2009). The Staff has consistently permitted exclusion of shareholder proposals where the proposal focused on ordinary business matters, even though it also related to a potential significant policy issue. For example, in *PetSmart, Inc.* (Mar. 24, 2011), the proposal requested that the company's board require suppliers to certify that they had not violated certain laws regulating the treatment of animals. Those laws affected a wide array of matters dealing with the company's ordinary business operations beyond the humane treatment of animals, which the Staff has recognized as a significant policy issue. In permitting exclusion under Rule 14a-8(i)(7), the Staff noted the company's view that "the scope of the laws covered by the proposal is 'fairly broad in nature from serious violations such as animal abuse to violations of

administrative matters such as record keeping.'" *See also, e.g., CIGNA Corp.* (Feb. 23, 2011) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the potential significant policy issue of access to affordable health care, it also asked the company to report on expense management, an ordinary business matter); *Capital One Financial Corp.* (Feb. 3, 2005) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the significant policy issue of outsourcing, it also asked the company to disclose information about how it manages its workforce, an ordinary business matter).

In this instance, even if the Proposal were to touch on a potential significant policy issue, the Proposal's overwhelming concern with how AbbVie decides to apply for a specific category of patents to protect investments in its innovative medicines demonstrates that the Proposal's focus is on ordinary business matters. In particular, the Proposal's supporting statement demonstrates this focus by highlighting specific decisions made by AbbVie related to its product development and associated intellectual property decisions. Therefore, even if the Proposal could be viewed as touching upon a significant policy issue, its focus is on ordinary business matters.

*B. The Proposal seeks to micromanage AbbVie.*

The Staff has consistently agreed that shareholder proposals attempting to micromanage a company by probing too deeply into matters of a complex nature upon which shareholders, as a group, are not in a position to make an informed judgment are excludable under Rule 14a-8(i)(7). *See* 1998 Release; *see also, e.g., The Coca-Cola Co.* (Feb. 16, 2022); *Deere & Co.* (Jan. 3, 2022); *JPMorgan Chase & Co.* (Mar. 22, 2019); *Royal Caribbean Cruises Ltd.* (Mar. 14, 2019); *Walgreens Boots Alliance, Inc.* (Nov. 20, 2018); *RH* (May 11, 2018); *Amazon.com, Inc.* (Jan. 18, 2018). As the Commission has explained, a proposal may probe too deeply into matters of a complex nature if it "involves intricate detail, or seeks to impose specific time-frames or methods for implementing complex policies." *See 1998 Release*. Recently, in Staff Legal Bulletin No. 14L (Nov. 3, 2021) ("SLB 14L"), the Staff explained that a proposal can be excluded on the basis of micromanagement based "on the level of granularity sought in the proposal and whether and to what extent it inappropriately limits discretion of the board or management."

In this instance, the Proposal seeks to micromanage AbbVie by dictating that AbbVie establish a process by which the impact of specific types of patents on one particular factor—product access—would be considered, and reported on, in deciding whether to file patent applications. The Proposal thus seeks to direct how AbbVie decides whether to protect its investments in innovative new medicines.

As described above, decisions concerning whether, when and how AbbVie applies for patents require complex business judgments by AbbVie's management

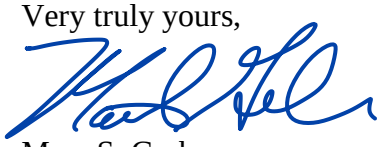
that must account for myriad factors—and these decisions are made countless times in relation to the robust number of assets in AbbVie's pipeline. In making such decisions, AbbVie's management must consider and balance these factors, including the science, innovation, legal and regulatory factors, among other matters, and take into consideration confidential, competitively sensitive and proprietary information in doing so. By seeking to impose a specific process on AbbVie's management of its patents, the Proposal attempts to micromanage AbbVie by probing too deeply into matters of a complex nature upon which shareholders, as a group, are not in a position to make an informed judgment.

Accordingly, the Proposal should be excluded from AbbVie's 2023 proxy materials pursuant to Rule 14a-8(i)(7) as relating to its ordinary business operations.

## V. Conclusion

Based upon the foregoing analysis, AbbVie respectfully requests that the Staff concur that it will take no action if AbbVie excludes the Proposal from its 2023 proxy materials. Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of AbbVie's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,



Marc S. Gerber

Enclosures

cc: Perry C. Siatis
Executive Vice President, General Counsel and Secretary
AbbVie Inc.

Amy Carr
Shareholder Advocate
Friends Fiduciary Corporation

Frank Wagemans, on behalf of Stichting Bewaarder Achmea Beleggingspools
Senior Engagement Specialist
Achmea Investment Management

Andrea Westkamp, OSB
Subprioress and Treasurer
Benedictine Sisters of Virginia

Patricia Regan, CDP
General Treasurer
Congregation of Divine Providence

Lydia Kuykendal, on behalf of Bon Secours Mercy Health, Inc.,
CommonSpirit Health and Mercy Investment Services, Inc.
Director of Shareholder Advocacy
Mercy Investment Services, Inc.

Seamus P. Finn, OMI
Missionary Oblates of Mary Immaculate–United States Province

Judy Byron, OP, on behalf of Providence St. Joseph Health
Northwest Coalition for Responsible Investment

Michela Gregory
Director, ESG Services, NEI Investments
Northwest & Ethical Investments L.P. (NEI Investments)

Alexis Fleming
Northwest Women Religious Investment Trust

Christina Dorett, on behalf of the Sisters of
Charity of the Blessed Virgin Mary
Seventh Generation Interfaith Inc.

Barbara Aires, SC
Coordinator of Corporate Responsibility
The Sisters of Charity of Saint Elizabeth

Tom McCaney
Director, Corporate Social Responsibility
The Sisters of St. Francis of Philadelphia

Catherine Rowan
Director, Socially Responsible Investments
Trinity Health

EXHIBIT A

(see attached)

Friends Fiduciary

ADDING VALUES TO STRONG PERFORMANCE.

November 14, 2022

VIA EXPRESS DELIVERY

Perry C. Siatis
Executive Vice President, General Counsel and Secretary
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064

Dear Mr. Siatis:

Friends Fiduciary Corporation ("Friends Fiduciary") is submitting the attached proposal (the "Proposal") pursuant to the Securities and Exchange Commission's Rule 14a-8 to be included in the proxy statement of AbbVie Inc. (the "Company") for its 2023 annual meeting of shareholders. Friends Fiduciary is the lead filer for the Proposal and may be joined by other shareholders as co-filers.

