United States Securities and Exchange Commission
Washington, DC 20549

NOTICE OF EXEMPT SOLICITATION

NAME OF REGISTRANT: Merck & Co., Inc

NAME OF PERSONS RELYING ON EXEMPTION: Province of Saint Joseph of the Capuchin Order

ADDRESS OF PERSON RELYING ON EXEMPTION: 1820 Mount Elliott Street, Detroit, MI 48207

WRITTEN MATERIALS: The attached written materials are submitted pursuant to Rule 14a-6(g)(1) (the "Rule") promulgated under the Securities Exchange Act of 1934. Submission is not required of this filer under the terms of the Rule, but is made voluntarily in the interest of public disclosure and consideration of these important issues.

11 April 2023

Dear Fellow Merck & Co. Shareholder,

The Province of Saint Joseph of the Capuchin Order write to urge you to vote **FOR PROPOSAL 8,** "Shareholder Proposal- to issue a report on Patent Process" (the "Proposal") at Merck & Co.'s ("Merck" or "the Company") Annual General Meeting on May 23rd, 2023.

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 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

Proposal 8- Patents and Access

The Proposal asks the Company to adopt and report on a process (the "Process") by which the impact on patient access to medicines is considered when deciding whether to apply for secondary or tertiary patents.

We believe that the Process would be beneficial to Merck because extended exclusivity periods gained from secondary patents, and the resulting delay in generic entry, limit patient access, create regulatory and reputational risk, and saddle the health care system with unsustainable costs.

Are Your Prescription Drugs Affordable?

Prescription drugs have assumed an increasingly important role in American health care, and that trend is likely to continue: 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."[1] Prescription drugs—and branded specialty medicines in particular—are costly in the U.S. The rise in spending on prescription drugs outpaces increases in health care spending more generally,[2] and 3 in 10 Americans on a prescription drug, report not taking their medicine as prescribed due to cost.[3] A poll asking respondents to identify their top priority issue appearing in the Build Back Better bill found that allowing the federal government to negotiate drug prices topped the list.[4]

[1] 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).

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

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

[4] https://www.politico.com/news/2021/10/01/drug-price-negotiation-poll-harvard-514831

Federal law tries to strike a balance between incentivizing innovation and promoting affordability. Obtaining a patent for a new drug gives the manufacturer a period of exclusive marketing rights, generally for 20 years.[5] 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.[6] An academic commentator described the balance struck by this regulatory regime:

> On the one hand, originators play an important role in developing new and improved medicines for the benefit of society. On the other hand, generic companies benefit society by supplying cheaper equivalents of the originators' medicines, which leads to the reduction of drug prices and facilitates access to affordable medicines. When the interests of these two players are kept in balance, benefits are maximized for society, which receives innovative and improved medicines, as well as timely access to generic drugs.[7]

Innovation versus Competitive Pricing

We believe that balance now places patients at a significant disadvantage. Given the high prices their drugs command absent competition, branded drug makers have strong incentives to delay generic competition as long as possible. One strategy they use is creating 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") that would be expensive and time-consuming for a potential generic manufacturer to challenge.[8] This strategy can allow branded drug makers to hold off generic (or biosimilar, in the case of a biologic medicine) competition for several years or more.

These later-filed patents, which are referred to as secondary and tertiary[9] patents, relate to properties of the drug other than the active ingredient, such as methods of administration, manufacturing processes, dosing regimens, and additional indications.[10] Critics of the practice argue that secondary patents tend to be low quality, as they are invalidated in litigation at a higher rate than primary patents, and that they allow drug makers to benefit from extended exclusivity periods without engaging in additional innovation.[11] Merck has filed for 95 secondary patents on Keytruda, their top selling drug approved for 17 different cancer fighting indications, but beyond the budget of the average patient.

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[5] https://sgp.fas.org/crs/misc/R46221.pdf, at 1.

[6] https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/ ("Prices can drop as much as 20% when the first generic enters the market; with multiple generics, the prices may eventually drop by 80–85%.")

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/

[8] See ncbi.nlm.nih.gov/pmc/articles/PMC7592140/(" The denser the web of secondary patents, the more difficult it is for generics to develop their generic equivalents, even if they know that only a few patents of a large portfolio would, in fact, be valid and infringed by their products."); https://sgp.fas.org/crs/misc/R46221.pdf, at 1-2.

[9] A secondary patent relates to "peripheral features" of a drug, while 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/

[10] https://sgp.fas.org/crs/misc/R46221.pdf, at 9.

[11] E.g., Editorial Board, "Save America's Patent System," The New York Times, Apr. 17, 2022 ("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."); https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html; https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf; Robin Feldman, "Our patent system is broken. And it could be stifling innovation," The Washington Post, Aug. 8, 2021

Secondary patents have a significant impact on health care spending, exacerbating inequalities in access to medicines and straining both public and private sector budgets. One study analyzed the 12 best-selling drugs, which had been on the market for an average of 15 years, and found large numbers of secondary patents providing an average exclusivity period of 38 years.[12] That study called patent abuse the "root cause" of unsustainably high drug prices.

