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

DIVISION OF
CORPORATION FINANCE

March 28, 2023

Kelly Grez
Merck & Co., Inc.

Re: Merck & Co., Inc. (the "Company")
Incoming letter dated January 13, 2023

Dear Kelly Grez:

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

The Proposal requests the 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: Robert Wotypka
Province of Saint Joseph of the Capuchin Order

Merck & Co., Inc.
2000 Galloping Hill Road
Kenilworth, NJ 07033
Email: office.secretary@merck.com

January 13, 2023

VIA E-MAIL

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

Re: *Merck & Co., Inc.*
Shareholder Proposal of Province of Saint Joseph of the Capuchin Order and co-filers[1]
Securities Exchange Act of 1934—Rule 14a-8

Ladies and Gentlemen:

This letter is to inform you that Merck & Co., Inc. ("Merck" or the "Company") intends to omit from its proxy statement and form of proxy for its 2023 Annual Meeting of Shareholders (collectively, the "2023 Proxy Materials") a shareholder proposal (the "Proposal") and statements in support thereof (the "Supporting Statement") received from Province of Saint Joseph of the Capuchin Order ("Province of Saint Joseph"). Province of Saint Joseph and the co-filers are sometimes collectively referred to as the "Proponents."

Pursuant to Rule 14a-8(j), the Company has:

- filed this letter with the Securities and Exchange Commission (the "Commission") no later than eighty (80) calendar days before the Company intends to file its definitive 2023 Proxy Materials with the Commission; and

- concurrently sent a copy of this correspondence to the Proponents.

Rule 14a-8(k) and Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D") provide that shareholder proponents are required to send companies a copy of any correspondence that the proponents elect to submit to the Commission or the staff of the Division of Corporation Finance (the "Staff"). Accordingly, the Company is taking this opportunity to inform the Proponents that if the Proponents elect to submit additional correspondence to the Commission or the Staff with respect to this Proposal (including correspondence regarding the status of any negotiations with

[1] The following shareholders have co-filed the Proposal: Sisters of Charity of the Blessed Virgin Mary; Trinity Health; Benedictine Sisters of Mount St. Scholastica; Sisters of St. Francis; Missionary Oblates of Mary Immaculate – United States Province; Benedictine Sisters of Virginia; CommonSpirit Health; Mercy Investment Services, Inc.; and Providence St. Joseph Health. The co-filers' submissions and related correspondence are not relevant to this no-action request and have been omitted from the exhibit hereto but may be supplementally provided upon the Staff's request.

the Company), a copy of that correspondence should be furnished concurrently to the undersigned on behalf of the Company pursuant to Rule 14a-8(k) and SLB 14D.

I. The Proposal

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

> **RESOLVED**, that shareholders of Merck & Co., Inc. ("Merck") 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 Merck's website.

II. Basis for Exclusion

The Company hereby respectfully requests that the Staff concur in the Company's view that the Proposal may be excluded from the 2023 Proxy Materials pursuant to Rule 14a-8(i)(7) because it relates to the Company's ordinary business.

III. Background

On November 29, 2022, the Company received the Proposal via email. On December 2, 2022, the Company received a letter from RBC Capital Markets, LLC verifying Province of Saint Joseph's stock ownership in the Company (the "Broker Letter").[2] Copies of the Proposal, Supporting Statement and Broker Letter are attached hereto as Exhibit A.

IV. The Proposal May be Excluded Under Rule 14a-8(i)(7) Because it Relates to the Company's Ordinary Business

A. Background

Rule 14a-8(i)(7) permits the exclusion of shareholder proposals dealing with matters relating to a company's "ordinary business operations." The Commission has stated that the underlying policy of the ordinary business exclusion is "to confine the resolution of ordinary business problems to management and the board of directors, since it is impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting." Exchange Act Release No. 40018 (May 21, 1998) (the "1998 Release"). The term "ordinary business" in this context refers to "matters that are not necessarily 'ordinary' in the common meaning of the word, and is rooted in the corporate law concept providing management with flexibility in directing certain core matters involving the company's business and operations." *Id.*

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[2] Merck received the Broker Letter, dated as of November 29, 2022, by email on December 2, 2022.

The ordinary business exclusion rests on two central considerations: (1) the subject matter of the proposal (*i.e.*, whether the subject matter involves a matter of ordinary business), provided the proposal does not raise significant social policy considerations that transcend ordinary business; and (2) the degree to which the proposal attempts to micromanage a 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." *Id.*

A shareholder proposal requesting the publication of a report is excludable pursuant to Rule 14a-8(i)(7) if the substance of the requested report deals with the ordinary business of the company. Exchange Act Release No. 20091 (Aug. 13, 1983) ("[T]he staff will consider whether the subject matter of the special report ... involves a matter of ordinary business; where it does, the proposal will be excludable..."). *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 risk 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 in the no-action letter that the proposal related to the ordinary business matter of the "nature, presentation and content of programming and film production").

B. The Proposal May Be Excluded Because It Relates to Ordinary Business Matters

The Staff has consistently acknowledged that shareholder proposals that relate to the products and services offered by a company are excludable under Rule 14a-8(i)(7). For example, in *DENTSPLY Int'l Inc.* (Mar. 21, 2013), the Staff permitted exclusion of a proposal under Rule 14a-8(i)(7) requesting a report summarizing the company's policies and plans for phasing out mercury from its products, noting that the proposal relates to the company's product development and that "[p]roposals concerning product development are generally excludable under Rule 14a-8(i)(7)." In *Wells Fargo & Co.* (Jan. 28, 2013, *recon. denied* Mar. 4, 2013), the Staff granted no-action relief under Rule 14a-8(i)(7) where the proposal requested a report discussing the adequacy of the company's policies in addressing the social and financial impacts of the company's direct deposit advance lending service, explaining that "the proposal relates to the products and services offered for sale by the [company]" and that "[p]roposals concerning the sale of particular products and services are generally excludable under rule 14a-8(i)(7)." Similarly, in *JPMorgan Chase & Co.* (Mar. 16, 2010), the Staff permitted the exclusion of a proposal under Rule 14a-8(i)(7) where such proposal requested the company's board implement a policy mandating that the company cease issuing refund anticipation loans, which the proponent claimed were predatory loans. In its no-action request, the company acknowledged that the proposal addressed an issue that the Staff recognized as a "significant policy issue." The company noted, however, that its "decisions as to whether to offer a particular product to its clients and the manner in which the [c]ompany offers those products and services, including pricing, are precisely the kind of fundamental, day-to-day operational matters meant to be covered by the ordinary business operations exception under Rule 14a-8(i)(7)." *See also Verizon Communications Inc.*(Jan. 29, 2019) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company offer its shareholders the same discounts on its products and services that are available to its employees, noting that the proposal "relates to the [c]ompany's

'discount pricing policies'"); *Pfizer Inc.* (Mar. 1, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report describing steps taken by the company to prevent the sale of its medicines for use in 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 approve the release of a certain film on Blu-ray, noting that the proposal "relates to the products and services offered for sale by the company"); *The TJX Companies, Inc.* (Apr. 16, 2018) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company's board develop and disclose a new universal and comprehensive animal welfare policy applying to the company's sale of products, with the majority of the proposal focusing on the company's sale of products containing fur).

Furthermore, the Staff has routinely acknowledged that exclusion of a shareholder proposal is permissible under Rule l4a-8(i)(7) when the actions sought by the proposal implicate tasks that are so fundamental to management's ability to run a company on a day-to-day basis that they could not be subject to direct shareholder oversight. For example, the Staff has determined that decisions regarding intellectual property are excludable under Rule 14a-8(i)(7) as ordinary business matters. In *International Business Machines Corporation* (Jan. 22, 2009), the Staff permitted exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company take steps to further the advancement of open source software, which, as the company explained, allows recipients to "freely copy, modify and distribute the program source code without paying a royalty fee." In its no-action letter, 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)." As another example of a proposal that dealt with ordinary business matters fundamental to management's ability to run the company, in *Equity LifeStyle Properties, Inc.* (Feb. 6, 2013), the Staff permitted exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on "the reputational risks associated with the setting of unfair, inequitable and excessive rent increases that cause undue hardship to older homeowners on fixed incomes" and "potential negative feedback stated directly to potential customers from current residents." The Staff noted in its response that the "setting of prices for products and services is fundamental to management's ability to run a company on a day-to-day basis."

Here, the action requested by the Proposal, establishing a process for evaluating certain patent application filing decisions, directly relates to the products offered for sale by the Company as well as tasks that are fundamental to management's ability to run the Company, including the Company's ability to develop innovative medicines and vaccines. Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the U.S. and in most major foreign markets.

The decisions of when to incur technical risk, time, effort, and expense to develop a new product or develop new indications or new medicine delivery options for an already-approved product (the typical innovation sources for the "secondary" patents), and when to permit copying of an already-approved product prior to investment recoupment are complicated and complex decisions at the core of the Company's business model. Furthermore, the Proposal implicates partnership agreements that the Company has entered into with third parties. Through collaboration agreements and license agreements, the Company develops, licenses, and markets

potential products with third parties. These arrangements often contain commitments by the Company to develop, manufacture, and commercialize a particular asset. The Proposal would infringe on the Company's ability to meet these commitments. For these reasons, implementing the Proposal could undermine the Company's core business model and result in fewer future products being developed by the Company, in turn, both decreasing value for shareholders and restricting continued innovation in the prevention, diagnosis and treatment of diseases at the expense of patients. Because such matters go to the very heart of the Company's business, the Proposal is excludable under Rule 14a-8(i)(7).

C. The Proposal Does Not Focus on a Significant Social Policy Issue

The Company recognizes that the Staff recently changed its approach to how it evaluates significant social policy issues, explaining in Staff Legal Bulletin No. 14L (Nov. 3, 2021) ("SLB 14L"):

> proposals that the staff previously viewed as excludable because they did not appear to raise a policy issue of significance for the company may no longer be viewed as excludable under Rule 14a-8(i)(7). For example, proposals squarely raising human capital management issues with a broad societal impact would not be subject to exclusion solely because the proponent did not demonstrate that the human capital management issue was significant to the company.

However, the Staff's shift in approach has not resulted in the significant social policy exception swallowing the rule that proposals dealing with ordinary business matters are excludable. Since the publication of SLB 14L, the Staff has continued to distinguish between proposals that focus on a significant social policy issue and those that contain references to a significant social policy issue but are actually directed at a company's ordinary business matters. *See, e.g.*, *Amazon. Inc.* (Apr. 7, 2022) (*UAW Retiree Medical Benefits Trust*) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on risks to the company related to staffing of its business and operations despite the suggestion by the proponent that the focus was on human capital management); *Amazon.com, Inc.* (Apr. 8, 2022) (*James McRitchie*) and *Repligen Corporation* (Apr. 1, 2022) (both permitting exclusion under Rule 14a-8(i)(7) of proposals requesting reports on information about the distribution of stock-based incentives to employees, including data about EEO-1 employee classification despite declarations in the supporting statements that the intention was for the proposals to address a significant social policy issue).

Here, while the Proposal references "access to medicines," the focus is squarely on the Company's specific patenting process and strategy with respect to its specific products and product candidates. As explained above, this is an ordinary business matter because it relates to the development of the Company's products and fundamental business operations. Without the Company's specific patenting process and strategy, the Company's ability to develop innovative products and, in turn, enhance shareholder value and patient benefits would be significantly limited. The Proposal's focus, therefore, is not on a significant social policy issue and thus does not transcend ordinary business.

