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

DIVISION OF
CORPORATION FINANCE

March 10, 2023

Sarkis Jebejian
Kirkland & Ellis LLP

Re: Eli Lilly and Company (the "Company")
Incoming letter dated December 23, 2022

Dear Sarkis Jebejian:

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

The Proposal requests that the Company's board of directors establish and report on a process by which the impact of extended patent exclusivities on product access would be considered in deciding whether to apply for secondary and tertiary patents.

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

We are unable to concur in your view that the Company may exclude the Proposal under Rule 14a-8(i)(10). Based on the information you have presented, it appears that the Company's public disclosures do not substantially implement the Proposal.

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: Catherine M. Rowan
Trinity Health

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

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December 23, 2022

VIA EMAIL

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

Email: shareholderproposals@sec.gov

Re: Shareholder Proposal of Trinity Health

Ladies and Gentlemen:

We submit this letter on behalf of Eli Lilly and Company ("*Lilly*" or the "*Company*") to notify the Securities and Exchange Commission (the "*Commission*") that the Company intends to omit from its proxy statement and form of proxy for its 2023 Annual Meeting of Shareholders (the "*2023 Annual Meeting"* and such materials, the "*2023 Proxy Materials*") a shareholder proposal and supporting statement (the "*Proposal*") submitted by Trinity Health and co-filed by certain other parties[1] (collectively, the "*Proponents*"). We also request confirmation that the staff of the Division of Corporation Finance (the "*Staff*") will not recommend enforcement action to the Commission if the Company omits the Proposal from the 2023 Proxy Materials for the reasons discussed below.

The Company currently anticipates filing a preliminary proxy statement with the Commission on or around February 24, 2023 due to the inclusion in the 2023 Proxy Materials of proposals to amend the Company's Amended Articles of Incorporation and expects to file its definitive 2023 Proxy Materials on or around March 17, 2023. Accordingly, in compliance with Rule 14a-8(j) of the Securities Exchange Act of 1934, as amended, we have filed this letter with the Commission no later than 80 calendar days before the Company intends to file its definitive 2023 Proxy Materials with the Commission. In light of the Company's timeline for filing a

[1] The following shareholders have co-filed the Proposal: The Sisters of Charity of Saint Elizabeth, The Sisters of St. Francis of Dubuque Charitable Trust, The Adrian Dominican Sisters, Bon Secours Mercy Health, Missionary Oblates of Mary Immaculate-US Province, Mercy Investment Services, Inc., Providence of St. Joseph Health, Friends Fiduciary Corporation, and The Daughters of Charity Province of St. Louise.

preliminary proxy statement, the Company requests that the Staff respond to this letter prior to February 24, 2023 if practicable.

In accordance with Section C of Staff Legal Bulletin No. 14D (Nov. 7, 2008), we are emailing this letter to the Staff at shareholderproposals@sec.gov. In accordance with Rule 14a-8(j), we are simultaneously sending a copy of this letter and its attachments to the Proponents as notice of the Company's intent to omit the Proposal from the 2023 Proxy Materials. Likewise, we take this opportunity to inform the Proponents that if the Proponents elects to submit any correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should be provided concurrently to the undersigned on behalf of the Company.

THE PROPOSAL

The Proposal sets forth the following resolution to be voted on by shareholders at the 2023 Annual Meeting:

> RESOLVED, that shareholders of Eli Lilly & Co. ("Lilly") 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 Lilly's website.[2]

[2] The Proposal in full is attached hereto as Exhibit A.

BASIS FOR EXCLUSION

The Company hereby respectfully requests that the Staff concur in its view that the Company may exclude the Proposal from the 2023 Proxy Materials pursuant to:

- Rule 14a-8(i)(7) because it relates to the Company's ordinary business; and
- Rule 14a-8(i)(10) because the Company has substantially implemented the Proposal.

ANALYSIS

1. 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.*

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 patent application 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 new, innovative medicines. The Company relies on patent exclusivity to develop and successfully market its products. Most companies could not operate to manufacture and deliver existing medicine for patients or in discovering and developing potential new medicines for patients, let alone generate profits for its shareholders, without a successful patent application strategy. 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 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 other pharmaceutical companies or operators. 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. 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 patent application process with respect to its products and product candidates. As explained above, this is an ordinary business matter because it relates to the Company's products and fundamental business operations. 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 analysis for every potential patent application for every potential product. The analysis is performed by the Company's patent attorneys (each of whom holds a science degree in addition to a law degree) with input from 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, a complicated evaluation of innovation for newness (novelty) and non-obviousness relative to what is publicly known is performed. Although newness or novelty is a relatively straightforward concept, obviousness (or "inventive step" outside the U.S), is a highly fact-specific inquiry sometimes involving "secondary" considerations such as "surprising results." 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 discussed further below).

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 topic that is outside the knowledge and expertise of shareholders, and therefore inappropriate for such oversight and vote. The Proposal is therefore excludable pursuant to Rule 14a-8(i)(7) for seeking to micromanage the Company.

Because the Proposal deals with the ordinary business matter of workforce management, 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).

2. The Proposal May be Excluded Under Rule 14a-8(i)(10) Because the Company Has Substantially Implemented the Proposal.

A. Background

The lifeblood of the biopharmaceutical industry and the Company lies in inventions – new, innovative medicines that can save millions of lives and reduce the need for other health care services. Patents play a critical role in that innovation, as patents protect new ideas and encourage useful innovations to spring from these ideas. Intellectual property ("*IP*") protections play a central role in driving innovations that result in better patient outcomes.

Lilly balances the pursuit of IP protection through patents with another major priority for the Company: expanding affordable access to medicines. One aspect of this is setting the list prices for the Company's medicines. Lilly has processes in place to ensure the Company considers access and patient affordability, while sustaining investments to research innovative life-changing treatments for some of today's most serious diseases through patent protections. When pricing its medicines, Lilly incorporates a variety of factors into its decision-making, including the cost of research, development, manufacturing and support services for customers; business trends and other economic factors, as well as the medicine's potential market size, and crucially, patent life, among others.

Strong IP protections, including all forms of patent protections, encourage innovators to focus on innovating to solve difficult problems like presently untreatable medical diseases. They are the bedrock for developing new treatments and cures, and are critical to improving patient care, spurring innovation and strengthening our economy. Without strong IP protections, innovation would mostly focus on low-risk ventures, leaving large swaths of unmet medical needs. IP protections are designed to reflect the time, cost and uncertainty related to the research-and-development process for medicines, and the substantial investment required for FDA approval.

B. Rule 14a-8(i)(10) Background

Rule 14a-8(i)(10) allows a company to exclude a shareholder proposal from its proxy materials if the company has substantially implemented the proposal. The purpose of Rule 14a-8(i)(10) is "to avoid the possibility of shareholders having to consider matters which have already been favorably acted upon by management." *S*EC Release No. 34-12598 (Jul. 7, 1976). Importantly, Rule 14a-8(i)(10) does not require a company to implement every detail of a proposal in order for the proposal to be excluded. The Staff has maintained this interpretation of Rule 14a-8(i)(10) since 1983, when the Commission reversed its prior position of permitting exclusion of a proposal only where a company's implementation efforts had "fully" effectuated the proposal. SEC Release No. 34-20091 (Aug. 16, 1983). The 1998 amendments to Rule 14a-8 codified this position. *See 1998 Release*, at n.30 and accompanying text.