Friends Fiduciary serves more than 430 Quaker meetings, churches, and organizations through our socially responsible investment services. Our investment philosophy is grounded in the beliefs of the Religious Society of Friends (Quakers), including peace, simplicity, integrity, and justice. We are long term investors and engage portfolio companies to witness to Quaker values and to protect and enhance the long-term value of our investments. We are increasingly concerned with the reputational and regulatory risks related to high drug prices and regulators' perceptions regarding abusive patenting practices.

Friends Fiduciary is available to meet with the Company via teleconference on: December 9, 2022, between 9:00am and 5:00pm Eastern or December 6, 2022, between 9:00am and 5:00pm Eastern. Any co-filers will authorize Friends Fiduciary to conduct the initial engagement meeting but may participate subject to their availability.

A representative of the filers will attend the shareholder meeting to move the resolution. We look forward to meaningful dialogue with your company on the issues raised in this proposal. Please note that the contact person for this proposal is Amy Carr at Friends Fiduciary ([redacted]).

Friends Fiduciary has continuously beneficially owned, for at least one year as of the date hereof, greater than $25,000 worth of the Company's common stock. Verification of this ownership is attached. Friends Fiduciary intends to continue to hold such shares through the date of the Company's 2023 annual meeting of shareholders.

Sincerely,

Jeffery W. Perkins
Executive Director

Enclosures

1700 Market Street | Suite 1535 | Philadelphia, PA 19103 | t: 215-241-7272 | f: 215-241-7871

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

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 and copay caps, have been adopted.[4] The House Committee on Oversight and Reform (the "Committee") launched a far-reaching investigation into drug pricing in 2019.[5]

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 try to delay generic competition by extending their exclusivity periods.

Such periods can be extended if secondary patents are granted. The Committee's December 2021 report described construction of a "patent thicket," which consists of many "secondary patents covering the formulations, dosing, or methods of using, administering, or manufacturing a drug" 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."

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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.

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.[7] AbbVie touted to investors in a 2015 presentation that challenging any of Humira's patents in litigation would take four to five years.[8]

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

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7 https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at ix, 17.

8 https://investors.abbvie.com/static-files/af79ccf2-5901-4b62-9354-982d2d95404c, slide 16.

Friends Fiduciary

ADDING VALUES TO STRONG PERFORMANCE.

January 13, 2023

Via e-mail at shareholderproposals@sec.gov

Securities and Exchange Commission
Office of the Chief Counsel
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549

Re: Request by AbbVie Inc. to omit proposal submitted by Friends Fiduciary Corp. and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Friends Fiduciary Corporation and 12 co-filers (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to AbbVie Inc. ("AbbVie" or the "Company"). The Proposal asks AbbVie to establish and report on a process by which the impact of extended patent exclusivities on patient access would be considered in deciding whether to apply for secondary and tertiary patents on AbbVie's products.

In a letter to the Division dated December 23, 2022 (the "No-Action Request"), AbbVie stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the 2023 annual meeting of shareholders. AbbVie argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), on the ground that the Proposal relates to AbbVie's ordinary business operations. Because the Proposal deals with the significant social policy issue of the impact of intellectual property ("IP") protections on patient access, AbbVie has not met its burden of proving its entitlement to exclude the Proposal, and the Proponents respectfully ask that its request for relief be denied.

**The Proposal**

The Proposal states:

> **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.

**Background**

Prescription drugs have assumed an increasingly important role in American health care: the proportion of health care spending attributable to retail prescription drugs rose from 7% in the 1990s to 12% in 2019.[1] Congress has carefully balanced incentivizing scientific innovation in pharmaceuticals with promoting competition in the name of affordability.[2] Obtaining a patent for a new drug gives the manufacturer exclusive marketing rights for a specified period, generally 20 years, to reward the company for the risk and expense involved in developing the drug.[3] Once the patent expires, manufacturers are free to make generic versions of the drug—or in the case of a biologic, a biosimilar version—which drives down prices.[4]

At least, that's how the system is supposed to work. Branded drug makers have powerful incentives to prolong exclusivity periods, especially those applicable to top-selling drugs. They exploit weaknesses in the U.S. patent and health care systems in several ways, including product hopping, or switching patients to a slightly different product with a later-expiring patent; pay-for-delay settlements, in which putative generic manufacturers receive something of value in exchange for not launching a generic competitor; and "evergreening" leading to so-called "patent thickets," numerous overlapping patents on a drug filed after the primary patent has been granted and the drug approved by the Food and Drug Administration ("FDA")—referred to as secondary and tertiary[5] patents--that are expensive and time-consuming for a potential generic manufacturer to challenge.[6]

Overpatenting keeps prices high, impeding access. That impact is particularly troubling given that U.S. drug prices are the highest in the world[7]; the rise in spending on prescription drugs outpaces increases in health care spending more generally[8]; and three in 10 Americans on a prescription drug report not taking their medicine as prescribed due to cost.[9] Studies show that the introduction of generic versions of a drug lead to significantly lower prices.[10] As of 2021, 247 patent applications had been filed on AbbVie's top-selling drug Humira, 89% of which were filed after

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[1] https://www.gao.gov/prescription-drug-spending
[2] https://www.healthaffairs.org/do/10.1377/forefront.20181106.217086/full/
[3] https://sgp.fas.org/crs/misc/R46221.pdf, at 1.
[4] https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf
[5] A tertiary patent applies to a drug-device combination, such as the EpiPen. https://blog.petrieflom.law.harvard.edu/2018/04/30/tertiary-patents-an-emerging-phenomenon/
[6] See https://sgp.fas.org/crs/misc/R46221.pdf, at 1-2. Secondary patents may address matters such as manufacturing methods, dosing, and methods of administering the drug. https://sgp.fas.org/crs/misc/R46221.pdf, at 9.
[7] https://www.commonwealthfund.org/publications/podcast/2022/feb/its-the-patents-stupid-why-drugs-cost-so-much-in-us
[8] https://sgp.fas.org/crs/misc/R46221.pdf, at 2.
[9] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
[10] https://www.fda.gov/media/133509/download, at 2; https://www.fda.gov/media/161540/download, at 6; https://pubmed.ncbi.nlm.nih.gov/34904207/; https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf; https://www.cbo.gov/publication/57772

Humira received FDA approval, giving Humira 39 years of market exclusivity.[11] The Proposal asks AbbVie to take the impact on patient access into account when making decisions about applying for secondary and tertiary patents on its medicines.

**Ordinary Business**

AbbVie argues that the Proposal deals with the Company's ordinary business operations, and is thus excludable in reliance on Rule 14a-8(i)(7), because it relates to the Company's products and how AbbVie "decides to safeguard and protect the investments in its innovative medicines via patent rights."[12] AbbVie also claims that the Proposal would micromanage it. Neither argument has merit.