D. The Proposal May Be Excluded Because It Seeks To Micromanage the Company

In addition to focusing on a core ordinary business matter and not on a significant social policy issue, the Proposal seeks to impermissibly micromanage 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." *1998 Release*.

The Proposal is comparable to several proposals that the Staff permitted to be excluded last season under Rule 14a-8(i)(7) for seeking to micromanage the companies "by probing too deeply into matters of a complex nature." In *Deere & Company* (Jan. 3, 2022), *Verizon Communications Inc.* (Mar. 17, 2022), and *American Express* (Mar. 11, 2022), the proposals requested publication of employee-training materials to allow investors to evaluate management's handling of risk associated with employment discrimination.

As part of its process for determining whether to apply for patent protection, the Company conducts a fact-specific and complicated scientific and legal analysis for every product-related invention that has the potential of being patented. The analysis is performed by the Company's experienced patent attorneys (each of whom holds a science degree, or otherwise has an extensive scientific background, in addition to a law degree) in close collaboration with science and medical professionals. The Company evaluates its innovations for potential patenting using similar processes that patent offices deploy when examining the merits of applications for patentability. That is, performing a complicated evaluation of the innovation for newness (novelty) and non-obviousness relative to what is publicly known. Although newness or novelty is often a relatively straightforward concept, non-obviousness (called "inventive step" outside the U.S.), is a highly fact-specific inquiry to assess, from the perspective of a person skilled in the subject matter, whether the invention is sufficiently different from prior public disclosures, and may include evaluating a host of what are called "secondary" considerations that may bolster a finding of non-obviousness (e.g., the failure of others to achieve the same result, or that the invention meets a long felt but unresolved need). The Company undertakes that analysis for each patent application it considers filing in addition to applying the Company's framework intended to affirm the biopharmaceutical industry's commitment to innovation and keep patients at the heart of our efforts.

As argued by the company in *Deere & Company* regarding the requested content in the proposal: "[D]ecisions concerning internal [diversity, equity, and inclusion] efforts are multi-faceted and are based on a range of factors that are outside the knowledge and expertise of shareholders, and therefore inappropriate for such oversight and vote."

Here too, the Proposal seeks to provide shareholder oversight on a complex scientific and legal topic that is outside the knowledge and expertise of shareholders, and therefore inappropriate for such oversight and vote. As described above, decisions concerning whether, when and how the Company applies for patents require complex scientific, legal, and business judgments by the Company's management that must account for myriad factors. In making such decisions, the Company's management with the insight and advice of the Company's subject matter experts (i.e., patent attorneys and scientific and medical professionals) must consider and balance these factors, including the costs incurred in developing intellectual property, compliance and risk considerations, legal and regulatory factors and the characteristics of the Company's products, among other matters. By seeking to impose a specific process on the

Company's management of its intellectual property, the Proposal attempts to micromanage the 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. The Proposal is therefore excludable pursuant to Rule 14a-8(i)(7) for seeking to micromanage the Company.

Because the Proposal deals with ordinary business matters, does not focus on a significant social policy issue, and seeks to micromanage the Company, the Proposal is excludable pursuant to Rule 14a-8(i)(7).

V. Conclusion

Based upon the foregoing analysis, the Company respectfully requests that the Staff concur that it will take no action if the Company excludes the Proposal from the 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 the Company's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Any such communication regarding this letter should be directed to me at office.secretary@merck.com or (908) 246-3341.

Very truly yours,

Kelly Grez

Enclosures

cc: Robert Wotypka, Province of Saint Joseph of the Capuchin Order
Gwen Farry, Sisters of Charity of the Blessed Virgin Mary
Catherine Rowan, Trinity Health
Christina Dorett, on behalf of Benedictine Sisters of Mount St. Scholastica; Sisters of St. Francis; Missionary Oblates of Mary Immaculate – United States Province; and Benedictine Sisters of Virginia
Lydia Kuykendal, on behalf of CommonSpirit Health; Mercy Investment Services, Inc.; and Providence St. Joseph Health

Exhibit A

(Attached)

The Province of St. Joseph of the Capuchin Order
Office of Corporate Responsibility

29 November 2022

Via: Email: *office.secretary@merck.com*

Jennifer Zachary
Executive Vice President, General Counsel and Corporate Secretary
Merck & Company, Inc.
2000 Galloping Hill Road
K1-4157
Kenilworth NJ 07033

Re: Shareholder proposal for 2023 Annual Shareholder Meeting

Dear Ms. Zachary:

The Province of Saint Joseph of the Capuchin Order (POSJ) is a shareholder in Merck and Company, Inc. My work as the Corporate Responsibility agent for the province requires that I engage the companies in which we are stakeholders to ensure that their policies, procedures, and practices recognize and support the common good. In communication with other investors, I bring you my concerns regarding the company's strategy on public financial support, vaccine access, and the impact this strategy has on corporate profits.

Acting on behalf of the Saint Joseph province, I am 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 Merck and Company, Inc. (the "Company") for its 2023 annual meeting of shareholders. I am the lead filer for the Proposal and will be joined by other shareholders as co-filers.

The POSJ has continuously beneficially owned, for at least three years as of the date hereof, at least $2,000 worth of the Company's common stock. Verification of this ownership will be sent under separate cover from RBC Wealth Management. POSJ intends to continue to hold such shares through the date of the Company's 2023 annual meeting of shareholders.

I am available to meet with the Company via teleconference on December 20th from 10am to noon or January 4th, 2023 from 2pm to 4pm Eastern time. Any co-filers have authorized POSJ to conduct the initial engagement meeting, but may participate subject to their availability.

Please feel free to contact me with any questions via email or at 313 308 0698. I am at your service should questions arise, and send thanks for the time and attention you commit to this matter. I wish you peace and all good.

Sincerely,

Robert J. Wotypka, OFM Cap.

Robert Wotypka, OFM Cap.
Corporate Responsibility agent – The Province of Saint Joseph of the Capuchin Order
robertw@thecapuchins.org

RESOLVED, that shareholders of Merck & Co., Inc. ("Merck") 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 Merck'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 an 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" 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."

Merck markets cancer drug Keytruda. According to I-MAK, Merck has filed for 95 secondary patents on Keytruda.[7] Forty percent of Merck's patent applications on Keytruda relate to "methods of production and processes that can be used to manufacture the drug," which can thwart competition even after the primary patent on the drug has expired.[8]

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1 www.rand.org/news/press/2021/01/28.html
2 www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
3 www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/
4 www.americanprogress.org/article/state-policies-to-address-prescription-drug-affordability-across-the-supply-chain/
5 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at i.
6 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 79.
7 http://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf, at 3.
8 http://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf, at 3.

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

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November 29, 2022

Jennifer Zachary
Executive Vice President, General Counsel and Corporate Secretary
Merck & Company, Inc.
2000 Galloping Hill Road
K1-4157
Kenilworth, NJ 07033

Re: Shareholder proposal for 2023 Annual Shareholder Meeting

Dear Ms. Zachary:

I write concerning a shareholder proposal (the "Proposal") submitted to Merck & Company, Inc. (the "Company") by The Province of St. Joseph of the Capuchin Order. As of November 29th, 2022, The Province of St. Joseph of the Capuchin Order beneficially owned, and had beneficially owned continuously for at least three years from the date of this letter, shares of the Company's common stock worth at least $2,000. RBC Capital Markets, LLC has acted as record holder of the Shares and is a DTC participant.

If you require any additional information, please do not hesitate to contact me at (262) 395-1114 or paul.wartman@rbc.com.

Thank you.

Paul Wartman
Senior Vice President-
Financial Advisor
RBC Capital Markets, LLC
(262) 395-1114

cc: Robert Wotypka

Merck & Co., Inc.
2000 Galloping Hill Road
Kenilworth, NJ 07033
Email: office.secretary@merck.com

Via email (rwotypka@cskdetroit.org)

December 1, 2022

Robert Wotypka, OFM Cap.
The Province of Saint Joseph of the Capuchin Order
1820 Mt. Elliott Street
Detroit, MI 48207

Re: Shareholder Proposal from the Province of Saint Joseph of the Capuchin Order (the "POSJ")

Dear Mr. Wotypka:

This is to acknowledge receipt of your letter on behalf of the POSJ to Merck & Co., Inc. ("Merck"), dated November 29, 2022 (the "Letter"), and the accompanying shareholder proposal regarding the establishment of, and a report on, a process by which the impact of extended patent exclusivities on product access would be considered in determining whether to apply for secondary and tertiary patents (the "Proposal") submitted for inclusion in the proxy materials for Merck's 2023 Annual Meeting of Shareholders (the "Annual Meeting").

I. Proof of Ownership (Rule 14a-8(b)(1)(i))

Rule 14a-8(b)(1)(i)(A) through (C) promulgated under the U.S. Securities Exchange Act of 1934, as amended, requires proponents to establish continuous ownership of: (A) at least $2,000 in market value of Merck securities entitled to vote on the Proposal for at least three years; **OR** (B) at least $15,000 in market value of Merck securities entitled to vote on the Proposal for at least two years; **OR** (C) at least $25,000 in market value of Merck securities entitled to vote on the proposal for at least one year (the "Share Ownership Requirements"). For purposes of Rule 14a-8(b)(1)(i), the POSJ may not aggregate its holdings with those of another shareholder or group of shareholders to meet the Share Ownership Requirements. Rule 14a-8(b) also sets forth the methods to satisfy the Share Ownership Requirements. Additional guidance with regard to Rule 14a-8(b) is provided under the SEC's Division of Corporate Finance Staff Legal Bulletins Nos. 14L, 14F and 14G, copies of which are attached.

A search of Merck records could not confirm that the POSJ is a registered holder of Merck securities and its letter did not otherwise provide information with respect to the Share Ownership Requirements.

As provided in Rule 14a-8(b)(2), if the POSJ wishes to proceed with the Proposal, within 14 calendar days of your receipt of this letter, the POSJ must respond in writing and provide us with documentation evidencing full compliance with at least one of the Share Ownership Requirements by submitting either:

- a written statement from the "record" holder of the securities (usually a broker or bank),

verifying that, at the time the Proposal was submitted, the POSJ continuously held at least $2,000, $15,000, or $25,000 in market value of Merck securities entitled to vote on the Proposal for at least three years, two years, or one year, respectively. Most large U.S. brokers and banks deposit their customers' securities with, and hold those securities through, the Depository Trust Company ("DTC"), a registered clearing agency acting as a securities depository. DTC participants and affiliates of a DTC participant will be viewed as "record" holders of November 7, 2022 securities that are deposited at DTC. You can confirm whether a particular broker or bank is a DTC participant by checking DTC's participant list, which is currently available at: https://www.dtcc.com/client-center/dtc-directories.aspx.

If your broker or bank is not on DTC's participant list or an affiliate of a DTC participant, you will need to obtain proof of ownership from the DTC participant through which the securities are held. This information should be available by asking your broker or bank.

If you are holding Merck securities through a securities intermediary that is not a broker or bank, a proof of ownership letter from that securities intermediary must be submitted. If the securities intermediary is not a DTC participant or an affiliate of a DTC participant, then you will also need to obtain a proof of ownership letter from the DTC participant or an affiliate of a DTC participant that can verify the holdings of the securities intermediary; **OR**

- (i) a copy of a filed Schedule 13D, Schedule 13G, Form 3, Form 4, Form 5, or amendments to those documents or updated forms, demonstrating that the POSJ meets at least one of the Share Ownership Requirements; **AND** (ii) a written statement that the POSJ continuously held at least $2,000, $15,000, or $25,000 in market value of Merck securities entitled to vote on the Proposal for at least three years, two years, or one year, respectively.

