



NOTICE OF EXEMPT SOLICITATION

NAME OF REGISTRANT: Eli Lilly and Company

NAME OF PERSON RELYING ON EXEMPTION: Trinity Health

ADDRESS OF PERSON RELYING ON EXEMPTION: Catherine Rowan

<rowancm@trinity-health.org>

Dear Fellow Eli Lilly Shareholder,

Trinity Health and co-filers Adrian Dominican Sisters, Mercy Investment Services, Bon Secours Mercy Health, Sisters of Charity of St. Elizabeth, Sisters of St. Francis of Dubuque Charitable Trust, Missionary Oblates of Mary Immaculate – US Provinces, Providence St. Joseph Health, Friends Fiduciary Corporation and the Daughters of Charity Province of St. Louise (“the Proponents”), write to urge you to vote **FOR** Item 9, “Proposal 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 or Tertiary Patents” (the “Proposal”), at the upcoming Eli Lilly and Company (“Eli Lilly” or “the Company”) annual shareholders’ meeting on May 1, 2023. The Proposal asks the Company to adopt and report on a policy (the “Policy”) 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 Policy would be beneficial to Eli Lilly 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.

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 three 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>

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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

We believe that balance is now out of whack. 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 tertiary⁹ 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

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.

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/](https://www.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^[11] (“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^[11]

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

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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 lead to significantly lower prices.¹⁴)

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

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.”¹⁷ Pursuant to the E.O., the FDA and Patent and Trademark Office (“PTO”) are collaborating to implement strategies to lower drug prices.¹⁸

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.¹⁹ 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.”²⁰

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

¹⁷ <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).

¹⁸ <https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf>

¹⁹ 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.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>

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

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Pharmaceutical firms 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.²¹ This timing suggests that patient benefit is not always the sole motivation for such innovations on approved medicines.

In its proxy statement, Eli Lilly states that it offers various patient support programs and copay assistance for its major products. Such programs, while facilitating access for certain 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.²²

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.²³ 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."²⁴

We recognize that Eli Lilly participates in the IP Principles for Advancing Cures and Therapies (IP-PACT).²⁵ However, the Principles do not address what the Proponents are seeking to understand: whether the impact on patient access is considered in secondary and/or tertiary patenting strategies.

²¹ See [ncbi.nlm.nih.gov/pmc/articles/PMC7592140/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/)

²² 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>.

²³ [ncbi.nlm.nih.gov/pmc/articles/PMC7592140/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/)

²⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/>

²⁵ <https://www.interpat.org/ip-pact/>

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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 policy like the one sought by the Proposal. The policy change is the Proposal's core element, and the reporting component is designed to ensure that shareholders are apprised of Eli Lilly's adoption of the Policy.

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 Item 9.

For more information, please contact Catherine Rowan, Director, Socially Responsible Investments, Trinity Health rowancm@trinity-health.org

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