It is true that the Division generally regards a company's product offerings and choices about IP protections, without more, as ordinary business matters. If a proposal focuses on a significant social policy issue, however, the fact that it implicates a company's products or IP does not support exclusion on ordinary business grounds.

Last season, the Staff considered and rejected arguments much like those AbbVie now makes when determining that three different proposals to pharmaceutical firms addressing IP transcended ordinary business. First, Johnson & Johnson ("JNJ") sought to exclude a proposal asking for a report on the public health costs of its limited sharing of COVID-19 vaccine IP. As AbbVie does here, JNJ argued that the proposal's subject was the distribution of the company's products, the licensing of its technologies, and/or decisions about safeguarding its IP, all of which JNJ urged were ordinary business.[13] The proponent framed the proposal's topic as "whether companies should pursue profits in a manner that degrades critical environmental and social systems, with a focus on the Company's approach to guarding intellectual property involving COVID-19 vaccine technology." The Staff declined to grant relief.

Second, the Staff did not grant two no-action requests making arguments nearly identical to AbbVie's here about proposals focusing on IP protections and access to vaccines. The proposals asked Pfizer and Moderna to report to shareholders on the feasibility of transferring intellectual property and technical knowledge to facilitate the production of COVID-19 vaccine doses in low- and middle-income countries. Both companies urged that the proposal addressed the ordinary business matters of the company's products and IP protections.[14] The proponent countered that the proposal's topic, ensuring equitable access to vaccines and the role of IP protections in maintaining inequity, was a significant social policy issue. The Staff did not concur with either company, stating that the proposal "transcends ordinary business matters."

Although the pandemic gave additional urgency to the issue of access to vaccines and COVID-19 therapeutics, that context is not necessary to avoid exclusion because the Staff has previously found that access to medicines and drug pricing are significant policy issues, even absent a pandemic. As far back as the 1990s, the Staff has declined to allow exclusion on ordinary business

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[11] https://www.i-mak.org/wp-content/uploads/2021/09/i-mak.humira.report.3.final-REVISED-2021-09-22.pdf
[12] No-Action Request, at 4.
[13] Johnson & Johnson (Feb. 8, 2022)
[14] Pfizer, Inc. (Feb. 23, 2022); Moderna, Inc. (Feb. 8, 2022).

grounds of proposals addressing drug pricing and access.[15] Last year's JNJ, Pfizer and Moderna determinations reinforce that a proposal will not be deemed excludable simply because it implicates products or IP, so long as the primary concern is access. The Proposal fits that description as well.

In the third set of determinations, the Staff declined to allow two pharmaceutical companies to exclude proposals dealing with anticompetitive practices on ordinary business grounds. The proposals asked the companies to report to shareholders on how their boards oversee risks related to anticompetitive practices. The supporting statements discussed patent thickets as well as other practices. The companies claimed that the proposals addressed the ordinary business matters of legal compliance and/or management of IP. The proponents urged that the proposals dealt with the significant social policy issue of "the strategic, reputational, and public policy risks created by anticompetitive practices."[16]

Similar outcomes have been reached on other kinds of proposals involving companies' products where a significant policy issue was implicated. For example:

- The Staff did not agree with JNJ's[17] claim that a proposal asking the company to establish and implement standards of response to the HIV/AIDS pandemic in developing countries could be excluded in reliance on the ordinary business exclusion because it addressed product development, research and testing; the proponent had urged that the proposal addressed the significant policy issue of the HIV/AIDS pandemic.
- Gilead's[18] argument that a proposal seeking a report on risks related to rising pressures to contain specialty drug prices was excludable on ordinary business grounds was not persuasive, even though Gilead pointed to the focus on its products and pricing decisions.
- In Denny's,[19] the Staff did not concur with the company's claim that a proposal asking it to sell at least 10% cage-free eggs by volume was excludable because it implicated the sale of particular products, siding with the proponent's characterization of the proposal's subject as the significant policy issue of "[r]educing cruel confinement conditions for egg-laying hens" (i.e., animal cruelty).

*Significant Social Policy Issue Analysis*

The role of IP protections in keeping drug prices high and limiting patient access is a subject of consistent and widespread public debate, the standard applied in determining whether a proposal's subject transcends ordinary business operations.[20]

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[15] See Eli Lilly and Company (Feb. 25, 1993); Bristol-Myers Squibb Company (Feb. 21, 2000) (same); Warner Lambert Company (Feb. 21, 2000) (same).

[16] AbbVie, Inc. (Mar. 11, 2022); Pfizer, Inc. (Mar. 8, 2022).

[17] Johnson & Johnson (Feb. 7, 2003)

[18] Gilead Sciences Inc. (Feb. 23, 2015); see also Celgene Corporation (Mar. 19, 2015); Vertex Pharmaceuticals Inc. (Feb. 25, 2015). The Staff has long declined to allow exclusion on ordinary business grounds of proposals addressing drug pricing, which quite directly implicate companies' products. See Eli Lilly and Company (Feb. 25, 1993); Bristol-Myers Squibb Company (Feb. 21, 2000) (same); Warner Lambert Company (Feb. 21, 2000) (same).

[19] Denny's Inc. (Mar. 17, 2009)

[20] See, e.g., www.sec.gov/interps/legal/cfslb14a.htm.

Media have given substantial attention to the issue in the past few years, despite its technical nature. Examples, some of which focus on Humira, include:

- Editorial Board, "Save America's Patent System," The New York Times, Apr. 17, 2022[21] ("Twelve of the drugs that Medicare spends the most on are protected by more than 600 patents in total, according to the committee. Many of those patents contain little that's truly new. But the thickets they create have the potential to extend product monopolies for decades. In so doing, they promise to add billions to the nation's soaring health care costs -- and to pharmaceutical coffers.")
- Editorial Board, "How Big Pharma plays games with drug patents and how to combat it," USA Today, Jan. 18, 2019[22] ("The pharmaceutical industry has shown contempt for this attempt at balance through a range of abusive tactics. Two common, and sometimes related, maneuvers are called 'evergreening' and 'thicketing.'")
- Robin Feldman, "Our patent system is broken. And it could be stifling innovation," The Washington Post, Aug. 8, 2021[23]
- Berkeley Lovelace Jr., "'Gaming' of U.S. patent system is keeping drug prices sky high, report says," NBCNews.com, Sept. 15, 2022[24]
- "Biden Drug Price Pressure on Patent Office Draws Skeptics," Bloomberg, Sept. 21, 2021[25] ("Patents—viewed by some as an obstacle to greater competition in pharmaceuticals—have seized the spotlight in a wide-ranging government effort to get at high drug costs.")
- Cynthia Koons, "This Shield of Patents Protects the World's Best-selling Drug," Bloomberg Businessweek, Sept. 7, 2017[26]
- Matthew Lane, "The Key to Lowering Drug Prices is Improving Patent Quality," Techdirt, July 21, 2021[27] ("One of the key drivers of these rising costs are the habit of drug makers of blocking competition on older drugs that have proven themselves to be blockbusters. And the best modern strategy for doing that is creating a patent thicket.")
- Alexander Sammon, "It's Time for Public Pharma," The American Prospect, July 25, 2022[28] ("Much of the research and development for new discoveries is publicly funded, and yet drugmakers charge whatever they want, with exclusive monopoly patent grants. Not content to just enjoy that bounty, those companies work to extend that monopoly period, through slight changes to the treatment (known as 'patent evergreening') or even bribing generic companies to not compete ('pay for delay').")