II. Conclusion

If the requirements under Rule 14a-8(b)(1)(i) cannot be satisfied, in accordance with Rule 14a-8(f), Merck will be entitled to exclude the Proposal. In the event that you comply with Rule 14a-8(b), Merck reserves the right and may seek to exclude the Proposal in accordance with SEC proxy rules. For your convenience, please find enclosed a copy of SEC Rule 14a-8 in its entirety.

Regards,

Anthony Wildasin
Assistant Corporate Secretary

cc: Kelly Grez
Corporate Secretary

Announcement

Shareholder Proposals: Staff Legal Bulletin No. 14L (CF)

Division of Corporation Finance
Securities and Exchange Commission

Action Publication of CF Staff Legal Bulletin

Date: November 3, 2021

Summary: This staff legal bulletin provides information for companies and shareholders regarding Rule 14a-8 under the Securities Exchange Act of 1934.

Supplementary Information: The statements in this bulletin represent the views of the Division of Corporation Finance (the "Division"). This bulletin is not a rule, regulation or statement of the Securities and Exchange Commi ion (the "Commi ion") Further, the Commi ion ha neither approved nor di approved it content Thi bulletin, like all staff guidance, has no legal force or effect: it does not alter or amend applicable law, and it creates no new or additional obligations for any person.

Contacts: For further information, please contact the Division's Office of Chief Counsel by submitting a web-based request form at https://www.sec.gov/forms/corp_fin_interpretive.

A. The Purpose of This Bulletin

The Division is rescinding Staff Legal Bulletin Nos. 14I, 14J and 14K (the "rescinded SLBs") after a review of staff experience applying the guidance in them. In addition, to the extent the views expressed in any other prior Division staff legal bulletin could be viewed as contrary to those expressed herein, this staff legal bulletin controls.

This bulletin outlines the Division's views on Rule 14a-8(i)(7), the ordinary business exception, and Rule 14a-8(i)(5), the economic relevance exception. We are also republishing, with primarily technical, conforming changes, the guidance contained in SLB No 14I and 14K relating to the u e of graphic and image , and proof of owner hip letters. In addition, we are providing new guidance on the use of e-mail for submission of proposals, delivery of notice of defects, and responses to those notices.

In Rule 14a-8, the Commission has provided a means by which shareholders can present proposals for the shareholders' consideration in the company's proxy statement. This process has become a cornerstone of shareholder engagement on important matters. Rule 14a-8 sets forth several bases for exclusion of such propo al Companie often reque t a urance that the taff will not recommend enforcement action if they omit a proposal based on one of these exclusions ("no-action relief"). The Division is issuing this bulletin to streamline and simplify our process for reviewing no-action requests, and to clarify the standards staff will apply when evaluating these requests.

B. Rule 14a-8(i)(7)

1. Background

Rule 14a-8(i)(7), the ordinary business exception, is one of the substantive bases for exclusion of a shareholder proposal in Rule 14a-8. It permits a company to exclude a proposal that "deals with a matter relating to the company' ordinary bu ine operation " The purpo e of the e ception i "to confine the re olution of ordinary business problems to management and the board of directors, since it is impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting."[1]

2. Significant Social Policy Exception

Based on a review of the rescinded SLBs and staff experience applying the guidance in them, we recognize that an undue empha i wa placed on evaluating the ignificance of a policy i ue to a particular company at the expense of whether the proposal focuses on a significant social policy,[2] complicating the application of Commission policy to proposals. In particular, we have found that focusing on the significance of a policy issue to a particular company has drawn the staff into factual considerations that do not advance the policy objectives behind the ordinary bu ine e ception We have al o concluded that uch analy i did not yield con i tent, predictable results.

Going forward, the taff will realign it approach for determining whether a propo al relate to "ordinary bu ine " with the standard the Commission initially articulated in 1976, which provided an exception for certain proposals that raise significant social policy issues,[3] and which the Commission subsequently reaffirmed in the 1998 Release. This exception is essential for preserving shareholders' right to bring important issues before other hareholder by mean of the company' pro y tatement, while al o recognizing the board' authority over mo t day-to-day business matters. For these reasons, staff will no longer focus on determining the nexus between a policy issue and the company, but will instead focus on the social policy significance of the issue that is the subject of the shareholder proposal. In making this determination, the staff will consider whether the proposal raises issues with a broad ocietal impact, uch that they tran cend the ordinary bu ine of the company [4]

Under this realigned approach, proposals that the staff previously viewed as excludable because they did not appear to rai e a policy i ue of ignificance for the company may no longer be viewed a e cludable under Rule 14a-8(i)(7). For example, proposals squarely raising human capital management issues with a broad societal impact would not be subject to exclusion solely because the proponent did not demonstrate that the human capital management issue was significant to the company.[5]

Because the staff is no longer taking a company-specific approach to evaluating the significance of a policy issue under Rule 14a-8(i)(7), it will no longer expect a board analysis as described in the rescinded SLBs as part of demon trating that the propo al i e cludable under the ordinary bu ine e clu ion Ba ed on our e perience, we believe that board analysis may distract the company and the staff from the proper application of the exclusion. Additionally, the "delta" component of board analysis – demonstrating that the difference between the company's existing actions addressing the policy issue and the proposal's request is insignificant – sometimes confounded the application of Rule 14a 8(i)(10)' ub tantial implementation tandard

3. Micromanagement

Upon further consideration, the staff has determined that its recent application of the micromanagement concept, as outlined in SLB Nos. 14J and 14K, expanded the concept of micromanagement beyond the Commission's policy directives. Specifically, we believe that the rescinded guidance may have been taken to mean that any limit on company or board di cretion con titute micromanagement

The Commission has stated that the policy underlying the ordinary business exception rests on two central con ideration The fir t relate to the propo al' ubject matter; the econd relate to the degree to which the proposal "micromanages" 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."[6] The Commission clarified in the 1998 Release that specific methods, timelines, or detail do not necessarily amount to micromanagement and are not di po itive of e cludability

Con i tent with Commi ion guidance, the taff will take a mea ured approach to evaluating companie ' micromanagement arguments – recognizing that proposals seeking detail or seeking to promote timeframes or methods do not per se constitute micromanagement. Instead, we will focus on the level of granularity sought in the proposal and whether and to what extent it inappropriately limits discretion of the board or management. We would e pect the level of detail included in a hareholder propo al to be con i tent with that needed to enable inve tor to assess an issuer's impacts, progress towards goals, risks or other strategic matters appropriate for shareholder input.

Our recent letter to ConocoPhillips Company[7] provides an example of our current approach to micromanagement. In that letter the staff denied no-action relief for a proposal requesting that the company set targets covering the greenhouse gas emissions of the company's operations and products. The proposal reque ted that the company et emi ion reduction target and it did not impo e a pecific method for doing o The staff concluded this proposal did not micromanage to such a degree to justify exclusion under Rule 14a-8(i)(7).

Additionally, in order to assess whether a proposal probes matters "too complex" for shareholders, as a group, to make an informed judgment,[8] we may consider the sophistication of investors generally on the matter, the availability of data, and the robustness of public discussion and analysis on the topic. The staff may also consider reference to well e tabli hed national or international framework when a e ing propo al related to disclosure, target setting, and timeframes as indicative of topics that shareholders are well-equipped to evaluate.

Thi approach i con i tent with the Commi ion' view on the ordinary bu ine e clu ion, which i de igned to preserve management's discretion on ordinary business matters but not prevent shareholders from providing high-level direction on large strategic corporate matters. As the Commission stated in its 1998 Release:

> [In] the Proposing Release we explained that one of the considerations in making the ordinary business determination was the degree to which the proposal seeks to micro-manage the company. We cited examples such as where the proposal seeks intricate detail, or seeks to impose specific time-frames or to impo e pecific method for implementing comple policie Some commenter thought that the e ample cited seemed to imply that all proposals seeking detail, or seeking to promote time-frames or methods, necessarily amount to 'ordinary business.' We did not intend such an implication. Timing questions, for instance, could involve significant policy where large differences are at stake, and proposals may seek a rea onable level of detail without running afoul of the e con ideration

While the analysis in this bulletin may apply to any subject matter, many of the proposals addressed in the re cinded SLB reque ted companie adopt timeframe or target to addre climate change that the taff concurred were excludable on micromanagement grounds.[9] Going forward we would not concur in the exclusion of similar proposals that suggest targets or timelines so long as the proposals afford discretion to management as to how to achieve such goals.[10] We believe our current approach to micromanagement will help to avoid the dilemma many proponent faced when eeking to craft propo al with ufficient pecificity and direction to avoid being excluded under Rule 14a-8(i)(10), substantial implementation, while being general enough to avoid exclusion for "micromanagement."[11]

C. Rule 14a-8(i)(5)

Rule 14a-8(i)(5), the "economic relevance" exception, permits a company to exclude a proposal that "relates to operations which account for less than 5 percent of the company's total assets at the end of its most recent fiscal year, and for less than 5 percent of its net earnings and gross sales for its most recent fiscal year, and is not otherwi e ignificantly related to the company' bu ine "

Based on a review of the rescinded SLBs and staff experience applying the guidance in them, we are returning to our long tanding approach, prior to SLB No 14I, of analyzing Rule 14a 8(i)(5) in a manner we believe i con i tent with Lovenheim v. Iroquois Brands, Ltd.[12] As a result, and consistent with our pre-SLB No. 14I approach and Lovenheim, proposals that raise issues of broad social or ethical concern related to the company's business may

not be excluded, even if the relevant business falls below the economic thresholds of Rule 14a-8(i)(5). In light of this approach, the staff will no longer expect a board analysis for its consideration of a no-action request under Rule 14a-8(i)(5).

D. Rule 14a-8(d)[13]

1. Background

Rule 14a-8(d) is one of the procedural bases for exclusion of a shareholder proposal in Rule 14a-8. It provides that a "proposal, including any accompanying supporting statement, may not exceed 500 words."

2. The Use of Images in Shareholder Proposals

Questions have arisen concerning the application of Rule 14a-8(d) to proposals that include graphs and/or images.[14] The staff has expressed the view that the use of "500 words" and absence of express reference to graphics or images in Rule 14a-8(d) do not prohibit the inclusion of graphs and/or images in proposals.[15] Just as companies include graphics that are not expressly permitted under the disclosure rules, the Division is of the view that Rule 14a-8(d) does not preclude shareholders from using graphics to convey information about their proposals.[16]

The Division recognizes the potential for abuse in this area. The Division believes, however, that these potential abuses can be addressed through other provisions of Rule 14a-8. For example, exclusion of graphs and/or images would be appropriate under Rule 14a-8(i)(3) where they:

- make the proposal materially false or misleading;
- render the proposal so inherently vague or indefinite that neither the stockholders voting on the proposal, nor the company in implementing it, would be able to determine with any reasonable certainty exactly what actions or measures the proposal requires;
- directly or indirectly impugn character, integrity or personal reputation, or directly or indirectly make charges concerning improper, illegal, or immoral conduct or association, without factual foundation; or
- are irrelevant to a consideration of the subject matter of the proposal, such that there is a strong likelihood that a reasonable shareholder would be uncertain as to the matter on which he or she is being asked to vote.[17]

Exclusion would also be appropriate under Rule 14a-8(d) if the total number of words in a proposal, including words in the graphics, exceeds 500.