The Staff has noted that "a determination that a company has substantially implemented the proposal depends upon whether [the company's] particular policies, practices and procedures compare favorably with the guidelines of the proposal." *Texaco, Inc.* (Mar. 28, 1991). Even if a company's actions do not go as far as those requested by the shareholder proposal, they nonetheless may be deemed to "compare favorably" with the requested actions. *See, e.g.*, *Advance Auto Parts, Inc.* (Apr. 9, 2019) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company issue a sustainability report "in consideration of the SASB Multiline and Specialty Retailers & Distributors standard," on the basis that the company's "public disclosures compare favorably with the guidelines of the [p]roposal and that the [c]ompany has, therefore, substantially implemented the [p]roposal," where the company argued that a combination of its existing disclosures sufficiently addressed the core purpose of the proposal, acknowledging that the disclosures deviated in certain respects from the SASB standard); *Applied Materials, Inc.* (Jan. 17, 2018) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company "improve the method to disclose the [c]ompany's executive compensation information with their actual compensation," on the basis that the company's "public disclosures compare favorably with the guidelines of the [p]roposal and that the [c]ompany has, therefore, substantially implemented the Proposal," where the company argued that its current disclosures follow requirements under applicable securities laws for disclosing executive compensation); *Exxon Mobil Corp.* (Mar. 23, 2009) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting a report regarding political contributions where the company's pre-existing political contribution policies and procedures compared favorably to the proposal at issue, despite the disclosures not being as fulsome as the proponent had contemplated, and the analysis not rising to the level of detail that the proponent desired); *Walgreen Co.* (Sept. 26, 2013) (permitting exclusion under Rule 14a-8(i)(10) of a proposal requesting elimination of supermajority voting requirements in the company's governing documents where the company had eliminated all but one of the supermajority voting requirements); and *Johnson & Johnson* (Feb. 17, 2006) (permitting exclusion under Rule 14a-8(i)(10) of a proposal that requested the company confirm the legitimacy of all current and future U.S. employees because the company had verified the legitimacy of 91% of its domestic workforce).

C. The Company Has Substantially Implemented the Proposal

The Company has substantially implemented the essential elements of the Proposal, which calls for the Company's board of directors (the "*Board*") to report to shareholders on the process by which the impact of extended patent exclusivities on product access is considered in deciding whether to apply for secondary and tertiary patents, because the Company already publicly discloses the factors it considers during its patent application evaluation process, including access and affordability concerns at a domestic and international level for all patents.

Lilly has already established and reported on the role that product access plays in the Company's intellectual property strategy. This process is reported to shareholders through the

Company's existing disclosures available on the Company's website, in the Company's Annual Report on Form 10-K filed February 23, 2022 (the "*10-K*")[3], and in the Company's Environmental, Social and Governance report (the "*ESG Report*")[4]. Principally, Lilly publicly announced its participation in the IP Principles for Advancing Cures and Therapies (the "*IP PACT*") [5], which serves as a framework for guiding the Company's commitment to innovation while keeping patients at the heart of its efforts. The IP PACT framework supported by the Company includes the following principles, among others:

- Patient and societal benefit will guide Lilly's approach to IP.
- Lilly will support initiatives to ensure patent quality, which help advance biopharmaceutical innovation.
- Lilly will use IP rights to facilitate collaboration and enable partnerships that advance global health.
- Lilly believes that accessible patent information promotes scientific progress and helps improve the procurement of medicines, and we support voluntary initiatives that advance these goals.
- Lilly will act responsibility and professionally in the Company's patent proceedings, and seek timely resolutions to enhance certainty for all stakeholders.
- Lilly believes that generic and biosimilar medicines are important for sustainable health systems, and that certain activities related to seeking regulatory approval should be exempt from patent infringement.
- Lilly believes that advancing public health depends on robust IP, rights as well as collaboration among stakeholders, and may call for tailored uses of our IP where these add value for patients.
- Lilly will approach IP in the world's poorest countries in ways that considers their unique socio-economic challenges.

These principles are necessarily broad-based because although they guide each of the Company's patent application decisions, each such decision is necessarily fact-intensive and requires consideration of myriad product-specific factors. The IP PACT does, however, provide detail where practicable with respect to certain issues concerning product access, including an

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[3] *Available at* https://www.sec.gov/ix?doc=/Archives/edgar/data/59478/000005947822000068/lly-20211231.htm at 8-13, 24-26, 39-40, 63, 101-102 with relevant excerpts attached hereto as Exhibit B.

[4] *Available at* https://esg.lilly.com/social#tab-control-tab1 and attached hereto as Exhibit C.

[5] *Available at*: https://www.lilly.com/news/stories/world-intellectual-property-day-commitment-to-patients and attached hereto as Exhibit D.

explanation of instances in which the Company supports exemptions from patent infringement for certain activities.

The Company's ESG Report also discusses the Company's commitment to equitable and affordable access to its medicines. "Lilly supports the removal of regulatory or pricing, reimbursement and access restrictions for generics and biosimilars when intellectual property protections expire. In addition, Lilly has a long-standing practice of not seeking or enforcing patents for medicines in least developed countries, as defined by the United Nations."[6]

The Company believes that intellectual property improves patient access by expanding the innovation base. "Intellectual property protections play a central role in driving innovations that result in better patient outcomes. For example, decades-long investments made by biopharmaceutical companies in new technologies, research and treatments helped prepare the industry to pivot quickly and develop therapies and vaccines in response to the COVID-19 pandemic. Sustaining a dependable intellectual propriety environment enhances the industry's ability to respond quickly to future public health challenges, promotes the pursuit of breakthroughs in areas of unmet need, like Alzheimer's disease and antimicrobial resistance, and emboldens investor confidence in keeping the engines of innovation operating at full speed."[7]

The Company's Form 10-K provides further descriptions of the U.S. and international intellectual property considerations, including that in "many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products relatively shortly after launch."[8] Furthermore, "intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines."[9] The situation here is analogous to the situation in, for example, *PG&E Corp.* (Mar. 10, 2010), where the Staff permitted exclusion under Rule 14a-8(i)(10) of a proposal requesting that the company provide a report disclosing, among other things, the company's standards for choosing the organizations to which the company makes charitable contributions and the "business rationale and purpose for each of the charitable contributions." In arguing that the proposal had been substantially implemented, the company pointed to a website where the company had described its policies and guidelines for determining the types of grants that it makes and the types of requests that the company typically does not fund. Although the proposal appeared to contemplate disclosure of each and every charitable contribution, the Staff concluded that the

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6 *See* Exhibit C; Intellectual Property.

7 *See* Exhibit C; Intellectual Property.

8 *See* Exhibit B at 8 and 25.

9 *See* Exhibit B at 9.

company had substantially implemented the proposal. Here, although the Proposal specifically requests a report on extended patent exclusivities for secondary and tertiary patents, the Company's current disclosure substantially implements the Proposal by providing its policy that applies equally to all patents.

The Company has already taken actions to address the essential elements of the Proposal by reporting to shareholders the process by which the impact of extended patent exclusivities on product access is considered when the Company decides whether to apply for patents, including secondary and tertiary patents. These disclosures collectively detail the process by which the Company considers the impact of patent exclusivities on product access and affordability. Therefore, consistent with the no-action precedent cited above, the Company has substantially implemented the Proposal and, accordingly, the Proposal should be excluded from the 2023 Proxy Materials pursuant to Rule 14a-8(i)(10).

* * *

CONCLUSION

Based upon the foregoing analysis, we respectfully request that the Staff concur that the Company may exclude the Proposal from the 2023 Proxy Materials. Should the Staff disagree with the conclusions set forth in this letter, or should you require any additional information in support of our position, we would welcome the opportunity to discuss these matters with you as you prepare your response. Any such communication regarding this letter should be directed to me at sarkis.jebejian@kirkland.com or (212) 446-5944.