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[21] https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html

[22] https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/

[23] https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/

[24] https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507

[25] https://news.bloomberglaw.com/health-law-and-business/biden-drug-price-pressure-on-patent-office-draws-skeptics

[26] https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

[27] https://www.techdirt.com/2021/07/21/key-to-lowering-drug-prices-is-improving-patent-quality/

[28] https://prospect.org/health/its-time-for-public-pharma/

- Joe Cahill, "Humira Patent Strategy Makes the Case for Reform," Crain's Chicago Business, May 20, 2019[29]
- Gunjan Sinha, "How Patent Extensions Keep Some Drug Costs High," Undark, June 16, 2021[30]
- Sarah Gantz, "Costs for lifesaving drugs have skyrocketed. Some experts say there are intentional moves to prevent generic competition," Philadelphia Inquirer, May 12, 2019
- Sarah Karlin-Smith and Brent D. Griffiths, "FDA to examine anticompetitive practices by drug industry," Politico, July 17, 2017[31]
- Ryan Chatelain, "House committee report blasts drug pricing strategies as 'troubling,'" NY1, Dec. 10, 2021[32]
- David Chanen, "Price caps on drugs part of AG's plan," Star Tribune (Minneapolis, MN), Feb. 20, 2020 (discussing Minnesota AG's report that highlighted abuse of patent system)
- Joe Nocera, "Here's how drug companies game the patent system," Chicago Tribune, Oct. 23, 2017[33]
- Matthew Lane, "To rein in Big Pharma over high drug prices, start with patent reform," Roll Call, Jan. 17, 2020[34] ("A significant reason for the skyrocketing price of prescription drugs is that major pharmaceutical companies have enjoyed an effective open season on raising drug prices. Armed with government-sponsored monopolies obtained through shameless abuse of the patent system, Big Pharma has been free to raise prices at their leisure.")
- Garrett Johnson and Wayne T. Brough, "Big pharma is abusing patents, and it's hurting America," CNN, Sept. 13, 2019[35] ("Large pharmaceutical companies have continually engaged in the strategic accumulation of patents to restrict patient access to more affordable drugs by delaying the entry of generic options into the market.")
- David Blumenthal, "The U.S. Can Lower Drug Prices Without Sacrificing Innovation," Harvard Business Review, Oct. 1, 2021[36] ("One strategy they use is creating so-called 'patent thickets' around existing products. . . . [Challenging those patents] can take years to adjudicate and cost huge sums in legal fees. Meanwhile, Big Pharma maintains its monopolies and pricing power for decades longer than the 17 years contemplated under current law.")
- Tahir Amin, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system," CNBC, June 25, 2018[37]
- "Congress takes aim again at pharmaceutical giant over patent-stacking for brand-name drugs," The Examiner (Washington, DC), May 20, 2021

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[29] https://www.chicagobusiness.com/joe-cahill-business/humira-patent-strategy-makes-case-reform

[30] https://undark.org/2021/06/16/how-patent-extensions-keep-some-drug-costs-high/

[31] https://www.politico.com/tipsheets/prescription-pulse/2017/07/17/fda-to-examine-anticompetitive-practices-by-drug-industry-221368

[32] https://www.ny1.com/nyc/all-boroughs/politics/2021/12/10/house-committee-report-blasts-drug-pricing-strategies-as--troubling-

[33] https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html

[34] https://www.rollcall.com/2020/01/17/to-rein-in-big-pharma-over-high-drug-prices-start-with-patent-reform/

[35] https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html

[36] https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation

[37] https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html

- Robert Pearl, "Why Patent Protection in the Drug Industry is Out of Control," Forbes, Jan. 19, 2017[38]
- Ahmed Aboulenein, "Consumer group says drugmakers abuse U.S. patent system to keep prices high," Reuters, Sept. 16, 2022[39]
- Sarah Jane Tribble, "Drugmakers Play the Patent Game to Ward Off Competitors," NBCNews.com, Oct. 2, 2018[40]

Legislators and regulators have also focused on the impact of IP protections—and secondary and tertiary patents in particular—on access.

Bipartisan legislation addressing patent thickets has been introduced in Congress. The REMEDY Act introduced in 2019 provided that a generic manufacturer could enter the market after primary patent expiration without having to litigate the validity of secondary patents.[41] The TERM Act, also introduced in 2019, would have shifted the burden of supporting secondary patents from the putative generic or biosimilar manufacturer to the branded drug maker and required the U.S. Patent and Trademark Office ("PTO") to review its practices related to secondary patents.[42] The Second Look at Drug Patents Act would have required publication of patents filed after approval of a new drug or abbreviated new drug application by the FDA in order to facilitate validity challenges.[43] The Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019[44] would have limited the number of patents that the manufacturer of a biologic medicine can assert in a lawsuit against a company seeking to sell a biosimilar version.

In 2021, the Affordable Prescriptions for Patients Through Promoting Competition Act, which prohibited product-hopping, was introduced.[45] Product hopping occurs when branded drug makers persuade prescribers to switch patients to products that have the same active ingredient as the branded medicine, but with a small difference like a more convenient dosing schedule, tweaked manufacturing process or different method of administration that forms the basis for a secondary or tertiary patent. These efforts generally occur shortly before the primary patent expires; the new product's later-expiring patent preserves exclusivity, minimizing revenue loss when generic versions of the original product become available.