E. Proof of Ownership Letters[18]

In relevant part, Rule 14a-8(b) provides that a proponent must prove eligibility to submit a proposal by offering proof that it "continuously held" the required amount of securities for the required amount of time.[19]

In Section C of SLB No. 14F, we identified two common errors shareholders make when submitting proof of ownership for purposes of satisfying Rule 14a-8(b)(2).[20] In an effort to reduce such errors, we provided a suggested format for shareholders and their brokers or banks to follow when supplying the required verification of ownership.[21] Below, we have updated the suggested format to reflect recent changes to the ownership thresholds due to the Commission's 2020 rulemaking.[22] We note that brokers and banks are not required to follow this format.

> "As of [date the proposal is submitted], [name of shareholder] held, and has held continuously for at least [one year] [two years] [three years], [number of securities] shares of [company name] [class of securities]."

Some companies apply an overly technical reading of proof of ownership letters as a means to exclude a proposal. We generally do not find arguments along these lines to be persuasive. For example, we did not concur with the excludability of a proposal based on Rule 14a-8(b) where the proof of ownership letter deviated from the format set forth in SLB No. 14F.[23] In those cases, we concluded that the proponent nonetheless had supplied documentary support sufficiently evidencing the requisite minimum ownership requirements, as required by Rule 14a-8(b). We took a plain meaning approach to interpreting the text of the proof of ownership letter, and we expect companies to apply a similar approach in their review of such letters.

While we encourage shareholders and their brokers or banks to use the sample language provided above to avoid this issue, such formulation is neither mandatory nor the exclusive means of demonstrating the ownership requirements of Rule 14a-8(b).[24] We recognize that the requirements of Rule 14a-8(b) can be quite technical. Accordingly, companies should not seek to exclude a shareholder proposal based on drafting variances in the proof of ownership letter if the language used in such letter is clear and sufficiently evidences the requisite minimum ownership requirements.

We also do not interpret the recent amendments to Rule 14a-8(b)[25] to contemplate a change in how brokers or banks fulfill their role. In our view, they may continue to provide confirmation as to how many shares the proponent held continuously and need not separately calculate the share valuation, which may instead be done by the proponent and presented to the receiving issuer consistent with the Commission's 2020 rulemaking.[26] Finally, we believe that companies should identify any specific defects in the proof of ownership letter, even if the company previously sent a deficiency notice prior to receiving the proponent's proof of ownership if such deficiency notice did not identify the specific defect(s).

F. Use of E-mail

Over the past few years, and particularly during the pandemic, both proponents and companies have increasingly relied on the use of emails to submit proposals and make other communications. Some companies and proponents have expressed a preference for emails, particularly in cases where offices are closed. Unlike the use of third-party mail delivery that provides the sender with a proof of delivery, parties should keep in mind that methods for the confirmation of email delivery may differ. Email delivery confirmations and company server logs may not be sufficient to prove receipt of emails as they only serve to prove that emails were sent. In addition, spam filters or incorrect email addresses can prevent an email from being delivered to the appropriate recipient. The staff therefore suggests that to prove delivery of an email for purposes of Rule 14a-8, the sender should seek a reply e-mail from the recipient in which the recipient acknowledges receipt of the e-mail. The staff also encourages both companies and shareholder proponents to acknowledge receipt of emails when requested. Email read receipts, if received by the sender, may also help to establish that emails were received.

1. Submission of Proposals

Rule 14a-8(e)(1) provides that in order to avoid controversy, shareholders should submit their proposals by means, including electronic means, that permit them to prove the date of delivery. Therefore, where a dispute arises regarding a proposal's timely delivery, shareholder proponents risk exclusion of their proposals if they do not receive a confirmation of receipt from the company in order to prove timely delivery with email submissions. Additionally, in those instances where the company does not disclose in its proxy statement an email address for submitting proposals, we encourage shareholder proponents to contact the company to obtain the correct email address for submitting proposals before doing so and we encourage companies to provide such email addresses upon request.

2. Delivery of Notices of Defects

Similarly, if companies use email to deliver deficiency notices to proponents, we encourage them to seek a confirmation of receipt from the proponent or the representative in order to prove timely delivery. Rule 14a-8(f)(1) provides that the company must notify the shareholder of any defects within 14 calendar days of receipt of the proposal, and accordingly, the company has the burden to prove timely delivery of the notice.

3. Submitting Responses to Notices of Defects

Rule 14a-8(f)(1) also provides that a shareholder's response to a deficiency notice must be postmarked, or transmitted electronically, no later than 14 days from the date of receipt of the company's notification. If a shareholder uses email to responds to a company's deficiency notice, the burden is on the shareholder or representative to use an appropriate email address (e.g., an email address provided by the company, or the email address of the counsel who sent the deficiency notice), and we encourage them to seek confirmation of receipt.

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[1] Release No. 34-40018 (May 21, 1998) (the "1998 Release"). Stated a bit differently, the Commission has explained that "[t]he 'ordinary business' exclusion is based in part on state corporate law establishing spheres of authority for the board of directors on one hand, and the company's shareholders on the other." Release No. 34-39093 (Sept. 18, 1997).

[2] For example, SLB No. 14K explained that the staff "takes a company-specific approach in evaluating significance, rather than recognizing particular issues or categories of issues as universally 'significant.'" Staff Legal Bulletin No. 14K (Oct. 16, 2019).

[3] Release No. 34-12999 (Nov. 22, 1976) (the "1976 Release") (stating, in part, "proposals of that nature [relating to the economic and safety considerations of a nuclear power plant], as well as others that have major implications, will in the future be considered beyond the realm of an issuer's ordinary business operations").

[4] 1998 Release ("[P]roposals . . . focusing on sufficiently significant social policy issues. . .generally would not be considered to be excludable, because the proposals would transcend the day-to-day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote")

[5] *See, e.g., Dollar General Corporation* (Mar. 6, 2020) (granting no-action relief for exclusion of a proposal requesting the board to issue a report on the use of contractual provisions requiring employees to arbitrate employment-related claims because the proposal did not focus on specific policy implications of the use of arbitration at the company). We note that in the 1998 Release the Commission stated: "[P]roposals relating to [workforce management] but focusing on sufficiently significant social policy issues (e.g., significant discrimination matters) generally would not be considered to be excludable, because the proposals would transcend the day to day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote." Matters related to employment discrimination are but one example of the workforce management proposals that may rise to the level of transcending the company's ordinary business operations.

[6] 1998 Release.

[7] *ConocoPhillips Company* (Mar. 19, 2021).

[8] *See* 1998 Release and 1976 Release

[9] *See, e.g.*, *PayPal Holdings, Inc.* (Mar. 6, 2018) (granting no-action relief for exclusion of a proposal asking the company to prepare a report on the feasibility of achieving net zero emissions by 2030 because the staff concluded it micromanaged the company); *Devon Energy Corporation* (Mar. 4, 2019) (granting no-action relief for exclusion of a proposal requesting that the board in annual reporting include disclosure of short-, medium- and long-term greenhouse gas targets aligned with the Paris Climate Agreement because the staff viewed the proposal as requiring the adoption of time bound targets)

[10] *See ConocoPhillips Company* (Mar. 19, 2021).

[11] To be more specific, shareholder proponents have expressed concerns that a proposal that was broadly worded might face exclusion under Rule 14a-8(i)(10). Conversely, if a proposal was too specific it risked exclusion under Rule 14a 8(i)(7) for micromanagement

[12] 618 F. Supp. 554 (D.D.C. 1985).

[13] This section previously appeared in SLB No. 14I (Nov. 1, 2017) and is republished here with only minor, conforming changes.

[14] Rule 14a-8(d) is intended to limit the amount of space a shareholder proposal may occupy in a company's proxy statement. *See* 1976 Release.

[15] *See General Electric Co.* (Feb. 3, 2017, Feb. 23, 2017); *General Electric Co.* (Feb. 23, 2016). These decisions were consistent with a longstanding Division position. *See Ferrofluidics Corp.* (Sept. 18, 1992).

[16]Companies should not minimize or otherwise diminish the appearance of a shareholder's graphic. For example, if the company includes its own graphics in its proxy statement, it should give similar prominence to a shareholder's graphics. If a company's proxy statement appears in black and white, however, the shareholder proposal and accompanying graphics may also appear in black and white.

[17] *See General Electric Co.* (Feb. 23, 2017).

[18] This section previously appeared in SLB No. 14K (Oct.16, 2019) and is republished here with minor, conforming changes. Additional discussion is provided in the final paragraph.

[19] Rule 14a-8(b) requires proponents to have continuously held at least $2,000, $15,000, or $25,000 in market value of the company's securities entitled to vote on the proposal for at least three years, two years, or one year, respectively.

[20]Staff Legal Bulletin No. 14F (Oct. 18, 2011).

[21]The Division suggested the following formulation: "As of [date the proposal is submitted], [name of shareholder] held, and has held continuously for at least one year, [number of securities] shares of [company name] [class of securities]."

[22] Release No. 34-89964 (Sept. 23, 2020) (the "2020 Release").

[23] *See Amazon.com, Inc.* (Apr. 3, 2019); *Gilead Sciences, Inc.* (Mar. 7, 2019).

[24] *See* Staff Legal Bulletin No.14F, n.11.

[25] *See* 2020 Release.

[26] 2020 Release at n.55 ("Due to market fluctuations, the value of a shareholder's investment in a company may vary throughout the applicable holding period before the shareholder submits the proposal. In order to determine whether the shareholder satisfies the relevant ownership threshold, the shareholder should look at whether, on any date within the 60 calendar days before the date the shareholder submits the proposal, the shareholder's investment is valued at the relevant threshold or greater. For these purposes, companies and shareholders should determine the market value by multiplying the number of securities the shareholder continuously held for the relevant period by the highest selling price during the 60 calendar days before the shareholder submitted the proposal. For purposes of this calculation, it is important to note that a security's highest selling price is not necessarily the same as its highest closing price.") (citations omitted).

Modified: Nov. 3, 2021

Shareholder Proposals

Staff Legal Bulletin No. 14F (CF)

Action: Publication of CF Staff Legal Bulletin

Date October 18, 2011

Summary: This staff legal bulletin provides information for companies and shareholders regarding Rule 14a-8 under the Securitie E change Act of 1934

Supplementary Information: The statements in this bulletin represent the views of the Division of Corporation Finance (the "Divi ion") Thi bulletin i not a rule, regulation or tatement of the Securitie and E change Commission (the "Commission"). Further, the Commission has neither approved nor disapproved its content.

Contact For further information, plea e contact the Divi ion' Office of Chief Coun el by calling (202) 551 3500 or by submitting a web-based request form at https://www.sec.gov/forms/corp_fin_interpretive.

A. The purpose of this bulletin

Thi bulletin i part of a continuing effort by the Divi ion to provide guidance on important i ue ari ing under Exchange Act Rule 14a-8. Specifically, this bulletin contains information regarding:

- Broker and bank that con titute "record" holder under Rule 14a 8(b)(2)(i) for purpo e of verifying whether a beneficial owner is eligible to submit a proposal under Rule 14a-8;
- Common errors shareholders can avoid when submitting proof of ownership to companies;
- The submission of revised proposals;
- Procedures for withdrawing no-action requests regarding proposals submitted by multiple proponents; and
- The Division's new process for transmitting Rule 14a-8 no-action responses by email.

You can find additional guidance regarding Rule 14a 8 in the following bulletin that are available on the Commission's website: SLB No. 14, SLB No. 14A, SLB No. 14B, SLB No. 14C, SLB No. 14D and SLB No. 14E.