Sincerely,

Sarkis Jebejian, P.C.

cc: Anat Hakim
Executive Vice President, General Counsel and Secretary, Eli Lilly and Company

Catherine M. Rowan
Director, Socially Responsible Investments, Trinity Health

Exhibit A
[Copy of Proposal]

RESOLVED, that shareholders of Eli Lilly & Co. ("Lilly") 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 Lilly's website.

Supporting Statement

Access to medicines, especially costly specialty drugs, is the subject of consistent and widespread public debate in the U.S. A 2021 Rand Corporation analysis concluded that U.S. prices for branded drugs were nearly 3.5 times higher than prices in 32 OECD member countries.[1] The Kaiser Family Foundation has "consistently found prescription drug costs to be an important health policy area of public interest and public concern."[2]

This high level of concern has driven policy responses. The Inflation Reduction Act empowers the federal government to negotiate some drug prices.[3] State measures, including drug price transparency legislation and copay caps, have also been adopted.[4] The House Committee on Oversight and Reform (the "Committee") launched a far-reaching investigation into drug pricing in January 2019.[5] The Committee and the Senate Finance Committee also undertook investigations into insulin pricing in 2019, which focused on Lilly's Humalog insulin and two other products.[6]

Intellectual property protections on branded drugs play an important role in maintaining high prices and impeding access. When patent protection on a drug ends, generic manufacturers can enter the market, reducing prices. But branded drug manufacturers may try to delay generic competition by extending their exclusivity periods.

Such periods can be extended if secondary patents are granted. The Committee's December 2021 report described construction of a "patent thicket," which consists of many "secondary patents covering the formulations, dosing, or methods of using, administering, or manufacturing a drug"; they are granted after the drug's primary patent, covering its main active ingredient or molecule, has been granted.[7] In June 2022, citing the impact of patent thickets on drug prices, a bipartisan group

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[1] https://www.rand.org/news/press/2021/01/28.html

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

[3] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

[4] https://www.americanprogress.org/article/state-policies-to-address-prescription-drug-affordability-across-the-supply-chain/

[5] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at i.

[6] https://www.grassley.senate.gov/news/news-releases/grassley-wyden-launch-bipartisan-investigation-insulin-prices

[7] https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 79.

of Senators urged the U.S. Patent and Trademark Office to "take regulatory steps to . . . eliminate large collections of patents on a single invention."

Lilly has raised the price of a 10 ml vial of Humalog by 1219% since its launch. Secondary patents on Humalog extended Lilly's exclusivity period by 17 years.[8]

In our view, a process that considers the impact of extended exclusivity periods on patient access would ensure that Lilly considers not only whether it can apply for secondary and tertiary patents but also whether it should do so. A more thoughtful process could, we believe, bolster Lilly's reputation and help avoid regulatory blowback resulting from high drug prices and perceptions regarding abusive patenting practices.

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8 https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 14, 81.

Exhibit B
[Copy of 10-K]

Generic Pharmaceuticals

One of the biggest competitive challenges we face is from generic pharmaceuticals. In the U.S. and Europe, the regulatory approval process for pharmaceuticals (other than biological products (biologics)) exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy of the innovator product. As a result, generic manufacturers generally invest far fewer resources than we do in research and development and can price their products significantly lower than our branded products. Accordingly, when a branded non-biologic pharmaceutical loses its market exclusivity, it normally faces intense price competition from generic forms of the product, which can cause us to lose a significant portion of the product's revenue in a very short period of time.

Further, public and private payers typically encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Laws in the U.S. generally allow, and in many cases require, pharmacists to substitute generic drugs that have been rated under government procedures to be essentially equivalent to a brand-name drug. Where substitution is mandatory, it must be made unless the prescribing physician expressly forbids it. In many countries outside the U.S., intellectual property protection is weak, and we must compete with generic or counterfeit versions of our products relatively shortly after launch.

Biosimilars

A number of our products and potential new medicines in our clinical-stage pipeline are biologics. In the U.S., the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and implementing regulations. Competition for Lilly's biologics may be affected by the approval of follow-on biologics, also known as biosimilars. A biosimilar is a subsequent version of an approved innovator biologic that, due to its analytical and clinical similarity to the innovator biologic, may be approved based on an abbreviated data package that relies in part on the full testing required of the innovator biologic. Approval by the FDA ultimately depends on many factors, including a showing that the biosimilar is "highly similar" to the original product and has no clinically meaningful differences from the original product in terms of safety, purity, and potency.

Globally, most governments have developed abbreviated regulatory pathways to approve biosimilars as follow-ons to innovator-developed biologics, including the Biologics Price Competition and Innovation Act of 2009 (the BPCIA) in the U.S. A number of biosimilars have been licensed under the BPCIA and in Europe. The patent and regulatory exclusivity for the existing innovator biologic generally must expire in a given market before biosimilars may enter that market. However, in the U.S., the product exclusivity period under the BPCIA could be affected by recent government proposals and litigation. See "- Patents, Trademarks, and Other Intellectual Property Rights." In addition, the extent to which a biosimilar, once approved, will be substituted for the innovator biologic in a way that is similar to traditional generic substitution for non-biologic products is not yet entirely clear, and will depend on a number of regulatory and marketplace factors that are still developing. In the U.S., currently only a biosimilar product that is determined to be "interchangeable" by the FDA will be considered substitutable for the original biologic product without the intervention of the health care provider who prescribed the original biologic product. To prove that a biosimilar product is interchangeable, the applicant must demonstrate that the product can be expected to produce the same clinical results as the original biologic product in any given patient, and if the product is administered more than once in a patient, that safety risks and potential for diminished efficacy of alternating or switching between the use of the interchangeable biosimilar biologic product and the original biologic product is no greater than the risk of using the original biologic product without switching. The FDA has begun to issue "interchangeable" designations for biosimilar products.

Biosimilars may present both competitive challenges and opportunities. For example, a competitor company has developed a version of insulin lispro that competes with our product Humalog. On the other hand, in collaboration with Boehringer Ingelheim, we developed Basaglar, an insulin glargine product, which has the same amino acid sequence as a product currently marketed by a competitor and has launched as a follow-on biologic in the U.S., and as a biosimilar in Europe and Japan. However, in March 2020, the FDA began regulating all of our insulin products as "biologics" rather than "drugs." Based on FDA draft guidance, this change may lessen the amount of data required for competitor biosimilar products to enter the market, some of which could be designated as interchangeable and therefore substituted for our insulin products at U.S. pharmacies. For example, in June 2020, the FDA approved a New Drug Application (NDA) for Semglee, a follow-on insulin glargine product that competes with Basaglar in the U.S., and, in July 2021, Semglee received additional FDA approval as a biosimilar that is interchangeable to its reference insulin glargine product. The FDA's interpretation of important aspects of the laws regulating biosimilars continues to evolve and, therefore, the

U.S. Private Sector Dynamics

In the U.S. private sector, consolidation and integration among healthcare providers significantly affects the competitive marketplace for pharmaceuticals. Health plans, managed care organizations, pharmacy benefit managers, wholesalers, and other supply chain stakeholders have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, typically maintain formularies that specify coverage (the conditions under which drugs are included on a plan's formulary) and reimbursement (the associated out-of-pocket cost to the consumer) to control costs by negotiating discounted prices in exchange for formulary inclusion.

