



## 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

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Dear Fellow Eli Lilly Shareholder,

Trinity Health and co-filers Adrian Dominican Sisters, Friends Fiduciary Corporation, Mercy Investment Services, Sisters of Charity of St. Elizabeth and Sisters of St. Francis of Dubuque Charitable Trust, (“the Proponents”), write to urge you to vote **FOR** Item 8 “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 6, 2024. 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.

An AARP Public Policy Institute study found that the list prices for the top 25 brand name drugs with the highest amount of Medicare Part D spending increased by an average of 226% - or more than tripled – since those drugs first entered the market. Eli Lilly’s drug Trulicity is on the list, with a reported 91% increase in its list price since it entered the market in 2014.<sup>1</sup>

The Commonwealth Fund noted in 2021 that “several studies and Congressional investigations have pointed to drugmakers’ use of the patent system to extend monopolies, increase prices, and delay generic or biosimilar competition.”<sup>2</sup> One study that analyzed all drugs on the market between 2005 and 2015 looked at “every instance in which a company added a new patent or exclusivity. The results show startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals....78% of the drugs with new patents were not new drugs, but existing ones, and extending protection is particularly pronounced among blockbuster drugs.”<sup>3</sup>

<sup>1</sup> <https://www.aarp.org/content/dam/aarp/ppi/topics/health/prescription-drugs/prices-top-medicare-part-d-drugs-tripled-entering-market.doi.10.26419-2fppi.00202.001.pdf.coredownload.pdf>

<sup>2</sup> <https://www.commonwealthfund.org/blog/2021/policymakers-attention-turns-drug-patents-debate-prices>

<sup>3</sup> <https://academic.oup.com/jlb/article/5/3/590/5232981?login=false>

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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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup>

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.<sup>7</sup> 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 patents are placed on the FDA’s master list of approved medications, medical devices and other therapeutics, known as the “Orange Book”.

A recent study in *PLOS Medicine*,<sup>8</sup> and subsequently reported in *Time*, looked at how insulin manufacturers such as Eli Lilly “have used patents and regulatory exclusivities on insulin products approved from 1986 to 2019 to extend periods of market exclusivity.” During this period, patents for 56 brand-name insulin products were approved. “Protection on insulin was enhanced by patents obtained after FDA approval, which lengthened expected market exclusivity in 9 cases by a median of 6 years. In addition, two-thirds of drug-device combinations had last-to-expire patents that were on the delivery devices; these last-to-expire device patents extended protection by a median of 5.2 years.”<sup>9</sup> The *PLOS* study also found that 17 cases in which the last-to-expire patent on a drug-device combination was a device patent with claims that made no mention of insulin, and these patents extended protection by a median of more than 4 years.

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

<sup>5</sup> <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%.”)

<sup>6</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/>

<sup>7</sup> 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.

<sup>8</sup> <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004309>

<sup>9</sup> <https://time.com/6336840/patent-manipulation-insulin-prices/>

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“For patients who’ve long held out hope for cheaper alternatives to their life-saving medication, a six-year extension of exclusivity could easily represent hundreds of thousands of dollars—or, if that expense is unmanageable, the forced use of cheaper and less-effective insulin delivery systems.”<sup>10</sup>

These later-filed patents, which are referred to as secondary and tertiary<sup>11</sup> patents, relate to properties of the drug other than the active ingredient, such as methods of administration, manufacturing processes, dosing regimens, and additional indications.<sup>12</sup> They allow drug makers to benefit from extended exclusivity periods without engaging in additional innovation.<sup>13</sup>

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.<sup>14</sup> That study called patent abuse the “root cause” of unsustainably high drug prices.

The role of secondary and tertiary patents in keeping prescription drug prices high has received increasing amounts of regulatory, legislative and media scrutiny.