B. The types of brokers and banks that constitute "record" holders under Rule 14a-8(b)(2)(i) for purposes of verifying whether a beneficial owner is eligible to submit a proposal under Rule 14a-8

1. Eligibility to submit a proposal under Rule 14a-8

To be eligible to submit a shareholder proposal, a shareholder must have continuously held at least $2,000 in market value, or 1%, of the company's securities entitled to be voted on the proposal at the shareholder meeting for at lea t one year a of the date the hareholder ubmit the propo al The hareholder mu t al o continue to hold the required amount of securities through the date of the meeting and must provide the company with a written statement of intent to do so.[1]

The tep that a hareholder mu t take to verify hi or her eligibility to ubmit a propo al depend on how the shareholder owns the securities. There are two types of security holders in the U.S.: registered owners and beneficial owners.[2] Registered owners have a direct relationship with the issuer because their ownership of shares is listed on the records maintained by the issuer or its transfer agent. If a shareholder is a registered owner, the company can independently confirm that the hareholder' holding ati fy Rule 14a 8(b)' eligibility requirement

The vast majority of investors in shares issued by U.S. companies, however, are beneficial owners, which means that they hold their ecuritie in book entry form through a ecuritie intermediary, uch a a broker or a bank Beneficial owners are sometimes referred to as "street name" holders. Rule 14a-8(b)(2)(i) provides that a beneficial owner can provide proof of ownership to support his or her eligibility to submit a proposal by submitting a written statement "from the 'record' holder of [the] securities (usually a broker or bank)," verifying that, at the time the propo al wa ubmitted, the hareholder held the required amount of ecuritie continuou ly for at lea t one year.[3]

2. The role of the Depository Trust Company

Most large U.S. brokers and banks deposit their customers' securities with, and hold those securities through, the Depository Trust Company ("DTC"), a registered clearing agency acting as a securities depository. Such brokers and bank are often referred to a "participant " in DTC [4] The name of the e DTC participant , however, do not appear as the registered owners of the securities deposited with DTC on the list of shareholders maintained by the company or, more typically, by its transfer agent. Rather, DTC's nominee, Cede & Co., appears on the shareholder list as the sole registered owner of securities deposited with DTC by the DTC participants. A company can request from DTC a " ecuritie po ition li ting" a of a pecified date, which identifie the DTC participant having a position in the company's securities and the number of securities held by each DTC participant on that date.[5]

3. Brokers and banks that constitute "record" holders under Rule 14a-8(b)(2)(i) for purposes of verifying whether a beneficial owner is eligible to submit a proposal under Rule 14a-8

In *The Hain Celestial Group, Inc.* (Oct. 1, 2008), we took the position that an introducing broker could be considered a "record" holder for purposes of Rule 14a-8(b)(2)(i). An introducing broker is a broker that engages in ale and other activitie involving cu tomer contact, uch a opening cu tomer account and accepting cu tomer orders, but is not permitted to maintain custody of customer funds and securities.[6] Instead, an introducing broker engages another broker, known as a "clearing broker," to hold custody of client funds and securities, to clear and execute customer trades, and to handle other functions such as issuing confirmations of customer trades and cu tomer account tatement Clearing broker generally are DTC participant ; introducing broker generally are not. As introducing brokers generally are not DTC participants, and therefore typically do not appear on DTC's securities position listing, *Hain Celestial* has required companies to accept proof of ownership letters from brokers in cases where, unlike the positions of registered owners and brokers and banks that are DTC participants, the company i unable to verify the po ition again t it own or it tran fer agent' record or again t DTC' ecuritie position listing.

In light of que tion we have received following two recent court ca e relating to proof of owner hip under Rule 14a-8[7] and in light of the Commission's discussion of registered and beneficial owners in the Proxy Mechanics Concept Release, we have reconsidered our views as to what types of brokers and banks should be considered "record" holders under Rule 14a-8(b)(2)(i). Because of the transparency of DTC participants' positions in a company' ecuritie , we will take the view going forward that, for Rule 14a 8(b)(2)(i) purpo e , only DTC participants should be viewed as "record" holders of securities that are deposited at DTC. As a result, we will no longer follow *Hain Celestial*.

We believe that taking this approach as to who constitutes a "record" holder for purposes of Rule 14a-8(b)(2)(i) will provide greater certainty to beneficial owners and companies. We also note that this approach is consistent with Exchange Act Rule 12g5-1 and a 1988 staff no-action letter addressing that rule,[8] under which brokers and banks

that are DTC participant are con idered to be the record holder of ecuritie on depo it with DTC when calculating the number of record holders for purposes of Sections 12(g) and 15(d) of the Exchange Act.

Companie have occa ionally e pre ed the view that, becau e DTC' nominee, Cede & Co , appear on the shareholder list as the sole registered owner of securities deposited with DTC by the DTC participants, only DTC or Cede & Co. should be viewed as the "record" holder of the securities held on deposit at DTC for purposes of Rule 14a-8(b)(2)(i). We have never interpreted the rule to require a shareholder to obtain a proof of ownership letter from DTC or Cede & Co , and nothing in thi guidance hould be con trued a changing that view

How can a shareholder determine whether his or her broker or bank is a DTC participant

Shareholders and companies can confirm whether a particular broker or bank is a DTC participant by checking DTC' participant li t, which i currently available on the Internet at http://www.dtcc.com/~/media/Files/Downloads/client-center/DTC/alpha.ashx.

What if a shareholder's broker or bank is not on DTC's participant list

The shareholder will need to obtain proof of ownership from the DTC participant through which the securities are held The hareholder hould be able to find out who thi DTC participant i by a king the hareholder' broker or bank.[9]

If the DTC participant know the hareholder' broker or bank' holding , but doe not know the shareholder's holdings, a shareholder could satisfy Rule 14a-8(b)(2)(i) by obtaining and submitting two proof of ownership statements verifying that, at the time the proposal was submitted, the required amount of securities were continuously held for at least one year – one from the shareholder's broker or bank confirming the hareholder' owner hip, and the other from the DTC participant confirming the broker or bank' ownership.

How will the staff process no action requests that argue for exclusion on the basis that the shareholder's proof of ownership is not from a DTC participant?

The taff will grant no action relief to a company on the ba i that the hareholder' proof of owner hip i not from a DTC participant only if the company's notice of defect describes the required proof of ownership in a manner that is consistent with the guidance contained in this bulletin. Under Rule 14a-8(f)(1), the shareholder will have an opportunity to obtain the requisite proof of ownership after receiving the notice of defect.

C. Common errors shareholders can avoid when submitting proof of ownership to companies

In this section, we describe two common errors shareholders make when submitting proof of ownership for purposes of Rule 14a-8(b)(2), and we provide guidance on how to avoid these errors.

First, Rule 14a-8(b) requires a shareholder to provide proof of ownership that he or she has "continuously held at least $2,000 in market value, or 1%, of the company's securities entitled to be voted on the proposal at the meeting for at least one year by the date you submit the proposal" (emphasis added).[10] We note that many proof of owner hip letter do not ati fy thi requirement becau e they do not verify the hareholder' beneficial ownership for the entire one-year period preceding and including the date the proposal is submitted. In some cases, the letter speaks as of a date *before* the date the proposal is submitted, thereby leaving a gap between the date of the verification and the date the proposal is submitted. In other cases, the letter speaks as of a date *after* the date the propo al wa ubmitted but cover a period of only one year, thu failing to verify the hareholder' beneficial ownership over the required full one-year period preceding the date of the proposal's submission.

Second, many letters fail to confirm continuous ownership of the securities. This can occur when a broker or bank submits a letter that confirms the shareholder's beneficial ownership only as of a specified date but omits any reference to continuous ownership for a one-year period.

We recognize that the requirements of Rule 14a-8(b) are highly prescriptive and can cause inconvenience for shareholders when submitting proposals. Although our administration of Rule 14a-8(b) is constrained by the terms of the rule, we believe that shareholders can avoid the two errors highlighted above by arranging to have their broker or bank provide the required verification of ownership as of the date they plan to submit the proposal using the following format:

> "As of [date the proposal is submitted], [name of shareholder] held, and has held continuously for at least one year, [number of securities] shares of [company name] [class of securities]."[11]

As discussed above, a shareholder may also need to provide a separate written statement from the DTC participant through which the shareholder's securities are held if the shareholder's broker or bank is not a DTC participant.

D. The submission of revised proposals

On occasion, a shareholder will revise a proposal after submitting it to a company. This section addresses questions we have received regarding revisions to a proposal or supporting statement.

1. A shareholder submits a timely proposal. The shareholder then submits a revised proposal before the company's deadline for receiving proposals. Must the company accept the revisions?

Yes. In this situation, we believe the revised proposal serves as a replacement of the initial proposal. By submitting a revised proposal, the shareholder has effectively withdrawn the initial proposal. Therefore, the shareholder is not in violation of the one-proposal limitation in Rule 14a-8(c).[12] If the company intends to submit a no-action request, it must do so with respect to the revised proposal.

We recognize that in Question and Answer E.2 of SLB No. 14, we indicated that if a shareholder makes revisions to a proposal before the company submits its no-action request, the company can choose whether to accept the revisions. However, this guidance has led some companies to believe that, in cases where shareholders attempt to make changes to an initial proposal, the company is free to ignore such revisions even if the revised proposal is submitted before the company's deadline for receiving shareholder proposals. We are revising our guidance on this issue to make clear that a company may not ignore a revised proposal in this situation.[13]

2. A shareholder submits a timely proposal. After the deadline for receiving proposals, the shareholder submits a revised proposal. Must the company accept the revisions?

No. If a shareholder submits revisions to a proposal after the deadline for receiving proposals under Rule 14a-8(e), the company is not required to accept the revisions. However, if the company does not accept the revisions, it must treat the revised proposal as a second proposal and submit a notice stating its intention to exclude the revised proposal, as required by Rule 14a-8(j). The company's notice may cite Rule 14a-8(e) as the reason for excluding the revised proposal. If the company does not accept the revisions and intends to exclude the initial proposal, it would also need to submit its reasons for excluding the initial proposal.

3. If a shareholder submits a revised proposal, as of which date must the shareholder prove his or her share ownership?

A shareholder must prove ownership as of the date the original proposal is submitted. When the Commission has discussed revisions to proposals,[14] it has not suggested that a revision triggers a requirement to provide proof of ownership a second time. As outlined in Rule 14a-8(b), proving ownership includes providing a written statement

that the shareholder intends to continue to hold the securities through the date of the shareholder meeting. Rule 14a-8(f)(2) provides that if the shareholder "fails in [his or her] promise to hold the required number of securities through the date of the meeting of shareholders, then the company will be permitted to exclude all of [the same shareholder's] proposals from its proxy materials for any meeting held in the following two calendar years." With these provisions in mind, we do not interpret Rule 14a-8 as requiring additional proof of ownership when a shareholder submits a revised proposal.[15]

E. Procedures for withdrawing no-action requests for proposals submitted by multiple proponents

We have previously addressed the requirements for withdrawing a Rule 14a-8 no-action request in SLB Nos. 14 and 14C. SLB No. 14 notes that a company should include with a withdrawal letter documentation demonstrating that a shareholder has withdrawn the proposal. In cases where a proposal submitted by multiple shareholders is withdrawn, SLB No. 14C states that, if each shareholder has designated a lead individual to act on its behalf and the company is able to demonstrate that the individual is authorized to act on behalf of all of the proponents, the company need only provide a letter from that lead individual indicating that the lead individual is withdrawing the proposal on behalf of all of the proponents.