In June 2022, a bipartisan group of Senators wrote to the director of the PTO about patent thickets. The letter stated: "In the drug industry, with the most minor, even cosmetic, tweaks to delivery mechanisms, dosages, and formulations, companies are able to obtain dozens or hundreds of patents for a single drug. This practice impedes generic drugs' production, hurts competition, and can even extend exclusivity beyond the congressionally mandated patent term." It closed by asking

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[38] https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/?sh=73fa684178ca

[39] https://www.reuters.com/business/healthcare-pharmaceuticals/consumer-group-says-drugmakers-abuse-us-patent-system-keep-prices-high-2022-09-16/

[40] https://www.nbcnews.com/health/health-news/drugmakers-play-patent-game-ward-competitors-n915911

[41] https://www.durbin.senate.gov/newsroom/press-releases/durbin-cassidy-introduce-remedy-act-to-lower-drug-prices-by-curbing-patent-manipulation-promoting-generic-competition#:~:text=The%20REMEDY%20Act%20amends%20FDA,that%20delay%20generic%20market%20entry.

[42] https://www.congress.gov/bill/116th-congress/house-bill/3199/text

[43] https://www.congress.gov/bill/116th-congress/senate-bill/1617

[44] https://www.congress.gov/bill/116th-congress/house-bill/3991

[45] https://www.congress.gov/bill/117th-congress/house-bill/2873

the PTO to "consider changes to your regulations and practices to address [overpatenting] problems where they start, during examination. . . We therefore ask that your office issue a notice of proposed rulemaking or a public request for comments" on several questions related to secondary patents.[46]

Congressional committees have held many hearings addressing secondary and tertiary patents and access to medicines. In July 2021, the Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights held a hearing on "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets." At that hearing, the vice president for Biosimilars Patents and Legal for Fresenius Kabi, a company that specializes in injectable medicines, biosimilars and medical technologies, testified that the "root cause" of unaffordable U.S. drug prices is patent thickets. She explained that numerous low-quality secondary patents extend exclusivity and are prohibitively expensive for a potential generic or biosimilar maker to challenge.[47]

The House Judiciary Antitrust Subcommittee held a hearing in April 2021 on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."[48] Experts on drug companies' anticompetitive practices testified, including Professor Robin Feldman, who discussed the relationship between secondary patents and product-hopping.[49]

The House Committee on Energy and Commerce's Subcommittee on Health held a hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition" in March 2019.[50] Witnesses testified regarding the impact of anticompetitive practices, including patent thickets. A government relations officer from Kaiser Permanente stated:

> Drug companies have virtually unfettered discretion to raise prices, which imposes considerable—and often devastating—financial hardship on patients and families. We are very concerned by over-patenting, exclusivity gaming and pernicious lifecycle management trends. Too often, the primary goal of these tactics is to leverage the law to stifle competition, rather than to protect meaningful clinical advancements.[51]

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[46] www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf

[47] https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf

[48] https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive

[49] https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-FeldmanR-20210429.pdf, at 3-4

[50] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to

[51] https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Barrueta-Drug%20Pricing%20Hearing-031319.pdf; see also https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Davis-Drug%20Pricing%20Hearing-031319.pdf (head of Association for Accessible Medicines stating that "Increasingly, brand-name drug companies are building patent 'estates' around their drugs, not just for the original innovative research, but for much smaller changes that may not be deserving of decades-long monopolies. . . . Addressing abuse of the patent system must be front-and-center if Congress is effectively going to reduce drug prices for patients.").

The House Oversight Committee initiated a sweeping investigation in 2019 into "pricing and business practices in the pharmaceutical industry."[52] After reviewing more than 1.5 million pages of internal company documents and holding five hearings, the Committee issued a report in December 2021, concluding that "companies have manipulated the patent system and marketing exclusivities granted by the Food and Drug Administration to extend their monopolies far longer than lawmakers envisioned when they created these systems."[53] The Committee found that the companies it investigated "have obtained over 600 patents on the 12 drugs examined, which could potentially extend their monopoly periods to a combined total of nearly 300 years."[54] Secondary patents were a focus of the Committee's investigation; its report opined that "in many cases, pharmaceutical companies have obtained secondary patents covering topics that are not particularly innovative."[55] The resulting extended exclusivity periods allow "drug companies to raise prices without threat to their market share, and lead to higher prices for American patients and increased spending by government programs."[56] Humira was among the drugs highlighted in the report.

The House Ways and Means Committee's Subcommittee on Health held a hearing in March 2019 on the cost of drugs to the Medicare program. In his opening statement, Subcommittee Chairman Doggett noted that "[o]ver the last decade, 74 percent of all pharmaceutical patent applications were not for new innovative cures, but were for modifying existing drugs, which often took the form of what's referred to as evergreening, simply to protect monopoly pricing, not to provide new drugs."[57] One witness commented that "instead of innovation, we are seeing secondary patents piled on to old drugs over and over again. When a company makes a secondary change to a drug, such as adjusting the drug's dosage, the R&D investment is often far less than is required for the drug's initial development. And in addition, the change may not mean much from a therapeutic standpoint. So, we may be lavishing rewards without getting the innovation that we desperately need."[58] Another witness identified patent thickets as key to high drug prices.[59]

The Senate Finance Committee held a hearing on "Drug Pricing in America: A Prescription for Change, Part I"[60] in January 2019, at which the Committee heard testimony on drug makers' anticompetitive practices. The Executive Vice President of the John and Laura Arnold Foundation linked patenting practices and drug prices, testifying at the hearing:

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52 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at i.

53 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at i.

54 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at ix.

55 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 81.

56 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 77.

57 https://www.youtube.com/watch?v=aA3cDgRp37s (at 3:15).

58 https://www.youtube.com/watch?v=aA3cDgRp37s (at 10:09).

59 https://www.youtube.com/watch?v=aA3cDgRp37s (at 20:22).

60 https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i

> Instead of encouraging research into the next generation of cures, firms with drugs approved by the Food and Drug Administration (FDA) are incentivized to hold on to their monopolies as long as possible and deploy as many anticompetitive tactics as possible to ensure generics or biosimilars are not available. . . . Between 2005 and 2015, over 75 percent of drugs associated with new patents were for drugs already on the market. Of the roughly 100 bestselling drugs, nearly 80 percent obtained an additional patent to extend their monopoly period at least once; nearly 50 percent extended it more than once. For the 12 top selling drugs in the United States, manufacturers filed, on average, 125 patent applications and were granted 71. For these same drugs, invoice prices have increased by 68 percent.[61]

A 2017 hearing held by the House Judiciary Committee addressed "Antitrust Concerns and the FDA Approval Process." Although some witnesses focused on other anticompetitive practices, the testimony from Harvard's Aaron Kesselheim, an expert on drug pricing, described the use of secondary patents to delay generic entry.[62] In addition to the general problem posed by patent thickets, Kesselheim explained how secondary patents facilitate product hopping.[63]