Formulary placement can lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations that result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles. Consequently, pharmaceutical companies face increased pressure in pricing and usage negotiation, and compete fiercely for formulary placement, not only on the basis of product attributes such as efficacy, safety profile, or patient ease of use, but also by providing rebates. As payers and pharmaceutical companies continue to negotiate formulary placement and pricing, value-based agreements, where pricing is based on achievement (or not) of specified outcomes, are another tool that may become increasingly prevalent. Price is an increasingly important factor in formulary decisions, particularly in treatment areas in which the payer has taken the position that multiple branded products are therapeutically comparable. We expect these downward pricing pressures will continue to negatively affect our consolidated results of operations. In addition to formulary placement, changes in insurance designs continue to drive greater consumer cost-sharing through high deductible plans and higher co-insurance or co-pays. For additional information on pricing and reimbursement for our pharmaceutical products, see "- Regulations and Private Payer Actions Affecting Pharmaceutical Pricing, Reimbursement, and Access - U.S."

Patents, Trademarks, and Other Intellectual Property Rights

Overview

Intellectual property protection is critical to our ability to successfully commercialize our life sciences innovations and invest in the search for new medicines. We own, have applied for, or are licensed under, a large number of patents in the U.S. and many other countries relating to products, product uses, formulations, and manufacturing processes. In addition, as discussed below, for some products we have effective intellectual property protection in the form of data protection under pharmaceutical regulatory laws.

The patent protection anticipated to be of most relevance to pharmaceuticals is provided by national patents claiming the active ingredient (the compound patent), particularly those in major markets such as the U.S., major European countries, and Japan. These patents may be issued based upon the filing of international patent applications, usually filed under the Patent Cooperation Treaty (PCT). Patent applications covering compounds are generally filed during the Discovery Phase of the drug discovery process, which is described in the "Research and Development" section below. In general, national patents in each relevant country are available for a period of 20 years from the filing date of the PCT application, which is often years prior to the launch of a commercial product. Further patent term adjustments and restorations may extend the original patent term:

- Patent term adjustment is a statutory right available to all U.S. patent applicants to provide relief in the event that a patent grant is delayed during examination by the United States Patent and Trademark Office (USPTO).
- Patent term restoration is a statutory right provided to U.S. patent holders that claim inventions subject to review by the FDA. To make up for a portion of the time invested in clinical trials and the FDA review process, a single patent for a pharmaceutical product may be eligible for patent term restoration. Patent term restoration is limited by a formula and cannot be calculated until product approval due to uncertainty about the duration of clinical trials and the time it takes the FDA to review an application. There is a five-year cap on any restoration, and no patent's expiration date may be extended beyond 14 years from FDA approval. Some countries outside the U.S. similarly offer forms of patent term restoration for patents claiming inventions subject to a local review by a regulatory agency. For example, Supplementary Protection Certificates are available to extend the life of a European patent up to an additional five years (subject to a 15-year cap from European Medicines Agency (EMA) approval). Also, in Japan, South Korea, and Australia, patent terms can be extended up to five years, depending on the length of regulatory review and other factors.

Loss of effective patent protection for pharmaceuticals, especially for non-biologic products, typically results in the loss of effective market exclusivity for the product, which often results in severe and rapid decline in revenues for the product. However, in some cases the innovator company may retain exclusivity despite approval of the generic, biosimilar, or other follow-on versions of a new medicine beyond the expiration of the compound patent through manufacturing trade secrets, later-expiring patents on manufacturing processes, methods of use or formulations, or data protection that may be available under pharmaceutical regulatory laws. Changes to the laws and regulations governing these protections could result in earlier loss of effective market exclusivity. The primary forms of data protection are as follows:

- Regulatory authorities in major markets generally grant data package protection for a period of years following new drug approvals in recognition of the substantial investment required to complete clinical trials. Data package protection prohibits other manufacturers from submitting regulatory applications for marketing approval in reliance on the innovator company's regulatory submission data for the drug. The base period of data package protection depends on the country. For example, the period is generally five years in the U.S. (12 years for new biologics as described below), effectively 10 years in Europe, and eight years in Japan. The period begins on the date of product approval and runs concurrently with the patent term for any relevant patent.
- Under the BPCIA, the FDA has the authority to approve biosimilars. A competitor seeking approval of a biosimilar must file an application to show its molecule is highly similar to an approved innovator biologic and include a certain amount of safety and efficacy data that the FDA will consider on a case-by-case basis. Under the data protection provisions of this law, the FDA cannot approve a biosimilar application until 12 years after initial marketing approval of the innovator biologic, subject to certain conditions.
- In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations within a specified time period. If granted, this "pediatric exclusivity" provides an additional six months of exclusivity, which is added to the term of data protection and, for products other than biologics, to the term of any relevant patents, to the extent these protections have not already expired. While the term of the pediatric exclusivity attaches to the term of any relevant patent, pediatric exclusivity is a regulatory exclusivity—i.e., a bar to generic or biosimilar approval, not a patent right.
- Under the U.S. orphan drug law, a specific use of a drug or biologic can receive "orphan" designation if it is intended to treat a disease or condition affecting fewer than 200,000 people in the U.S., or affecting more than 200,000 people but not reasonably expected to recover its development and marketing costs through U.S. sales. Among other benefits, orphan designation entitles the particular use of the drug to seven years of market exclusivity, meaning that the FDA cannot (with limited exceptions) approve another marketing application for the same drug for the same indication until expiration of the seven-year period. Unlike pediatric exclusivity, the orphan exclusivity period is independent of and runs in parallel with any applicable patents.

Outside the major markets, the adequacy and effectiveness of intellectual property protection for pharmaceuticals varies widely, and in a number of these markets we are unable to patent our products or to enforce the patents we receive for our products. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization, more than 140 countries have agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to patent owners. Certain developing countries limit protection for biopharmaceutical products under their interpretation of "flexibilities" allowed under the agreement. Thus, some types of patents, such as those on new uses of compounds or new forms of molecules, are not available in certain developing countries. Further, many developing countries, and some developed countries, do not provide effective data package protection even though it is specified in TRIPs.

Our Intellectual Property Portfolio

We consider intellectual property protection for certain products, processes, uses, and formulations—particularly with respect to those products discussed below—to be important to our operations. In addition to the patents and data protection identified below, we may hold patents on manufacturing processes, formulations, devices, or uses that extend exclusivity beyond the dates shown below. For approved products, dates include, where applicable, pending or granted patent term extensions.

The most relevant U.S. patent protection or data protection and associated expiry dates for our major or recently launched patent-protected marketed products are as follows:

- Alimta is protected by pediatric exclusivity (2022). See Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies," for information regarding our settlement agreement with Eagle Pharmaceuticals, Inc. and its impact on our exclusivity for Alimta.
- Baqsimi® is protected by data protection (2022).
- Cyramza is protected by a compound patent and biologics data protection (2026).
- Emgality is protected by a compound patent (2033) and biologics data protection (2030).
- Jardiance, and the related combination product Glyxambi, is protected by a compound patent (2028).
- Olumiant is protected by a compound patent (2032).
- Retevmo is protected by a compound patent (2037) and by data protection (2025).
- Reyvow® is protected by a compound patent (2030).
- Taltz is protected by a compound patent (2030) and by biologics data protection (2028).
- Trulicity is protected by a compound patent (2027) and by biologics data protection (2026).
- Verzenio is protected by a compound patent (2031) and by data protection (2022).