On November 7, 2023, the Federal Trade Commission announced a challenge of “more than 100 patents held by manufacturers of brand-name asthma inhalers, epinephrine autoinjectors, and other drug products as improperly or inaccurately listed in... the ‘Orange Book.’ The Commission has also notified FDA that it disputes the accuracy or relevance of the listed information for these patents, which may require that the manufacturers remove the listing or certify under penalty of perjury that the listings comply with applicable statutory and regulatory requirements.”<sup>15</sup> This action came after the FTC warned in September 2023 that it “‘intends to scrutinize’ whether companies are illegally engaging in an unfair method of competition when they exploit a regulatory loophole that can delay rivals from entering the market.”<sup>16</sup>

<sup>10</sup> *Ibid.*

<sup>11</sup> 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/>

<sup>12</sup> <https://sgp.fas.org/crs/misc/R46221.pdf>, at 9.

<sup>13</sup> *E.g.*, Editorial Board, “Save America’s Patent System,” *The New York Times*, Apr. 17, 2022<sup>13</sup> (“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.cnn.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<sup>13</sup>

<sup>14</sup> <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

<sup>15</sup> <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book>

<sup>16</sup> <https://www.nytimes.com/2023/09/14/business/ftc-drug-patents-inhalers.html>

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The *Time* article notes that “the FTC’s current list of patents under scrutiny doesn’t include insulin products, but the changes it causes could affect them. It’s possible that could trigger pharma companies to evaluate their patents in other areas—including insulin—as well.”

In January 2024, a bipartisan bill was introduced in the Senate (Sens. Welch, Braun and Klobuchar) and a similar bill in the House by Republican Rep. Arrington that would address patent thickets by codifying “the practice that many federal district courts across the country already apply to limit the number of patents or patent claims a company can assert in litigation.

Specifically, this bipartisan bill:

- Streamlines patent litigation by limiting to one, the number of patents per patent thicket a pharmaceutical company can assert in litigation.
- Prohibits a patent owner from asserting multiple patents from the same thicket in separate actions against the same alleged infringer to circumvent the intent of the law.
- Safeguards quality patents that improve existing drugs, benefiting patients.”<sup>17</sup>

The Senate Committee on Health, Education, Labor and Pensions held a hearing in February 2024 on US drug pricing that raised concerns about patent thickets and other uses of the patent system and received wide press coverage.<sup>18</sup>

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.<sup>19</sup> This timing suggests that patient benefit is not always the sole motivation for such innovations on approved medicines.

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.<sup>20</sup> 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.”<sup>21</sup>

<sup>17</sup> <https://www.welch.senate.gov/welch-braun-and-klobuchar-introduce-bipartisan-legislation-to-streamline-drug-patent-litigation-lower-cost-of-prescription-drugs/>

<sup>18</sup> <https://edition.cnn.com/2024/02/08/health/senate-hearing-drug-prices/index.html> <https://www.nytimes.com/2024/02/08/us/politics/senate-hearing-drug-prices.html>

<https://www.cnbc.com/2024/02/08/jj-merck-bristol-myers-squibb-ceos-senate-drug-price-hearing.html>

<sup>19</sup> See [ncbi.nlm.nih.gov/pmc/articles/PMC7592140/](https://ncbi.nlm.nih.gov/pmc/articles/PMC7592140/)

<sup>20</sup> [ncbi.nlm.nih.gov/pmc/articles/PMC7592140/](https://ncbi.nlm.nih.gov/pmc/articles/PMC7592140/)

<sup>21</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6534750/>

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In its proxy statement, Eli Lilly describes its process for patent protection for new innovations and secondary and tertiary patents. However, it does not disclose whether access is considered when deciding whether to apply for secondary or tertiary patents. This issue is at the heart of the Proposal, and the Company does not address it. Eli Lilly provides information on its approach to access to medicine, but it does not make a connection between its access approach and its patenting strategy.

We recognize that Eli Lilly participates in the IP Principles for Advancing Cures and Therapies (IP-PACT).<sup>22</sup> 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.

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 8.**

For more information, please contact Catherine Rowan, Director, Socially Responsible Investments, Trinity Health [rowancm@trinity-health.org](mailto:rowancm@trinity-health.org)

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<sup>22</sup> <https://www.interpat.org/ip-pact/>

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