Anticompetitive conduct in the pharmaceutical industry, including abuse of the patent system, is a priority for federal agencies. In 2021, President Biden issued Executive Order 14036 entitled "Executive Order on Promoting Competition in the American economy" (the "E.O."). It provided, among other things, that "[t]he Secretary of Health and Human Services shall . . . [work to] lower the prices of and improve access to prescription drugs and biologics [and] continue to promote generic drug and biosimilar competition" by "help[ing] ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law."[64] The E.O. also directed the Secretary of Health and Human Services to take various steps to "promote generic drug and biosimilar competition." Pursuant to the E.O., the FDA and PTO are collaborating to implement strategies to lower drug prices.[65]

The previous administration also focused on how patenting practices can delay generic entry. In 2017, the FDA sought comment on the "appropriate balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs."[66] The Federal Register notice of the related meeting explained that, "In some cases . . . the legal framework surrounding [patents and first-generic exclusivities] may have been applied to delay generic competition to an extent that may not have been intended by the Hatch-Waxman Amendments, and in ways that may not serve the public health. Relatedly, certain elements of the approval process for both innovator and generic drugs have been used in ways that may (depending on the circumstances) inappropriately hinder generic competition."[67] The FDA specifically sought stakeholder input on patents, the citizen petition process, and obstacles faced by potential generic

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[61] https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf

[62] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf

[63] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf, at 6-7.

[64] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/, at section 5(p)(vi).

[65] https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

[66] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

[67] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

competitors in obtaining branded drug samples for testing.[68] The Acting Director of the FTC's Bureau of Competition testified in 2017 that "[a]lthough the widespread introduction of generic drugs has saved Americans hundreds of billions of dollars in drug costs, some companies have exploited the ability to delay generic entry through abuse of government processes."[69]

In 2020, Minnesota State Attorney General Keith Ellison released recommendations for addressing prescription drug costs, including the creation of a commission that could investigate industry practices and cap the prices of some drugs. His report cited the abuse of the patent system—and patent thickets specifically--as a key factor contributing to high drug prices. Highlighting Humira, it stated, "First, the misuse and abuse of federal patent and exclusivity laws by drug manufacturers has led to high-cost branded drugs being insulated from generic competition for years— if not decades—beyond the initial patent and exclusivity periods. For example, AbbVie created a 'patent thicket' for Humira, which is used to treat arthritis and is the top-selling drug in the world, by securing 132 patents for the drug, which resulted in 39 years of patent protection."[70]

Health care payors have also called for patent reform to moderate drug price increases. A senior vice president for government relations at Kaiser Permanente opined recently that patent thickets deter development of biosimilars for costly biologic medicines and drive up health care costs. He urged Congress to revisit patent laws to "address[] how drugmakers manipulate the patent system to maximize profit on long-existing products."[71] In December 2021, America's Health Insurance Plans, the trade association for health insurers, released a study regarding drug prices and exclusivity protections. It found that "many drugs with long periods of patent protection are the result of Big Pharma shenanigans and anti-competitive tactics like patent thicketing, patent evergreening, and pay-for-delay settlements."[72]

In 2022, Priti Krishtel, co-founder and co-executive director of patent watchdog group the Initiative for Medicines, Access and Knowledge (I-MAK) was selected to receive a MacArthur Fellowship (sometimes referred to as the "genius grant"). When announcing her selection, the program described I-MAK's work on patent reform and the impact of secondary patents on access: "Patents are intended to incentivize innovation by ensuring that only the patent holder can sell and profit from the product for a fixed time. However, many pharmaceutical companies seek to extend their monopolies by filing multiple patents on small changes (such as changes in dosage) to existing drugs over several years. This stifles competition, delays generic production, and keeps medicines out of the hands of people who need them the most."[73]

The existence of a significant social policy issue, then, distinguishes the Proposal from those analyzed in the determinations AbbVie cites on pages 3-4 of the No-Action Request. In Wells Fargo[74] and JPMorgan Chase,[75] the proposals focused on specific products that the proponents argued were forms of predatory lending, which had previously been found to transcend ordinary

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[68] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

[69] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-MeierM-20170727.pdf

[70] https://www.ag.state.mn.us/Office/Initiatives/PharmaceuticalDrugPrices/Taskforce.asp

[71] https://about.kaiserpermanente.org/news/want-to-lower-drug-prices-reform-the-us-patent-system

[72] https://www.ahip.org/news/press-releases/new-research-big-pharma-companies-earn-big-revenues-through-patent-gaming

[73] https://www.macfound.org/fellows/class-of-2022/priti-krishtel#searchresults

[74] Wells Fargo & Co. (Jan. 28, 2013, *recon. denied* Mar. 4, 2013).

[75] JPMorgan Chase & Co. (Mar. 16, 2010).

business. The Staff granted relief, characterizing the proposals as relating to the ordinary business matter of products and services offered by the companies. It is reasonable to infer that the Staff was not convinced that the products in the proposals were tantamount to predatory lending.

In the three other determinations on which AbbVie relies, the proponents unsuccessfully argued that the proposals' subjects—the use of the company's products for lethal injection, the controversy over releasing the film "Song of the South" on Blu-ray, and the company's stewardship program for specific products--were significant social policy issues. The proponent did not even respond to the company's no-action request in IBM,[76] where the proposal asked the company to assume a greater role in promoting open source software. Thus, IBM's characterization of the proposal's subject as the marketing, delivery and support of its software products went unchallenged. In any event, the determinations from last proxy season dealing with IP discussed above have more persuasive power than IBM, given how long ago it was issued.

The Proposal does not focus on ordinary business matters despite touching upon a significant policy issue, as AbbVie claims.[77] Instead, access to AbbVie's products and its policies regarding IP protection are integral elements of the significant policy issue on which the Proposal focuses. Put another way, the *sole* focus of the Proposal is a significant policy issue. In contrast, the determinations AbbVie cites involved proposals that raised a significant policy issue, but also grafted on elements that implicated day-to-day management:

- In PetSmart,[78] the proposal asked the company to require its suppliers to attest that they had not violated certain laws related to animal cruelty. PetSmart urged that the laws in question governed not only animal cruelty, a significant policy issue, but also mundane matters such as record keeping. The Staff concurred and granted relief, citing the breadth of the laws referenced in the proposal. Importantly, however, the Staff did not concur with PetSmart's more sweeping argument, which is similar to the one AbbVie makes here: that even if animal cruelty is a significant social policy issue, the selection of suppliers is an ordinary business matter, essentially negating significant social policy issue status.
- The proposal in CIGNA[79] asked the company to report on how it was "responding to regulatory, legislative and public pressures to ensure affordable health care coverage" as well as "the measures our company is taking to contain the price increases of health insurance premiums." CIGNA argued that the second part of the resolved clause focused on the ordinary business matter of expense management, rather than health care reform, as shown by the supporting statement's discussion of the relationship between administrative costs and premiums. The Staff concurred with CIGNA's view that the proposal was excludable because it addressed "the manner in which the company manages its expenses."
- Capital One[80] successfully argued that a proposal went beyond addressing the arguably significant policy issue of outsourcing to include several ordinary business matters such as "estimated or anticipated cost savings associated with job elimination actions taken by the company over the past five years."