Because there is no relief granted by the staff in cases where a no-action request is withdrawn following the withdrawal of the related proposal, we recognize that the threshold for withdrawing a no-action request need not be overly burdensome. Going forward, we will process a withdrawal request if the company provides a letter from the lead filer that includes a representation that the lead filer is authorized to withdraw the proposal on behalf of each proponent identified in the company's no-action request.[16]

F. Use of email to transmit our Rule 14a-8 no-action responses to companies and proponents

To date, the Division has transmitted copies of our Rule 14a-8 no-action responses, including copies of the correspondence we have received in connection with such requests, by U.S. mail to companies and proponents. We also post our response and the related correspondence to the Commission's website shortly after issuance of our response.

In order to accelerate delivery of staff responses to companies and proponents, and to reduce our copying and postage costs, going forward, we intend to transmit our Rule 14a-8 no-action responses by email to companies and proponents. We therefore encourage both companies and proponents to include email contact information in any correspondence to each other and to us. We will use U.S. mail to transmit our no-action response to any company or proponent for which we do not have email contact information.

Given the availability of our responses and the related correspondence on the Commission's website and the requirement under Rule 14a-8 for companies and proponents to copy each other on correspondence submitted to the Commission, we believe it is unnecessary to transmit copies of the related correspondence along with our no-action response. Therefore, we intend to transmit only our staff response and not the correspondence we receive from the parties. We will continue to post to the Commission's website copies of this correspondence at the same time that we post our staff no-action response.

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[1] *See* Rule 14a-8(b).

[2] For an explanation of the types of share ownership in the U.S., see Concept Release on U.S. Proxy System, Release No. 34-62495 (July 14, 2010) [75 FR 42982] ("Proxy Mechanics Concept Release"), at Section II.A. The term "beneficial owner" does not have a uniform meaning under the federal securities laws. It has a different meaning in this bulletin as compared to "beneficial owner" and "beneficial ownership" in Sections 13 and 16 of the

Exchange Act. Our use of the term in this bulletin is not intended to suggest that registered owners are not beneficial owners for purposes of those Exchange Act provisions. *See* Proposed Amendments to Rule 14a-8 under the Securities Exchange Act of 1934 Relating to Proposals by Security Holders, Release No. 34-12598 (July 7, 1976) [41 FR 29982], at n.2 ("The term 'beneficial owner' when used in the context of the proxy rules, and in light of the purposes of those rules, may be interpreted to have a broader meaning than it would for certain other purpose[s] under the federal securities laws, such as reporting pursuant to the Williams Act.").

[3] If a shareholder has filed a Schedule 13D, Schedule 13G, Form 3, Form 4 or Form 5 reflecting ownership of the required amount of shares, the shareholder may instead prove ownership by submitting a copy of such filings and providing the additional information that is described in Rule 14a-8(b)(2)(ii).

[4] DTC holds the deposited securities in "fungible bulk," meaning that there are no specifically identifiable shares directly owned by the DTC participants. Rather, each DTC participant holds a pro rata interest or position in the aggregate number of shares of a particular issuer held at DTC. Correspondingly, each customer of a DTC participant – such as an individual investor – owns a pro rata interest in the shares in which the DTC participant has a pro rata interest. *See* Proxy Mechanics Concept Release, at Section II.B.2.a.

[5] *See* Exchange Act Rule 17Ad-8.

[6] *See* Net Capital Rule, Release No. 34-31511 (Nov. 24, 1992) [57 FR 56973] ("Net Capital Rule Release"), at Section II.C.

[7] *See KBR Inc. v. Chevedden*, Civil Action No. H-11-0196, 2011 U.S. Dist. LEXIS 36431, 2011 WL 1463611 (S.D. Tex. Apr. 4, 2011); *Apache Corp. v. Chevedden,* 696 F. Supp. 2d 723 (S.D. Tex. 2010). In both cases, the court concluded that a securities intermediary was not a record holder for purposes of Rule 14a-8(b) because it did not appear on a list of the company's non-objecting beneficial owners or on any DTC securities position listing, nor was the intermediary a DTC participant.

[8] *Techne Corp.* (Sept. 20, 1988).

[9] In addition, if the shareholder's broker is an introducing broker, the shareholder's account statements should include the clearing broker's identity and telephone number. *See* Net Capital Rule Release, at Section II.C.(iii). The clearing broker will generally be a DTC participant.

[10] For purposes of Rule 14a-8(b), the submission date of a proposal will generally precede the company's receipt date of the proposal, absent the use of electronic or other means of same-day delivery.

[11] This format is acceptable for purposes of Rule 14a-8(b), but it is not mandatory or exclusive.

[12] As such, it is not appropriate for a company to send a notice of defect for multiple proposals under Rule 14a-8(c) upon receiving a revised proposal.

[13] This position will apply to all proposals submitted after an initial proposal but before the company's deadline for receiving proposals, regardless of whether they are explicitly labeled as "revisions" to an initial proposal, unless the shareholder affirmatively indicates an intent to submit a second, *additional* proposal for inclusion in the company's proxy materials. In that case, the company must send the shareholder a notice of defect pursuant to Rule 14a-8(f)(1) if it intends to exclude either proposal from its proxy materials in reliance on Rule 14a-8(c). In light of this guidance, with respect to proposals or revisions received before a company's deadline for submission, we will no longer follow *Layne Christensen Co.* (Mar. 21, 2011) and other prior staff no-action letters in which we took the view that a proposal would violate the Rule 14a-8(c) one-proposal limitation if such proposal is submitted to a company after the company has either submitted a Rule 14a-8 no-action request to exclude an earlier proposal submitted by the same proponent or notified the proponent that the earlier proposal was excludable under the rule.

[14] *See, e.g.*, Adoption of Amendments Relating to Proposals by Security Holders, Release No. 34-12999 (Nov. 22, 1976) [41 FR 52994].

[15] Because the relevant date for proving ownership under Rule 14a-8(b) is the date the proposal is submitted, a proponent who does not adequately prove ownership in connection with a proposal is not permitted to submit another proposal for the same meeting on a later date.

[16] Nothing in this staff position has any effect on the status of any shareholder proposal that is not withdrawn by the proponent or its authorized representative.

Modified: Oct. 18, 2011

Shareholder Proposals

Staff Legal Bulletin No. 14G (CF)

Action: Publication of CF Staff Legal Bulletin

Date October 16, 2012

Summary: This staff legal bulletin provides information for companies and shareholders regarding Rule 14a-8 under the Securitie E change Act of 1934

Supplementary Information: The statements in this bulletin represent the views of the Division of Corporation Finance (the "Divi ion") Thi bulletin i not a rule, regulation or tatement of the Securitie and E change Commission (the "Commission"). Further, the Commission has neither approved nor disapproved its content.

Contact For further information, plea e contact the Divi ion' Office of Chief Coun el by calling (202) 551 3500 or by submitting a web-based request form at https://www.sec.gov/forms/corp_fin_interpretive.

A. The purpose of this bulletin

Thi bulletin i part of a continuing effort by the Divi ion to provide guidance on important i ue ari ing under Exchange Act Rule 14a-8. Specifically, this bulletin contains information regarding:

- the partie that can provide proof of owner hip under Rule 14a 8(b)(2)(i) for purpo e of verifying whether a beneficial owner is eligible to submit a proposal under Rule 14a-8;
- the manner in which companie hould notify proponent of a failure to provide proof of owner hip for the one-year period required under Rule 14a-8(b)(1); and
- the u e of web ite reference in propo al and upporting tatement

You can find additional guidance regarding Rule 14a-8 in the following bulletins that are available on the Commi ion' web ite SLB No 14, SLB No 14A, SLB No 14B, SLB No 14C, SLB No 14D, SLB No 14E and SLB No. 14F.

B. Parties that can provide proof of ownership under Rule 14a-8(b)(2)(i) for purposes of verifying whether a beneficial owner is eligible to submit a proposal under Rule 14a-8

1. Sufficiency of proof of ownership letters provided by affiliates of DTC participants for purposes of Rule 14a-8(b)(2)(i)

To be eligible to ubmit a propo al under Rule 14a 8, a hareholder mu t, among other thing , provide documentation evidencing that the shareholder has continuously held at least $2,000 in market value, or 1%, of the company's securities entitled to be voted on the proposal at the shareholder meeting for at least one year as of the date the shareholder submits the proposal. If the shareholder is a beneficial owner of the securities, which

mean that the ecuritie are held in book entry form through a ecuritie intermediary, Rule 14a 8(b)(2)(i) provides that this documentation can be in the form of a "written statement from the 'record' holder of your securities (usually a broker or bank)…."

In SLB No. 14F, the Division described its view that only securities intermediaries that are participants in the Depository Trust Company ("DTC") should be viewed as "record" holders of securities that are deposited at DTC for purposes of Rule 14a-8(b)(2)(i). Therefore, a beneficial owner must obtain a proof of ownership letter from the DTC participant through which it ecuritie are held at DTC in order to ati fy the proof of owner hip requirement in Rule 14a-8.

During the mo t recent pro y ea on, ome companie que tioned the ufficiency of proof of owner hip letter from entities that were not themselves DTC participants, but were affiliates of DTC participants.[1] By virtue of the affiliate relationship, we believe that a securities intermediary holding shares through its affiliated DTC participant should be in a position to verify its customers' ownership of securities. Accordingly, we are of the view that, for purpo e of Rule 14a 8(b)(2)(i), a proof of owner hip letter from an affiliate of a DTC participant ati fie the requirement to provide a proof of ownership letter from a DTC participant.

2. Adequacy of proof of ownership letters from securities intermediaries that are not brokers or banks

We under tand that there are circum tance in which ecuritie intermediarie that are not broker or bank maintain securities accounts in the ordinary course of their business. A shareholder who holds securities through a securities intermediary that is not a broker or bank can satisfy Rule 14a-8's documentation requirement by submitting a proof of ownership letter from that securities intermediary.[2] If the securities intermediary is not a DTC participant or an affiliate of a DTC participant, then the hareholder will al o need to obtain a proof of owner hip letter from the DTC participant or an affiliate of a DTC participant that can verify the holdings of the securities intermediary.

C. Manner in which companies should notify proponents of a failure to provide proof of ownership for the one-year period required under Rule 14a-8(b)(1)

As discussed in Section C of SLB No. 14F, a common error in proof of ownership letters is that they do not verify a proponent's beneficial ownership for the entire one-year period preceding and including the date the proposal was submitted, as required by Rule 14a-8(b)(1). In some cases, the letter speaks as of a date *before* the date the propo al wa ubmitted, thereby leaving a gap between the date of verification and the date the propo al wa submitted. In other cases, the letter speaks as of a date *after* the date the proposal was submitted but covers a period of only one year, thus failing to verify the proponent's beneficial ownership over the required full one-year period preceding the date of the proposal's submission.

Under Rule 14a-8(f), if a proponent fails to follow one of the eligibility or procedural requirements of the rule, a company may exclude the proposal only if it notifies the proponent of the defect and the proponent fails to correct it In SLB No 14 and SLB No 14B, we e plained that companie hould provide adequate detail about what a proponent must do to remedy all eligibility or procedural defects.