Outside the U.S., important patent protection or data protection includes:

- Baqsimi is protected by data protection in Japan (2026).
- Cyramza is protected by a compound patent (2028) and by data protection (2024) in major European countries, and by a compound patent (2026) and by data protection (2023) in Japan.
- Emgality is protected by a compound patent (2033) and by data protection (2028) in major European countries, and by a compound patent (2035) and by data protection (2029) in Japan.
- Jardiance is protected by a compound patent in major European countries (2029) and Japan (2030).
- Olumiant is protected by a compound patent (2032) and by data protection (2027) in major European countries, and by a compound patent (2033) and by data protection (2025) in Japan.
- Retevmo is protected by a compound patent (2037) and by data protection (2031) in major European countries, and by a compound patent (2038) and by data protection (2029) in Japan.
- Reyvow is protected by a compound patent (2026) and by data protection (2032) in Japan.
- Taltz is protected by a compound patent (2031) and data protection (2027) in major European countries and a compound patent (2030) and data protection (2024) in Japan.
- Trulicity is protected by a compound patent (2029) and by data protection (2024) in major European countries and by a compound patent (2029) and by data protection (2023) in Japan.
- Verzenio is protected by a compound patent (2033) and data protection (2028) in major European countries and by a compound patent (2034) and data protection (2026) in Japan.

The following product candidates are currently under regulatory review. Upon approval, we expect relevant compound patent and data protections to apply:

- We have commenced a rolling submission in the U.S. for donanemab for the treatment of Alzheimer's disease.
- We have commenced a rolling submission in the U.S. for pirtobrutinib (LOXO-305) for the treatment of mantle cell lymphoma.

Worldwide, we sell all of our major products under trademarks consisting of our product names, logos, and unique product appearances (e.g., the appearance of our Trulicity autoinjector) which we consider in the aggregate to be important to our operations. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used, and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms. Trademark protection typically extends beyond the patent and data protection for a product.

Patent Licenses and Collaborations

Most of our major products are not subject to significant license and collaboration agreements. For information on our license and collaboration agreements, see Item 8, "Financial Statements and Supplementary Data - Note 4, Collaborations and Other Arrangements."

Patent Challenges

In the U.S., the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, authorizes the FDA to approve generic versions of innovative pharmaceuticals (other than biologics, which are discussed below in more detail) when the generic manufacturer has not conducted safety and efficacy studies but files an Abbreviated New Drug Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only "pharmaceutical equivalence" and "bioequivalence" between the generic version and the NDA-approved drug—not safety and efficacy. Establishing pharmaceutical equivalence and bioequivalence is generally straightforward and inexpensive for the generic company.

Absent a patent challenge, the FDA cannot approve an ANDA until after certain of the innovator's patents expire. However, after the innovator has marketed its product for four years, a generic manufacturer may file an ANDA alleging that one or more or all of the patents listed in the innovator's NDA are invalid or not infringed. This allegation is commonly known as a "Paragraph IV certification." If the innovator responds by filing suit against the generic manufacturer, the FDA is then prohibited from approving the generic company's application for a 30-month period (which can be shortened or extended by the trial court judge hearing the patent challenge). If one or more of the NDA-listed patents are challenged, the first filer(s) of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers.

Generic manufacturers use Paragraph IV certifications extensively to challenge patents on innovative pharmaceuticals. In addition, generic companies have shown willingness to launch "at risk," i.e., after receiving ANDA approval but before final resolution of their patent challenge.

Under the BPCIA, the FDA cannot approve an application for a biosimilar product until data protection expires, 12 years after initial marketing approval of the innovator biologic, and an application may not be submitted until four years following the date the innovator biologic was first approved. However, the BPCIA does provide a mechanism for a competitor to challenge the validity of an innovator's patents as early as four years after initial marketing approval of the innovator biologic.

The patent litigation scheme under the BPCIA, and the BPCIA itself, is complex and continues to be interpreted and implemented by the FDA as well as courts. Courts have held that biosimilar applicants are not required to engage in the BPCIA patent litigation scheme and patent holders retain the right to bring suit under normal patent law procedures if a biosimilar applicant attempts to commercialize a product prior to patent expiration. Further, in the U.S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. See also "- Competition - Biosimilars." In addition, there is a procedure in U.S. patent law, known as inter partes review (IPR), which allows any member of the public to file a petition with the USPTO seeking the review of any issued U.S. patent for validity. IPRs are conducted before Administrative Patent Judges in the USPTO using a lower standard of proof than used in federal district court. In addition, the challenged patents are not accorded the presumption of validity as they are in federal district court. Generic drug companies and even some investment firms have engaged in the IPR process in attempts to invalidate our patents. The use of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch-Waxman Act is currently a topic of debate among legislators. We expect additional changes to the Patent Trial and Appeal Board (PTAB), including potentially to the policy to discretionarily deny an otherwise meritorious petition for IPR in light of a concurrent district court proceeding. See "Risk Factors—Risks Related to Our Business—Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected."

Outside the U.S., the legal doctrines and processes by which pharmaceutical patents can be challenged vary widely. In recent years, we have experienced an increase in patent challenges from generic manufacturers in many countries outside the U.S.

For more information on administrative challenges and litigation involving our intellectual property rights, see Item 8, "Financial Statements and Supplementary Data - Note 16, Contingencies."

Government Regulation of Our Operations

Our operations are regulated extensively by numerous national, state, and local agencies.

Regulation of Products

The lengthy process of laboratory and clinical testing, data analysis, manufacturing development, and regulatory review necessary for governmental approvals of our products is extremely costly and can significantly delay product introductions and revenue generation. In addition, our operations are subject to complex federal, state, local, and foreign laws and regulations concerning relationships with healthcare providers and suppliers, the environment, occupational health and safety, data privacy, and other matters. Evolving regulatory priorities have intensified governmental scrutiny of our operations, including with respect to current Good Manufacturing Practices (cGMP), quality assurance, and similar regulations. Compliance with the laws and regulations affecting the manufacture and sale of current products and the discovery, development, and introduction of new products will continue to require substantial effort, expense, and capital investment.

Of particular importance to our business is regulation by the FDA in the U.S. Pursuant to laws and regulations that include the Federal Food, Drug, and Cosmetic Act, the FDA has jurisdiction over all of our products and devices in the U.S. and administers requirements covering the testing, safety, effectiveness, manufacturing, quality control, distribution, labeling, marketing, promotion, advertising, dissemination of information, and post-marketing surveillance of those products.

Following approval, our products remain subject to regulation by various agencies in connection with labeling, import, export, storage, recordkeeping, advertising, promotion, and safety reporting. We conduct extensive post-marketing surveillance of the safety of the products we sell. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after a product reaches the market. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA extensively regulates all aspects of manufacturing quality for pharmaceuticals under its cGMP regulations. Outside the U.S., our products and operations are subject to similar regulatory requirements, notably by the EMA in Europe, the Ministry of Health, Labor and Welfare in Japan, and the National Medical Products Administration in China. Specific regulatory requirements vary from country to country. Regulatory requirements and approval processes outside the U.S. may differ from those in the U.S. and may involve additional costs, uncertainties, and risks.

We make substantial investments of capital and operating expenses to implement comprehensive, company-wide quality systems and controls in our manufacturing, product development, and process development operations in an effort to maintain sustained compliance with cGMP and similar regulations. However, in the event we fail to adhere to these requirements, we become subject to potential government investigations, regulatory and legal actions, product recalls and seizures, fines and penalties, interruption of production leading to product shortages, import bans or denials of import certifications, delays or denials in new product approvals, and reputational harm, any of which would adversely affect our business. Certain of our products are manufactured by third parties, and their failure to comply with these regulations could adversely affect us, including through failure to supply product to us or delays in new product approvals. Any determination by the FDA or other regulatory authorities of manufacturing or other deficiencies could adversely affect our business.