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[76] International Business Machines Corp. (Jan. 22, 2009).
[77] No-Action Request, at 5.
[78] PetSmart, Inc. (Mar. 24, 2011).
[79] CIGNA Corporation (Feb. 23, 2015).
[80] Capital One Financial Corp. (Feb. 3, 2005).

In the 2021 proxy season, JNJ[81] unsuccessfully advanced an argument similar to the one AbbVie makes here in an effort to exclude a proposal seeking disclosure regarding the role of public funding in JNJ's decisions affecting access to its COVID-19 products. JNJ claimed that the proposal addressed the ordinary business matter of its pricing decisions in addition to an unidentified "potential significant policy issue" (presumably the COVID-19 pandemic or access to vaccines and therapeutics). The proponent contended that access to COVID-19 vaccines and therapeutics, including the role of public funding in decisions regarding such access, was a significant policy issue despite the connection to pricing of JNJ's products and was the only subject of the proposal. The Staff declined to grant relief.

*Micromanagement*

Finally, the Proposal would not micromanage AbbVie. Staff Legal Bulletin ("SLB") 14L recently clarified the Staff's approach to micromanagement claims. It states that the Staff will analyze "the level of granularity sought in the proposal and to what extent it inappropriately limits the discretion of the board or management."[82] SLB 14L indicated that climate change proposals that "suggest targets or timelines so long as the proposals afford discretion to management as to how to achieve such goals" will not be deemed excludable on micromanagement grounds. Thus, a proposal can ask a company to change its behavior, even to set a specific objective like an emissions reduction target, as long as it doesn't instruct management or the board on exactly how to implement the change.

AbbVie argues that the Proposal would micromanage by "dictating that AbbVie establish a process by which the impact of specific types of patents on one particular factor—product access—would be considered, and reported on, in deciding whether to file patent applications."[83] But the Proposal does not specify any details around implementation. It does not prescribe the weight to be accorded to access considerations, dictate how they should be balanced against other factors, or control how the impact on access should be measured. The Proposal, then, suggests a factor to be included in the deliberative process but "afford[s] discretion to management as to how to achieve" that outcome, in the words of SLB 14L.

Last season, despite similar arguments, the Staff did not concur with JNJ that it should be permitted to exclude a proposal advocating for a change in the company's approach to executive incentive compensation.[84] The proposal asked JNJ's board to adopt a policy that legal and compliance costs should not be excluded when calculating metrics for senior executives' executive compensation awards. JNJ urged that the proposal micromanaged because it sought to inappropriately limit the discretion of the JNJ board's compensation committee by dictating how financial performance metrics could be adjusted.

Moderna also argued that the proposal about IP transfer and vaccine equity would micromanage it. Specifically, like AbbVie, Moderna claimed that its "determinations about how to use and protect its intellectual property require a deep understanding of the Company's business, strategy, risk profile and operating environment as well as an assessment of a variety of complex

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[81] Johnson & Johnson (Feb. 12, 2021).
[82] Staff Legal Bulletin 14L (Nov. 3, 2021).
[83] No-Action Request, at 6.
[84] Johnson & Johnson (Mar. 2, 2022).

factors and risks, including costs, protection of intellectual property, feasibility of manufacture and financial results, among others." The Staff declined to grant relief.

The Proposal is no more prescriptive than last year's JNJ and Moderna proposals. The Proposal suggests an input but leaves room for discretion in how to determine the impact on access and incorporate it into other factors AbbVie already takes into account. The JNJ proposal prohibited an input—legal and compliance costs—from being removed from an executive compensation formula. These costs are established through the financial accounting process and management does not have discretion over their amounts or the fact that expenses are subtracted from revenues to produce net income. By its nature, then, the change requested in last year's JNJ proposal affords less opportunity for management to exercise discretion over the proposal's implementation than the Proposal does. And the Moderna proposal stated that the feasibility analysis should focus only on sharing with qualified manufacturers in certain countries, a level of detail on par with—or a bit higher than--that in the Proposal.

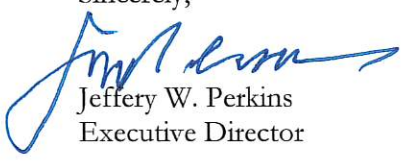
In sum, AbbVie is not entitled to exclude the Proposal on ordinary business grounds because the role IP protections play in access to medicines—the Proposal's sole subject--is a significant social policy issue transcending ordinary business, as evidenced by the consistent and widespread public debate in the media and among policy makers. The Proposal gives AbbVie's management significant discretion over how to incorporate the impact on patient access into the decision making process regarding secondary and tertiary patents, ensuring that the Proposal would not micromanage AbbVie.

* * *

For the reasons set forth above, AbbVie has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7). The Proponents thus respectfully request that AbbVie's request for relief be denied.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (215) 241-7272.

Sincerely,



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January 23, 2023

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Chief Counsel
100 F Street, N.E.
Washington, D.C. 20549

RE: AbbVie Inc. – 2023 Annual Meeting
Supplement to Letter dated December 23, 2022
Relating to Shareholder Proposal of
Friends Fiduciary Corporation and co-filers

Ladies and Gentlemen:

We refer to our letter dated December 23, 2022 (the "No-Action Request"), submitted on behalf of our client, AbbVie Inc., a Delaware corporation ("AbbVie"), pursuant to which we requested that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") concur with AbbVie's view that the shareholder proposal and supporting statement (the "Proposal") submitted by Friends Fiduciary Corporation ("Friends Fiduciary") and co-filers (collectively with Friends Fiduciary, the "Proponents") may be excluded from the proxy materials to be distributed by AbbVie in connection with its 2023 annual meeting of shareholders (the "2023 proxy materials").

This letter is in response to the letter to the Staff, dated January 13, 2023, submitted by Friends Fiduciary (the "Proponents' Letter"), and supplements the No-Action Request. In accordance with Rule 14a-8(j), a copy of this letter also is being sent to the Proponents.

The Proponents' Letter presents an uncompelling attempt to rebut the No-Action Request. In particular, it argues that the Proposal should not be excluded as relating to AbbVie's ordinary business because it focuses on a significant policy issue. As explained below, this argument is not persuasive.