We are concerned that companie ' notice of defect are not adequately de cribing the defect or e plaining what a proponent must do to remedy defects in proof of ownership letters. For example, some companies' notices of defect make no mention of the gap in the period of ownership covered by the proponent's proof of ownership letter or other specific deficiencies that the company has identified. We do not believe that such notices of defect serve the purpo e of Rule 14a 8(f)

Accordingly, going forward, we will not concur in the exclusion of a proposal under Rules 14a-8(b) and 14a-8(f) on the ba i that a proponent' proof of owner hip doe not cover the one year period preceding and including the

date the propo al i ubmitted unle the company provide a notice of defect that identifie the pecific date on which the proposal was submitted and explains that the proponent must obtain a new proof of ownership letter verifying continuous ownership of the requisite amount of securities for the one-year period preceding and including such date to cure the defect. We view the proposal's date of submission as the date the proposal is po tmarked or tran mitted electronically Identifying in the notice of defect the pecific date on which the propo al was submitted will help a proponent better understand how to remedy the defects described above and will be particularly helpful in those instances in which it may be difficult for a proponent to determine the date of submission, such as when the proposal is not postmarked on the same day it is placed in the mail. In addition, companie hould include copie of the po tmark or evidence of electronic tran mi ion with their no action requests.

D. Use of website addresses in proposals and supporting statements

Recently, a number of proponent have included in their propo al or in their upporting tatement the addre e to websites that provide more information about their proposals. In some cases, companies have sought to exclude either the website address or the entire proposal due to the reference to the website address.

In SLB No. 14, we explained that a reference to a website address in a proposal does not raise the concerns addressed by the 500-word limitation in Rule 14a-8(d). We continue to be of this view and, accordingly, we will continue to count a website address as one word for purposes of Rule 14a-8(d). To the extent that the company eek the e clu ion of a web ite reference in a propo al, but not the propo al it elf, we will continue to follow the guidance stated in SLB No. 14, which provides that references to website addresses in proposals or supporting statements could be subject to exclusion under Rule 14a-8(i)(3) if the information contained on the website is materially false or misleading, irrelevant to the subject matter of the proposal or otherwise in contravention of the pro y rule , including Rule 14a 9 [3]

In light of the growing interest in including references to website addresses in proposals and supporting tatement , we are providing additional guidance on the appropriate u e of web ite addre e in propo al and supporting statements.[4]

1. References to website addresses in a proposal or supporting statement and Rule 14a-8(i)(3)

Reference to web ite in a propo al or upporting tatement may rai e concern under Rule 14a 8(i)(3) In SLB No. 14B, we stated that the exclusion of a proposal under Rule 14a-8(i)(3) as vague and indefinite may be appropriate if neither the shareholders voting on the proposal, nor the company in implementing the proposal (if adopted), would be able to determine with any reasonable certainty exactly what actions or measures the proposal require In evaluating whether a propo al may be e cluded on thi ba i , we con ider only the information contained in the proposal and supporting statement and determine whether, based on that information, shareholders and the company can determine what actions the proposal seeks.

If a proposal or supporting statement refers to a website that provides information necessary for shareholders and the company to understand with reasonable certainty exactly what actions or measures the proposal requires, and such information is not also contained in the proposal or in the supporting statement, then we believe the proposal would rai e concern under Rule 14a 9 and would be ubject to e clu ion under Rule 14a 8(i)(3) a vague and indefinite. By contrast, if shareholders and the company can understand with reasonable certainty exactly what actions or measures the proposal requires without reviewing the information provided on the website, then we believe that the proposal would not be subject to exclusion under Rule 14a-8(i)(3) on the basis of the reference to the web ite addre In thi ca e, the information on the web ite only upplement the information contained in the proposal and in the supporting statement.

2. Providing the company with the materials that will be published on the referenced website

We recognize that if a proposal references a website that is not operational at the time the proposal is submitted, it will be impossible for a company or the staff to evaluate whether the website reference may be excluded. In our view, a reference to a non-operational website in a proposal or supporting statement could be excluded under Rule 14a-8(i)(3) as irrelevant to the subject matter of a proposal. We understand, however, that a proponent may wish to include a reference to a website containing information related to the proposal but wait to activate the website until it becomes clear that the proposal will be included in the company's proxy materials. Therefore, we will not concur that a reference to a website may be excluded as irrelevant under Rule 14a-8(i)(3) on the basis that it is not yet operational if the proponent, at the time the proposal is submitted, provides the company with the materials that are intended for publication on the website and a representation that the website will become operational at, or prior to, the time the company files its definitive proxy materials.

3. Potential issues that may arise if the content of a referenced website changes after the proposal is submitted

To the extent the information on a website changes after submission of a proposal and the company believes the revised information renders the website reference excludable under Rule 14a-8, a company seeking our concurrence that the website reference may be excluded must submit a letter presenting its reasons for doing so. While Rule 14a-8(j) requires a company to submit its reasons for exclusion with the Commission no later than 80 calendar days before it files its definitive proxy materials, we may concur that the changes to the referenced website constitute "good cause" for the company to file its reasons for excluding the website reference after the 80-day deadline and grant the company's request that the 80-day requirement be waived.

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[1] An entity is an "affiliate" of a DTC participant if such entity directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the DTC participant.

[2] Rule 14a-8(b)(2)(i) itself acknowledges that the record holder is "usually," but not always, a broker or bank.

[3] Rule 14a-9 prohibits statements in proxy materials which, at the time and in the light of the circumstances under which they are made, are false or misleading with respect to any material fact, or which omit to state any material fact necessary in order to make the statements not false or misleading.

[4] A website that provides more information about a shareholder proposal may constitute a proxy solicitation under the proxy rules. Accordingly, we remind shareholders who elect to include website addresses in their proposals to comply with all applicable rules regarding proxy solicitations.

Modified: Oct. 16, 2012

The Province of St. Joseph of the Capuchin Order
Office of Corporate Responsibility

February 9, 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 Merck & Co., Inc. to omit proposal submitted by Province of Saint Joseph of the Capuchin Order and co-filers

Ladies and Gentlemen:

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Province of Saint Joseph of the Capuchin Order and nine co-filers (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to Merck & Co., Inc. ("Merck" or the "Company"). The Proposal asks Merck's board to establish and report on a process by which the impact of extended patent exclusivities on product access would be considered when deciding whether to apply for secondary and tertiary patents.

In a letter to the Division dated January 13, 2023 (the "No-Action Request"), Merck stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2023 annual meeting of shareholders. Merck argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), on the ground that the Proposal deals with Merck's ordinary business operations. As discussed more fully below, Merck has not met its burden of proving its entitlement to exclude the Proposal in reliance on that exclusion and the Proponents respectfully request that Merck's request for relief be denied.

The Proposal

The Proposal states:

> RESOLVED, that shareholders of Merck & Co., Inc. ("Merck") 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 Merck'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] One study estimates that "[p]rescription drug spending on retail and non-retail drugs is poised to grow 63% from 2020 to 2030, reaching $917 billion dollars."[2]

Congress has carefully balanced incentivizing scientific innovation in pharmaceuticals with promoting competition in the name of affordability.[3] 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.[4] 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.[5]

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[6] patents--that are expensive and time-consuming for a potential generic manufacturer to challenge.[7]

Overpatenting keeps prices high, impeding access. That impact is particularly troubling given that U.S. drug prices are the highest in the world[8]; the rise in spending on prescription drugs

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1 https://www.gao.gov/prescription-drug-spending

2 https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 2 (citing Charles Roehrig and Ani Turner, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report, Altarum, July 2022).

3 https://www.healthaffairs.org/do/10.1377/forefront.20181106.217086/full/

4 https://sgp.fas.org/crs/misc/R46221.pdf, at 1.

5 https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf

6 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/

7 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.

8 https://www.commonwealthfund.org/publications/podcast/2022/feb/its-the-patents-stupid-why-drugs-cost-so-much-in-us

outpaces increases in health care spending more generally[9]; and three in 10 Americans on a prescription drug report not taking their medicine as prescribed due to cost.[10] Studies show that the introduction of generic versions of a drug lead to significantly lower prices.[11] As of May 2021, Merck had filed for 95 secondary patents on Merck's cancer drug Keytruda.[12] More recently, Merck announced that it was developing a subcutaneous injection form of Keytruda—the drug is currently administered by infusion—which could enjoy exclusivity until as late as 2040.[13] The Proposal asks Merck to take the impact on patient access into account when making decisions about applying for secondary and tertiary patents on its medicines.

Ordinary Business

Merck 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 Merck safeguards its intellectual property ("IP"). Merck also claims that the Proposal would micromanage it. Neither argument has merit.

The Division generally regards a company's product offerings and choices about IP protections as ordinary business matters. However, the fact that a proposal implicates one of those subjects does not support exclusion if it focuses on a significant social policy issue, which is the case with the Proposal. For that reason, Merck's blanket statements that "decisions regarding intellectual property" and "shareholder proposals that relate to the products and services offered by a company" are excludable under Rule 14a-8(i)(7) are simplistic and inaccurate.

Last season, the Staff considered and rejected arguments much like those Merck now makes when determining that three different proposals to pharmaceutical firms addressing their products and 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 Merck 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.[14] 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 Merck'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,[15] as Merck does here. The

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9 https://sgp.fas.org/crs/misc/R46221.pdf, at 2.

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

11 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

12 http://www.i-mak.org/wp-content/uploads/2021/05/i-mak.keytruda.report-2021-05-06F.pdf, at 3.

13 See https://www.marketwatch.com/press-release/merck-stock-went-up-as-it-relied-on-a-new-formulation-of-keytruda-to-avoid-a-patent-cliff-2022-12-02

14 Johnson & Johnson (Feb. 8, 2022).

15 Pfizer, Inc. (Feb. 23, 2022); Moderna, Inc. (Feb. 8, 2022).

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 grounds of proposals addressing drug pricing and access.[16] 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 patient 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."[17] Although the proposals addressed anticompetitive practices other than patent thickets, these determinations illustrate that addressing IP does not doom a proposal.

Similar outcomes have been reached on other proposals involving pharmaceutical companies' products where a significant policy issue was implicated. The Staff did not agree with JNJ's 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[18] unsuccessfully argued that a proposal seeking a report on risks related to rising pressures to contain specialty drug prices was excludable on ordinary business grounds, pointing 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

In November 2021, the Staff shifted its approach to deciding whether a proposal's subject is a significant social policy issue. In Staff Legal Bulletin ("SLB") 14L,[20] the Staff announced that it would no longer focus on the significance of an issue to a particular company, but rather would

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

17 AbbVie, Inc. (Mar. 11, 2022); Pfizer, Inc. (Mar. 8, 2022).

18 Gilead Sciences Inc. (Feb. 23, 2015).

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

20 Staff Legal Bulletin 14L (Nov. 3, 2021)

analyze whether the proposal raises issues with a broad societal impact, such that they transcend the ordinary business of the company." The Proponents believe that the Proposal's subject would have qualified as a significant policy issue under the previous approach, but the focus on societal impact strengthens the case significantly. The role of IP protections in keeping drug prices high and limiting patient access is clearly a subject of consistent and widespread public debate, the standard applied in determining whether a proposal's subject transcends ordinary business operations.[21]

Media have given substantial attention to the issue, despite its technical nature. Examples include:

- Editorial Board, "Save America's Patent System," The New York Times, Apr. 17, 2022[22] ("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.")
- Rebecca Robbins, "How a Drug Company Made $114 Billion By Gaming the U.S. Patent System," The New York Times, Jan. 28, 2023 ("AbbVie orchestrated the delay [in loss of exclusivity, by six years] by building a formidable wall of intellectual property protection and suing would-be competitors before settling with them to delay their product launches until this year. The strategy has been a gold mine for AbbVie, at the expense of patients and taxpayers.")
- Editorial Board, "How Big Pharma plays games with drug patents and how to combat it," USA Today, Jan. 18, 2019[23] ("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[24]
- Berkeley Lovelace Jr., "'Gaming' of U.S. patent system is keeping drug prices sky high, report says," NBCNews.com, Sept. 15, 2022[25]
- "Biden Drug Price Pressure on Patent Office Draws Skeptics," Bloomberg, Sept. 21, 2021[26] ("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.")