We are also subject to a variety of federal, state, local, and foreign environmental, health and safety, and other laws and regulations that may affect our research, development or production efforts.

market impact, recession, or depression continue for a prolonged period, these risks could be exacerbated, causing further impact on our business and operations in the future.

- **Pharmaceutical research and development is very costly and highly uncertain; we may not succeed in developing, licensing, or acquiring commercially successful products sufficient in number or value to replace revenues of products that have lost or will soon lose intellectual property protection or are displaced by competing products or therapies.**

  There are many difficulties and uncertainties inherent in pharmaceutical research and development, the introduction of new products, and business development activities to enhance our product pipeline.

  There is a high rate of failure inherent in new drug discovery and development. To bring a drug from the discovery phase to market can take over a decade and often costs in excess of $2 billion. Failure can occur at any point in the process, including in later stages after substantial investment. As a result, most funds invested in research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payer reimbursement or coverage, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of new or better competitive products, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delays and uncertainties in drug approval processes can result in delays in product launches and lost market opportunity. In addition, it can be very difficult to predict revenue growth rates of new products and indications.

  We cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful.

  We must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products, both through our internal efforts and our business development activities, sufficient both to cover our substantial research and development costs and to replace revenues that are lost as profitable products lose intellectual property exclusivity or are displaced by competing products or therapies. Failure to do so in the short-term or long-term would have a material adverse effect on our business, results of operations, cash flows, and financial position.

  We engage in various forms of business development activities to enhance our product pipeline, including licensing arrangements, co-development agreements, co-promotion arrangements, joint ventures, acquisitions, and equity investments. There are substantial risks associated with identifying successful business development targets and consummating related transactions. Increased focus on business combinations in our industry, including by the Federal Trade Commission, and heightened competition for attractive targets has and could continue to delay, jeopardize or increase the costs of our business development activities. In addition, failures or difficulties in integrating or retaining new personnel or the operations of the businesses, products, or assets we acquire (including related technology, commercial operations, compliance programs, manufacturing, distribution, and general business operations and procedures) may affect our ability to realize the expected benefits of business development transactions and may result in our incurrence of substantial asset impairment or restructuring charges. We also may fail to generate the expected revenue and pipeline enhancement from business development activities due to developments outside our control, including unsuccessful clinical trials, issues related to the quality, integrity, or broad applicability of data, regulatory impediments, and commercialization challenges. Accordingly, business development transactions may not be completed in a timely manner (if at all), may not result in successful commercialization of any product, and may give rise to legal proceedings or regulatory scrutiny.

  See Item 1, "Business - Research and Development - Phases of New Drug Development" and Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Late-Stage Pipeline," for more details about our current product pipeline.

- **We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; we have lost or soon will lose effective intellectual property protection for a number of our products, which has resulted and is likely to continue to result in rapid and severe declines in revenues.**

  A number of our products, including Alimta and Forteo, have recently lost, or soon will lose, significant patent protection and/or data protection in the U.S. as well as in key jurisdictions outside the U.S. We have faced, and remain exposed to, generic competition following the loss of such intellectual property protection. In particular, we expect that the entry of generic competition for Alimta in the U.S. following the loss of patent exclusivity will cause a rapid and severe decline in revenue for the product and have a material adverse effect on our consolidated results of operations and cash flows.

  Certain other significant products no longer have effective exclusivity through patent protection or data protection. For non-biologic products, loss of exclusivity (whether by expiration of legal rights or by termination thereof as a consequence of litigation) typically results in the entry of one or more generic competitors, leading to a rapid and severe decline in revenues, especially in the U.S. For biologics (such as Humalog, Humulin, Erbitux, Cyramza, Trulicity, Taltz, and Emgality), loss of exclusivity may or may not result in the near-term entry of competitor versions (i.e., biosimilars) due to many factors, including development timelines, manufacturing challenges, and/or uncertainties regarding the regulatory pathways for approval of the competitor versions. Generic pharmaceutical companies could also introduce a generic product before resolution of any related patent litigation.

  There is no assurance that the patents we are seeking will be granted or that the patents we hold will be found valid and enforceable if challenged. Moreover, patents relating to particular products, uses, formulations, or processes do not preclude other manufacturers from employing alternative processes or marketing alternative products or formulations that compete with our patented products. In addition, competitors or other third parties may assert claims that our activities infringe patents or other intellectual property rights held by them, or allege a third-party right of ownership in our existing intellectual property. See Item 7, "Management's Discussion and Analysis - Results of Operations - Executive Overview - Other Matters - Patent Matters," and Item 1, "Business - Patents, Trademarks, and Other Intellectual Property Rights," for more details.

- **Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected.**

  Our long-term success depends on our ability to continually discover or acquire, develop, and commercialize innovative new medicines. Without strong intellectual property protection, we would be unable to generate the returns necessary to support our significant investments in research and development, as well as the other expenditures required to bring new drugs to the market. Intellectual property protection varies throughout the world and is subject to change over time, depending on local laws and regulations. Changes to such laws and regulations could reduce protections for our innovative products. In the U.S., in addition to the process for challenging patents set forth in the BPCIA, which applies to biologic products, the Hatch-Waxman Act provides generic companies substantial incentives to seek to invalidate our patents covering pharmaceutical products. As a result, we expect that our U.S. patents on major pharmaceutical products, including biologics, will continue to be routinely challenged in litigation and may not be upheld. In addition, a separate IPR process currently allows competitors to seek invalidation of patents at the USPTO without the protections of the BPCIA or Hatch-Waxman Act. The use of IPR proceedings after the institution of litigation pursuant to the BPCIA or Hatch-Waxman Act is currently a topic of debate among legislators and the future ability of our competitors to use IPR proceedings as an alternative to Hatch-Waxman Act or BPCIA litigation procedures to challenge our patents remains uncertain. However, if our patents are challenged through this expedited review process, even if we prevail in demonstrating the validity of our patent, our win provides limited precedential value at the PTAB and no precedential value in federal district court, meaning the same patent can be challenged by other competitors. We face many generic manufacturer challenges to our patents outside the U.S. as well. The entry of generic competitors typically results in rapid and severe declines in revenues. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay significant damages for past infringement or royalties on future sales. In addition, intellectual property protection in certain jurisdictions outside the U.S. is weak and we face additional risks to our intellectual property rights, including competition with generic or counterfeit versions of our products relatively shortly after launch. See Item 1, "Business -

Patents, Trademarks, and Other Intellectual Property Rights," and Item 8, "Financial Statements and Supplementary Data - Note 16: Contingencies," for more details.

- **We and our products face intense competition from multinational pharmaceutical companies, biotechnology companies, and lower-cost generic and biosimilar manufacturers, and such competition could have a material adverse effect on our business.**

  We compete with a large number of multinational pharmaceutical companies, biotechnology companies, and generic pharmaceutical companies and, in many cases, our products compete against the leading products of one or more of our competitors. To compete successfully, we must continue to deliver to the market innovative, cost-effective products that meet important medical needs. Our product revenues can be adversely affected by the introduction by competitors of branded products that are perceived as superior by the marketplace, by generic or biosimilar versions of our branded products, and by generic or biosimilar versions of other products in the same therapeutic class as our branded products. Our revenues can also be adversely affected by treatment innovations that eliminate or minimize the need for treatment with our drugs.

  Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, recent health authority guidelines and legislative proposals could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the U.S., the FDA has begun issuing "interchangeability" designations for biosimilar products, which could – subject to state law requirements – enable pharmacies to substitute biosimilars for innovator biological products. Given the importance of biologic products to our clinical-stage pipeline, such regulation could have a material adverse effect on our business. See Item 1, "Business - Competition" and "Business - Research and Development," for more details.