Notably, the Proponents' Letter concedes that a company's product offerings and choices about intellectual property protections are ordinary business matters and does not dispute that these are the Proposal's focus. Given that, to our knowledge, the Staff has never recognized a significant policy issue relating to the general role of specific types of patents in access to medicines in ordinary circumstances, this should be the end of the analysis.

Nevertheless, the Proponents' Letter asserts that the Staff should recognize a new significant policy issue for various reasons. In doing so, the Proponents' Letter attempts to draw support from a number of unrelated prior decisions where the Staff did not permit exclusion of proposals under Rule 14a-8(i)(7). Specifically, the Proponents' Letter tries to draw support from *Johnson & Johnson* (Feb. 8, 2022), *Pfizer, Inc.* (Feb. 23, 2022) and *Moderna, Inc.* (Feb. 8, 2022). These instances are inapposite, however, as they were related to proposals focused on the narrow question of intellectual property decisions relating to COVID-19 vaccines in the midst of a global pandemic. These letters simply established the Staff's view that the subject of intellectual property decisions involving COVID-19 vaccines during the height of the pandemic transcended the companies' ordinary business matters, rather than standing for the Proponents' sweeping characterization that specific intellectual property decisions concerning pharmaceutical products allegedly impacting patient access to those products always transcends a pharmaceutical company's ordinary business.

The Proponents' Letter further attempts to extrapolate from the Staff's prior decisions in *Gilead Sciences, Inc.* (Feb. 23, 2015), *Vertex Pharmaceuticals Inc.* (Feb. 25, 2015), *Celgene Corp.* (Mar. 19, 2015), *Bristol-Myers Squibb Company* (Feb. 21, 2000), *Warner Lambert Company* (Feb. 21, 2000) and *Eli Lilly and Company* (Feb. 25, 1993). In doing so, the Proponents read the Staff's decisions as the Proponents wish they had been decided rather than how they were actually decided. As the Staff described, those proposals focused on each company's "fundamental business strategy with respect to its pricing policies for pharmaceutical products," which established the Staff's view that the subject of drug pricing in certain instances could transcend the companies' ordinary business matters. None of these decisions, however, support the Proponents' proposition that simply referencing patient access when submitting a proposal to a pharmaceutical company always converts an otherwise ordinary business matter into a matter that transcends a pharmaceutical company's ordinary business.

In particular, decisions with respect to how AbbVie decides to apply for specific patents associated with the products it develops and sells are distinct from questions of "fundamental business strategy with respect to [AbbVie's] pricing policies for pharmaceutical products." As described in the No-Action Request, oversight of AbbVie's intellectual property portfolio and strategy involves complex scientific, legal and other determinations as they relate to specific inventions. While intellectual property protection plays an important role in fostering innovation, these decisions do not rise to the same level of the pricing policies that were the subject of the proposals in *Gilead*, *Vertex*, *Celgene*, *Bristol-Myers Squibb Company*, *Warner Lambert Company* and *Eli Lilly and Company*. Stated another way, there are numerous ordinary business decisions that may be taken into consideration when a pharmaceutical company develops pricing for its products, and the ultimate business strategy with respect to pricing policies may, in some cases, transcend a company's ordinary business. But that does not mean that each of those numerous ordinary business decisions themselves transcends a company's ordinary business. How a company goes about deciding to apply for specific patents is one such ordinary business matter that does not rise to the level of transcending a company's ordinary business.

The Proponents' Letter also attempts to draw support from *Pfizer, Inc.* (Mar. 8, 2022) and *AbbVie, Inc.* (Mar. 11, 2022), but these instances similarly do not support the Proponents' broad assertions. As the Proponents' Letter describes, the proposals in these instances focused on "the strategic, reputational, and public policy risks created by anticompetitive practices," rather than the specific matter of the alleged impact of intellectual property protections on patient access at issue here. Accordingly, the Staff's prior no-action decisions relied on by the Proponents' Letter fail to demonstrate that the Proposal implicates a significant policy issue previously recognized by the Staff.

Perhaps recognizing these shortcomings, the Proponents' Letter also attempts to demonstrate that there is broad societal interest in the matter raised by the Proposal through lengthy discussions of past media publications, proposed legislation, Congressional hearings, federal agency and other executive branch actions and certain statements from the private sector on patent practices. These citations, however, fail to establish a broad societal focus on the issue of the impact of specific types of patents on patient access to pharmaceutical products generally. Given that the pharmaceutical industry and patent protections are highly regulated areas, it is not surprising that pharmaceutical companies' patent practices have drawn attention of certain groups of interested parties and become the topic of Congressional hearings and proposed legislation from time to time. That fact alone does not support the Proponents' assertion that the Proposal's topic transcends the company's ordinary business matters. The test for whether a significant policy issue

exists is not whether select groups find the issue significant; instead, the test is whether the issue holds broad societal significance. The Proponents' Letter only demonstrates interest from a small group with a vested interest in the matter.

Accordingly, the Proposal should be excluded from AbbVie's 2023 proxy materials pursuant to Rule 14a-8(i)(7) as relating to its ordinary business operations.

Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of AbbVie's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,

Marc S. Gerber

cc: Perry C. Siatis
Executive Vice President, General Counsel and Secretary
AbbVie Inc.

Amy Carr
Shareholder Advocate
Friends Fiduciary Corporation

Frank Wagemans, on behalf of Stichting Bewaarder Achmea Beleggingspools
Senior Engagement Specialist
Achmea Investment Management

Andrea Westkamp, OSB
Subprioress and Treasurer
Benedictine Sisters of Virginia

Patricia Regan, CDP
General Treasurer
Congregation of Divine Providence

Lydia Kuykendal, on behalf of Bon Secours Mercy Health, Inc., CommonSpirit Health and Mercy Investment Services, Inc.
Director of Shareholder Advocacy
Mercy Investment Services, Inc.

Seamus P. Finn, OMI
Missionary Oblates of Mary Immaculate–United States Province

Judy Byron, OP, on behalf of Providence St. Joseph Health
Northwest Coalition for Responsible Investment

Michela Gregory
Director, ESG Services, NEI Investments
Northwest & Ethical Investments L.P. (NEI Investments)

Alexis Fleming
Northwest Women Religious Investment Trust

Christina Dorett, on behalf of the Sisters of Charity of the Blessed Virgin Mary
Seventh Generation Interfaith Inc.

Barbara Aires, SC
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Tom McCaney
Director, Corporate Social Responsibility
The Sisters of St. Francis of Philadelphia

Catherine Rowan
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Trinity Health