Another study by the same organization found "questionable – and likely unmerited" secondary patents on three blockbuster drugs and estimated that the U.S. healthcare system would bear approximately $55 billion in excess costs for those three drugs during the extended exclusivity periods facilitated by the drugs' secondary patents.[13] Studies show that the introduction of generic versions of a drug results in significantly lower prices.[14]

The Fight to End Gaming the U.S. Patent System

The role of secondary and tertiary patents in keeping prescription drug prices high has received increasing amounts of media and regulatory scrutiny. For example, the editorial boards of *The New York Times*[15] and *USA Today* published editorials decrying the proliferation of such patents and their impact on the health care system. Patent thickets are often depicted as "gaming" or "abusing" the U.S. patent system. [16]

On February 22nd, 2023, United States Senators Elizabeth Warren (D-Mass.) and Bernard Sanders (I-Vt.) and Representatives Pramila Jayapal (D-Wash.) and Katie Porter (D-Calif.) sent a letter to the United States Patent and Trademark Office (USPTO), urging the agency to give close scrutiny to any of Merck's requests for new patents for Keytruda, a biological treatment used to treat cancer, citing new reports about Merck's ongoing abuse of the patent system to protect its monopoly on the drug.[17] Senator Warren and Rep. Jayapal also wrote to the USPTO in December 2022 regarding their concerns about the pharmaceutical industry's broad use of anti-competitive practices that raise costs for patients and families.

Rising pressures to contain specialty drug costs, combined with a perception that branded drug firms are engaged in anti-competitive behavior, could lead to increased regulation. Indeed, President Biden issued an Executive Order (the "E.O.") in 2021 directing the Secretary of Health and Human Services to "promote generic drug and biosimilar competition."[18] Pursuant to the E.O., the FDA and Patent and Trademark Office ("PTO") are collaborating to implement strategies to lower drug prices.[19]

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[12] https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf

[13] https://www.i-mak.org/americas-overspend/

[14] 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

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

[16] See, e.g., https://www.reuters.com/business/healthcare-pharmaceuticals/consumer-group-says-drugmakers-abuse-us-patent-system-keep-prices-high-2022-09-16/; https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html; https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.htm; https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507

[17] https://www.warren.senate.gov/imo/media/doc/2023.02.22%20Letter%20to%20USPTO%20re%20Keytruda%20patent1.pdf

[18] 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).

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

The relationship between extended exclusivity periods and high drug prices is addressed in several bills that have been introduced, as well as in congressional hearings.[20] In June 2022, a bipartisan group of Senators wrote to the director of the USPTO 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 USPTO to "consider changes to your regulations and practices to address [overpatenting] problems where they start, during examination."[21]

Detrimental Impact on Patients

Pharmaceutical companies argue that secondary and tertiary patents are necessary to incentivize continued innovation related to a drug. But the Proposal does not seek to prohibit the Company from applying for secondary and tertiary patents on its medicines, only for the impact on patient access to be part of the mix of considerations. There is evidence that companies delay marketing an innovation on an existing drug by filing for secondary patents strategically, close to the primary patent's expiration, in order to provide the longest exclusivity extension.[22] This timing suggests that patient benefit is not always the sole motivation for such innovations on approved medicines.

While Merck has patient access programs and websites to support access, such programs, while facilitating access for a select group of patients, do not promote affordability more generally, as the introduction of a generic drug would. Helping a relatively small number of patients does not address systemic issues, such as the strain placed on the health care system by extended exclusivity periods and the societal impact of undertreatment of disease, which can include lower labor force participation and productivity, increased social services costs, poorer patient quality of life, and higher health care costs later on in a patient's life when the impact of undertreatment may be more difficult to remedy.[23]

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[20] See 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; https://www.congress.gov/bill/117th-congress/house-bill/2873; https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf; https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive; https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to; https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i

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

[22] See ncbi.nlm.nih.gov/pmc/articles/PMC7592140/

[23] See, e.g., https://www.oecd.org/els/health-systems/Focus-on-Health-Making-Mental-Health-Count.pdf; https://www.lse.ac.uk/business/consulting/assets/documents/the-value-of-early-diagnosis-and-treatment-in-parkinsons-disease.pdf; https://www2.deloitte.com/us/en/insights/industry/health-care/economic-cost-of-health-disparities.html; https://www.mathematica.org/news/new-study-uncovers-the-heavy-financial-toll-of-untreated-maternal-mental-health-conditions.

More generally, reliance on patent thickets may actually diminish branded drug manufacturers' incentives to continue developing innovative medicines. If a manufacturer can obtain a longer period of exclusivity for a top-selling drug, it has a reduced motivation to develop new drugs.[24] As one academic study put it: "Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending the patent life of old products. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical companies should be in the lab, not in the legal department."[25]

Finally, the existence of disclosure on a company's pricing and/or access programs is sometimes held up as a reason the Proposal is unnecessary. Disclosures, standing alone, are insufficient because they do not effect a change in process like the one sought by the Proposal. The process change is the Proposal's core element, and the reporting component is designed to ensure that shareholders are apprised of Merck's adoption of the Process.

We recognize the value created by pharmaceutical innovation, and the Proposal would not limit in any way the Company's ability to obtain so-called primary patents covering drugs' active ingredients or require a particular outcome when the Company analyzes whether to pursue secondary and tertiary patents. The Proposal simply asks the Company to take the impact on patient access into account when making decisions about applying for such patents. It would not impose a specific weighting for access considerations, nor would it dictate how access should be measured. The Company would have total discretion over those and other details.

We therefore urge shareholders to vote FOR Shareholder Proposal #8.

Sincerely,

Robert Wotypka, OFM Cap.
Corporate Responsibility Agent
Province of Saint Joseph of the Capuchin Order

NOTE: This is not a solicitation of authority to vote your proxy. Please DO NOT send us your proxy card; The Province of Saint Joseph of the Capuchin Order (POSJ) is not able to vote your proxies, nor does this communication contemplate such an event. POSJ urges shareholders to vote for Proposal #8 following the instructions provided on management's proxy mailing.

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[24] ncbi.nlm.nih.gov/pmc/articles/PMC7592140/

[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/