  In addition, we rely on our ability to attract, engage, and retain highly qualified and skilled personnel in order to compete effectively. To continue to commercialize our products, and advance the research, development, and commercialization of additional modalities and product candidates, we may need to expand our workforce, including in the areas of manufacturing, clinical trials management, regulatory affairs, and sales and marketing, both in and outside the U.S. We continue to face intense competition for qualified individuals from numerous multinational pharmaceutical companies, biotechnology companies, academic and other research institutions, as well as employers near our manufacturing and other facilities, which has and may continue to increase our labor costs. Our ability to attract and retain talent in our increasingly competitive environment may be further complicated by evolving employment trends arising from the COVID-19 pandemic, including vaccination mandates, increased preferences for remote, alternative, or flexible work arrangements, and other factors. Our failure to compete effectively for talent could negatively affect sales of our current and any future approved products, and could result in material financial, legal, commercial, or reputational harm to our business.

- **Failure, inadequacy, breach of, or unauthorized access to, our IT systems or those of our third-party service providers, unauthorized access to our confidential information, or violations of data protection laws, could each result in material harm to our business and reputation.**

  A great deal of confidential information owned by us or our business partners or other third parties is stored in our information systems, networks, and facilities or those of third parties. This includes valuable trade secrets and intellectual property, clinical trial information, corporate strategic plans, marketing plans, customer information, and personally identifiable information, such as employee and patient information (collectively, confidential information). We also rely, to a large extent, on the efficient and uninterrupted operation of complex information technology systems, infrastructure, and hardware (together, IT systems), some of which are within our control and some of which are within the control of third parties, to accumulate, process, store, and transmit large amounts of confidential information and other data. We are subject to a variety of continuously evolving and developing laws and regulations around the world related to privacy, data protection, and data security. Maintaining the security, confidentiality, integrity and availability of our IT systems and confidential information is vital to our business. Our failure, or the failure of our third party service providers, to protect and maintain the security, confidentiality, integrity, and availability of our (or their) IT systems and our confidential information and other data could significantly harm our reputation as well as result in significant costs, including those related to fines, litigation, and obligations to comply with applicable data breach laws.

Our pipeline also contains several new indication line extension (NILEX) products. The following certain NILEX products for use in the indication described are currently in Phase II or Phase III clinical trials or have been submitted for regulatory review in the U.S., Europe, or Japan. The following table reflects the status of certain NILEX products, including certain other developments since our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021:

Compound	Indication	Status	Developments
Diabetes			
Empagliflozin (Jardiance®)[1]	Heart failure with preserved ejection fraction	Submitted	Granted FDA Breakthrough Therapy designation[2] and FDA Fast Track designation[3]. Submitted in the U.S. and Europe in 2021 and in Japan in January 2022. The FDA granted priority review for adults with heart failure independent of left ventricular ejection fraction.
	Chronic kidney disease	Phase III	Granted FDA Fast Track designation[3]. Phase III trials are ongoing.
Immunology			
Baricitinib (Olumiant®)	COVID-19	Emergency Use Authorization[4]	Submitted in the U.S. and the FDA granted priority review in January 2022.
	Alopecia areata	Submitted	Granted FDA Breakthrough Therapy designation[2]. Submitted in U.S., Europe and Japan in 2021.
	Systemic lupus erythematosus	Discontinued	Announced in January 2022 that, based on top-line efficacy results from Phase III trials, we discontinued development.
Oncology			
Abemaciclib (Verzenio®)	HR+, HER2- Adjuvant breast cancer	Approved	Approved in the U.S. and Japan in the fourth quarter of 2021.
	Prostate cancer	Phase III	Phase III trial is ongoing.
	HR+, HER2+ Adjuvant breast cancer	Discontinued	Announced in January 2022 that we will discontinue the Phase III trial in response to the changing treatment landscape and global enrollment challenges.

[1] In collaboration with Boehringer Ingelheim.

[2] Breakthrough Therapy designation is designed to expedite the development and review of potential medicines that are intended to treat a serious condition where preliminary clinical evidence indicates that the treatment may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

[3] Fast Track designation is designed to expedite the development and review of new therapies to treat serious conditions and address unmet medical needs.

[4] The FDA granted EUA for treatment with or without remdesivir in hospitalized COVID-19 patients.

There are many difficulties and uncertainties inherent in pharmaceutical research and development and the introduction of new products, as well as a high rate of failure inherent in new drug discovery and development. To bring a drug from the discovery phase to market can take over a decade and often costs in excess of $2 billion. Failure can occur at any point in the process, including in later stages after substantial investment. As a result, most funds invested in research programs will not generate financial returns. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payer reimbursement or coverage, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of new or better competitive products, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies establish high hurdles for the efficacy and safety of new products and

We manage research and development spending across our portfolio of potential new medicines. A delay in, or termination of, any one project will not necessarily cause a significant change in our total research and development spending. Due to the risks and uncertainties involved in the research and development process, we cannot reliably estimate the nature, timing, and costs of the efforts necessary to complete the development of our research and development projects, nor can we reliably estimate the future potential revenue that will be generated from any successful research and development project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated research and development expense. While we do accumulate certain research and development costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total research and development costs by project, by preclinical versus clinical spend, or by therapeutic category.

Other Matters

Patent Matters

We depend on patents or other forms of intellectual property protection for most of our revenue, cash flows, and earnings.

In 2021, our vitamin regimen patents for Alimta® expired worldwide. Following the loss of patent exclusivity in major European countries and Japan, we faced, and remain exposed to, generic competition which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels. In the U.S., we expect pediatric data exclusivity to provide us with protection through May 2022. However, we and Eagle Pharmaceuticals, Inc. (Eagle) reached an agreement in December 2019 to settle all pending U.S. patent litigation, allowing Eagle a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022. We expect that the entry of generic competition in the U.S. following the loss of exclusivity will cause a rapid and severe decline in revenue and will have a material adverse effect on our consolidated results of operations and cash flows. See Note 16 to the consolidated financial statements for a more detailed account of the legal proceedings currently pending regarding, among others, our Alimta patents.

Our compound patent for Humalog® (insulin lispro) has expired in major markets. Global regulators have different legal pathways to approve similar versions of insulin lispro. A competitor has similar version of insulin lispro in the U.S. and in certain European markets. While it is difficult to estimate the severity of the impact of insulin lispro products entering the market, we do not expect and have not experienced a rapid and severe decline in revenue; however, we expect additional pricing pressure and some loss of market share that may continue over time.

Our formulation and use patents for Forteo® have expired in major markets. We expect further decline in revenue as a result of the entry of generic and biosimilar competition due to the loss of patent exclusivity in major markets.

Our regulatory data and patent exclusivity for Cymbalta® expired in Japan. Beginning in mid-2021, we have faced, and remain exposed to, generic competition which has eroded revenue and is likely to continue to rapidly and severely erode revenue from current levels.

Foreign Currency Exchange Rates

As a global company, we face foreign currency risk exposure from fluctuating currency exchange rates, primarily the U.S. dollar against the euro, Japanese yen, and Chinese yuan. While we seek to manage a portion of these exposures through hedging and other risk management techniques, significant fluctuations in currency rates can have a material impact, either positive or negative, on operating expenses. While there is uncertainty in the future movements in foreign exchange rates, fluctuations in these rates could adversely impact our future consolidated results of operations and cash flows.