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21 See, e.g., www.sec.gov/interps/legal/cfslb14a.htm.

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

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

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

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

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

- Cynthia Koons, "This Shield of Patents Protects the World's Best-selling Drug," Bloomberg Businessweek, Sept. 7, 2017[27]
- Matthew Lane, "The Key to Lowering Drug Prices is Improving Patent Quality," Techdirt, July 21, 2021[28] ("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[29] ("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').")
- Joe Cahill, "Humira Patent Strategy Makes the Case for Reform," Crain's Chicago Business, May 20, 2019[30]
- Gunjan Sinha, "How Patent Extensions Keep Some Drug Costs High," Undark, June 16, 2021[31]
- 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[32]
- Ryan Chatelain, "House committee report blasts drug pricing strategies as 'troubling,'" NY1, Dec. 10, 2021[33]
- 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[34]
- Matthew Lane, "To rein in Big Pharma over high drug prices, start with patent reform," Roll Call, Jan. 17, 2020[35] ("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

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

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

29 https://prospect.org/health/its-time-for-public-pharma/

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

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

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

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

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

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

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[36] ("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[37] ("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[38]
- "Congress takes aim again at pharmaceutical giant over patent-stacking for brand-name drugs," The Examiner (Washington, DC), May 20, 2021
- Robert Pearl, "Why Patent Protection in the Drug Industry is Out of Control," Forbes, Jan. 19, 2017[39]
- Ahmed Aboulenein, "Consumer group says drugmakers abuse U.S. patent system to keep prices high," Reuters, Sept. 16, 2022[40]
- Sarah Jane Tribble, "Drugmakers Play the Patent Game to Ward Off Competitors," NBCNews.com, Oct. 2, 2018[41]

Legislators and regulators have also focused on the impact of IP protections—and secondary and tertiary patents in particular—on access. Although attention shifted to the COVID-19 pandemic in 2020, policy initiatives proliferated both before and after that year.

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.[42] 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.[43] 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

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

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

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

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

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

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

42 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.

43 https://www.congress.gov/bill/116th-congress/house-bill/3199/text

challenges.[44] The Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019[45] 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.[46] 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 new 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 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.[47]

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.[48]

The House Judiciary Antitrust Subcommittee held a hearing in April 2021 on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."[49] Experts on drug companies' anticompetitive practices testified, including Professor Robin Feldman, who discussed the relationship between secondary patents and product-hopping.[50]

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

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44 https://www.congress.gov/bill/116th-congress/senate-bill/1617

45 https://www.congress.gov/bill/116th-congress/house-bill/3991

46 https://www.congress.gov/bill/117th-congress/house-bill/2873

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

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

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

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

2019.[51] 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.[52]

The House Oversight Committee initiated a sweeping investigation in 2019 into "pricing and business practices in the pharmaceutical industry."[53] 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."[54] 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."[55] 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."[56] 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."[57]

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

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

52 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.").

53 Until recently, the Committee's report on this investigation was available at oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf. With the change in control of the House from Democratic to Republican, the report appears no longer to be available online. Pinpoint cites are provided below to show the location of specific information cited in this response in the event the report is again made publicly available.

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

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

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

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

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."[58] 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."[59] Another witness identified patent thickets as key to high drug prices.[60]

The Senate Finance Committee held a hearing on "Drug Pricing in America: A Prescription for Change, Part I"[61] 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:

> 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.[62]

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.[63] In addition to the general problem posed by patent thickets, Kesselheim explained how secondary patents facilitate product hopping.[64]

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."[65] The E.O. also directed the Secretary of

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

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

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

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

62 https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf

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

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

65 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).

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.[66]

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."[67] 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."[68] The FDA specifically sought stakeholder input on patents, the citizen petition process, and obstacles faced by potential generic competitors in obtaining branded drug samples for testing.[69] 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."[70]

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.[71]

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."[72] 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."[73]

In 2022, Priti Krishtel, co-founder and co-executive director of patent watchdog group 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

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

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

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

69 https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

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

71 https://www.ag.state.mn.us/Office/Initiatives/PharmaceuticalDrugPrices/Taskforce.asp

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

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

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."[74]

The existence of a significant social policy issue, then, distinguishes the Proposal from those analyzed in the determinations Merck cites on pages 3-5 of the No-Action Request. All of those proposals sought to affect the kind of matters that are, in the Commission's words, "fundamental to management's ability to run a company on a day-to-day basis" and thus poorly suited for shareholder input.[75]

In many of the determinations on which Merck relies, the proponents unsuccessfully argued that the proposals' subjects were significant social policy issues. In Wells Fargo[76] and JPMorgan Chase,[77] the proposals focused on specific products that the proponents argued were forms of predatory lending, which had previously been found to transcend ordinary 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.

The same is true for the proposals in the Verizon,[78] Pfizer,[79] Disney,[80] and TJX[81] determinations, in which the proponents failed to convince the Staff that the proposals' subjects—a shareholder discount policy, the use of the company's products for lethal injection, the controversy over releasing the film "Song of the South" on Blu-ray, and an animal welfare policy applicable to the company's suppliers--were significant social policy issues. The proponent did not even respond to the company's no-action request in IBM,[82] 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 are more salient than IBM, given how long ago it was issued.

Merck claims that implementing the Proposal would "infringe on" its ability to meet commitments under collaboration and license agreements with third parties that require Merck to "develop, manufacture, and commercialize a particular asset."[83] But this problem has myriad drafting solutions. For example, Merck could formulate a process that carves out such products from the

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

75 See Exchange Act Release No. 40018 (May 21, 1998).

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

77 JPMorgan Chase & Co. (Mar. 16, 2010).

78 Verizon Communications Inc. (Jan. 29, 2019)

79 Pfizer Inc. (Mar. 1, 2016)

80 The Walt Disney Co. (Nov. 23, 2015)

81 The TJX Companies, Inc. (Apr. 16, 2018)

82 International Business Machines Corp. (Jan. 22, 2009). Likewise, the proponenr of the Equity Lifestyles proposal never responded to the company's no-action request. Equity LifeStyle Properties, Inc. (Feb. 6, 2013)

83 No-Action Request, at 4-5.

operation of the process altogether, either by specifically referencing these types of agreements or by excusing compliance whenever applying the process would conflict with a contractual obligation. The process could also allow partners to weigh in, or even give them veto power, on the application of the policy to products on which they are collaborating with Merck. Potential impact on collaborations does not provide a basis for excluding the Proposal on ordinary business grounds.

The Proposal does not focus on ordinary business matters despite "references to" a significant policy issue, as Merck claims.[84] Instead, access to Merck'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.

The determinations Merck cites involved proposals that addressed workforce issues that had never been deemed significant policy issues by the Staff. Amazon[85] proposal asked for disclosure of risks associated with ensuring adequate staffing of its operations, including the company's reliance on part-time and contingent workers and impact on its strategy. Those kinds of risks implicated the nitty gritty of Amazon's day-to-day operations much more than the Proposal does, given its focus on board oversight. Second, the significant social policy issue advanced by the Amazon proponent was very broad—"the labor market tightening known as the 'Great Resignation' or 'Great Quit'"--which the proponent asserted was causing the company to miss delivery commitments and raise prices for its Prime membership. Those consequences were important for Amazon, but likely do not constitute broad societal impacts.

In the 2021 proxy season, JNJ[86] unsuccessfully advanced an argument similar to the one Merck 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 Merck. SLB 14L also 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."[87] 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 take an action, 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.

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84 No-Action Request, at 5.

85 Amazon. Inc. (Apr. 7, 2022) (UAW Retiree Medical Benefits Trust)

86 Johnson & Johnson (Feb. 12, 2021).

87 Staff Legal Bulletin 14L (Nov. 3, 2021).

Merck argues that the Proposal would micromanage because it would "provide shareholder oversight on a complex scientific and legal topic that is outside the knowledge and expertise of shareholders, and therefore inappropriate for such oversight and vote."[88] "Oversight" overstates the extent to which the Proposal would control the substance of any process Merck would formulate in implementing the Proposal, though. The Proposal simply suggests a factor to be considered and does not specify any details around implementation. It urges that Merck consider the impact on access when making decisions regarding seeking secondary and tertiary patents, but does not prescribe the weight to be accorded to access considerations, dictate how they should be balanced against other factors, or specify how the impact on access should be measured. The Proposal "afford[s] discretion to management as to how to achieve" the requested outcome, in the words of SLB 14L.

Merck also claims that shareholders are "not in a position to make an informed judgment"[89] about the Proposal's subject. But Merck's 10-K includes many discussions of patents, presumably because Merck believes this is valuable information for shareholders. There is a section entitled "Patents, Trademarks and Licenses" in Merck's description of its business.[90] That section lists the patents on Merck's drugs and drug candidates, along with the date (or anticipated date) of expiration.[91] The 10-K even describes the impact of "later-expiring" patents on a product's period of market exclusivity.[92] The first material risk factor listed in the 10-K involves patents: "The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected."[93]

Given the centrality of patent protection to Merck's business model, it is a stretch to suggest that the Proposal is too difficult for shareholders to understand. The fact that one of Merck's key disclosure documents treats the subject in detail suggests that Merck does not view shareholders as incapable of assessing information about IP and evaluating policies regarding IP like the one advanced in the Proposal. Shareholders need not have mastered technical concepts related to patents in order to form a view about the desirability of considering access when making decisions about them.

The determinations cited on page 6 of the No-Action Request are inapposite because, unlike the Proposal, those proposals requested an excessive amount of detail. The Deere,[94] Verizon,[95] and American Express[96] resolutions asked the companies to disclose, each year, <u>all</u> employee-training materials offered to any subset of employees, including material conveyed orally. The Staff concurred with the companies that the proposals micromanaged, explaining that they sought disclosure of "intricate details" regarding employment and training practices.

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

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88 No-Action Request, at 6.

89 No-Action Request, at 7.

90 Merck & Co., Inc. Filing on Form 10-K filed on Feb. 25, 2022, at 13-15 (hereinafter, "2022 10-K").

91 2022 10-K, at 14-15.

92 2022 10-K, at 15.

93 2022 10-K, at 37.

94 Deere & Company (Jan. 3, 2022).

95 Verizon Communications Inc. (Mar. 17, 2022)

96 American Express Company (Mar. 11, 2022)

to achieve" that outcome, in the words of SLB 14L. Nor would it require disclosure of intricate detail regarding Merck's process, as the Deere, Verizon and American Express proposals would have done.

In its no-action request submitted last season, Moderna made an argument very similar to Merck's here. 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 factors and risks, including costs, protection of intellectual property, feasibility of manufacture and financial results, among others." In other words, Moderna urged that the subject of the Proposal was too technical and difficult for shareholders and thus would micromanage the company. The Staff declined to grant relief.

In sum, Merck 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. Merck's inclusion of information in its periodic reports regarding patents, patent litigation, and the impact of the loss of market exclusivity on the Company's business is strong evidence that the Proposal's subject is not too complex for shareholders to understand. And because the Proposal neither inappropriately limits the discretion of Merck's management nor requests intricate detail, it would not micromanage Merck.

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For the reasons set forth above, Merck 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 Merck'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 (___) ___-____.

Sincerely,

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