Sales Returns - Background and Uncertainties

- When product sales occur, to determine the appropriate transaction price for our sales, we estimate a reserve for future product returns related to those sales using an expected value approach. This estimate is based on several factors, including: historical return rates, expiration date by product (on average, approximately 24 months after the initial sale of a product to our customer), and estimated levels of inventory in the wholesale and retail channels, as well as any other specifically-identified anticipated returns due to known factors such as the loss of patent exclusivity, product recalls and discontinuances, or a changing competitive environment. We maintain a returns policy that allows most U.S. customers to return product for dating issues within a specified period prior to and subsequent to the product's expiration date. Following the loss of exclusivity for a patent-dependent product, we expect to experience an elevated level of product returns as product inventory remaining in the wholesale and retail channels expires. Adjustments to the returns reserve have been and may in the future be required based on revised estimates to our assumptions. We record the return amounts as a deduction to arrive at our net product revenue. Once the product is returned, it is destroyed; we do not record a right of return asset. Our returns policies outside the U.S. are generally more restrictive than in the U.S. as returns are not allowed for reasons other than failure to meet product specifications in many countries. Our reserve for future product returns for product sales outside the U.S. is not material.
- As a part of our process to estimate a reserve for product returns, we regularly review the supply levels of our significant products at the major wholesalers in the U.S. and in major markets outside the U.S., primarily by reviewing periodic inventory reports supplied by our major wholesalers and available prescription volume information for our products, or alternative approaches. We attempt to maintain U.S. wholesaler inventory levels at an average of approximately one month or less on a consistent basis across our product portfolio. Causes of unusual wholesaler buying patterns include actual or anticipated product-supply issues, weather patterns, anticipated changes in the transportation network, redundant holiday stocking, and changes in wholesaler business operations. In the U.S., the current structure of our arrangements provides us with data on inventory levels at our wholesalers; however, our data on inventory levels in the retail channel is more limited. Wholesaler stocking and destocking activity historically has not caused any material changes in the rate of actual product returns.
- Actual U.S. product returns have been less than 2 percent of our U.S. revenue during each of the past three years and have not fluctuated significantly as a percentage of revenue, although fluctuations are more likely in periods following loss of patent exclusivity for major products in the U.S. market.

Adjustments to Revenue

We record adjustments to revenue as a result of changes in estimates, for the judgments described above, for our most significant U.S. sales returns, rebates and discounts liability balances. Such adjustments for products shipped in previous periods resulted in approximately 2 percent or less increase to U.S revenue during each of the years ended December 31, 2021, 2020, and 2019.

Collaboration and Other Arrangements

We recognize several types of revenue from our collaborations and other arrangements, which we discuss in general terms immediately below and more specifically in Note 4 for each of our material collaborations and other arrangements. Our collaborations and other arrangements are not contracts with customers but are evaluated to determine whether any aspects of the arrangements are contracts with customers.

- Revenue related to products we sell pursuant to these arrangements is included in net product revenue, while other sources of revenue (e.g., royalties and profit sharing from our partner) are included in collaboration and other revenue.
- Initial fees and developmental milestones we receive in collaborative and other similar arrangements from the partnering of our compounds under development are generally deferred and amortized into income through the expected product approval date.
- Profit-sharing due from our collaboration partners, which is based upon gross margins reported to us by our partners, is recognized as collaboration and other revenue as earned.

Note 16: Contingencies

We are involved in various lawsuits, claims, government investigations and other legal proceedings that arise in the ordinary course of business. These claims or proceedings can involve various types of parties, including governments, competitors, customers, suppliers, service providers, licensees, employees, or shareholders, among others. These matters may involve patent infringement, antitrust, securities, pricing, sales and marketing practices, environmental, commercial, contractual rights, licensing obligations, health and safety matters, consumer fraud, employment matters, product liability and insurance coverage, among others. The resolution of these matters often develops over a long period of time and expectations can change as a result of new findings, rulings, appeals or settlement arrangements. Legal proceedings that are significant or that we believe could become significant or material are described below.

We believe the legal proceedings in which we are named as defendants are without merit and we are defending against them vigorously. It is not possible to determine the final outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss in excess of amounts accrued for any of these matters; however, we believe that the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity, but could possibly be material to our consolidated results of operations in any one accounting period.

Litigation accruals, environmental liabilities, and the related estimated insurance recoverables are reflected on a gross basis as liabilities and assets, respectively, on our consolidated balance sheets. With respect to the product liability claims currently asserted against us, we have accrued for our estimated exposures to the extent they are both probable and reasonably estimable based on the information available to us. We accrue for certain product liability claims incurred but not filed to the extent we can formulate a reasonable estimate of their costs. We estimate these expenses based primarily on historical claims experience and data regarding product usage. Legal defense costs expected to be incurred in connection with significant product liability loss contingencies are accrued when both probable and reasonably estimable.

Because of the nature of pharmaceutical products, it is possible that we could become subject to large numbers of additional product liability and related claims in the future. Due to a very restrictive market for litigation liability insurance, we are self-insured for litigation liability losses for all our currently and previously marketed products.

Patent Litigation

Alimta Patent Litigation

U.S. Patent Litigation

Alimta (pemetrexed) was protected by a vitamin regimen patent until November 2021, and since then has been protected by pediatric exclusivity through May 2022.

In December 2019, we settled a lawsuit we filed against Eagle Pharmaceuticals, Inc. (Eagle) in response to its application to market a product using an alternative form of pemetrexed. Per the settlement agreement, Eagle has a limited initial entry into the market with its product starting February 2022 (up to an approximate three-week supply) and subsequent unlimited entry starting April 2022.

European Patent Litigation

In Europe, Alimta was protected by the vitamin regimen patent through June 2021. Despite the recent patent expiration, a number of legal proceedings that were initiated prior to expiration are ongoing.

Emgality Patent Litigation

In September 2018, we were named as a defendant in litigation filed by Teva Pharmaceuticals International GMBH and Teva Pharmaceuticals USA, Inc. (collectively, Teva) in the U.S. District Court for the District of Massachusetts seeking a ruling that various claims in nine different Teva patents would be infringed by our launch and continued sales of Emgality for the prevention of migraine in adults. Trial is currently scheduled to begin in October 2022. In June 2021, we were named as a defendant in a second litigation filed by Teva in the U.S. District Court for the District of Massachusetts seeking a ruling that two of Teva's patents, which are directed toward use of the active ingredient in Emgality to treat migraine, would be infringed by our continued sales of Emgality.

Jardiance Patent Litigation

In November 2018, Boehringer Ingelheim (BI), our partner in marketing and development of Jardiance, initiated U.S. patent litigation in the U.S. District Court of Delaware alleging infringement arising from submissions of Abbreviated New Drug Applications (ANDA) by a number of generic companies seeking approval to market generic versions of Jardiance, Glyxambi, and Synjardy in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act). Particularly with respect to Jardiance, the generic companies' ANDAs seek approval to market generic versions of Jardiance prior to the expiration of the relevant patents, and allege that certain patents, including in some allegations the compound patent, are invalid or would not be infringed. We are not a party to this litigation. This litigation has been stayed.

Taltz Patent Litigation

In April 2021, we petitioned the High Court of Ireland to declare invalid the patent that Novartis Pharma AG (Novartis) purchased from Genentech, Inc. in 2020. Novartis responded by filing a claim against us alleging patent infringement related to our commercialization of Taltz and seeking damages for past infringement and an injunction against future infringement. This matter is ongoing.

In April 2021 and November 2021, Novartis petitioned the Court of Rome Intellectual Property Division and the Swiss Federal Patent Court, respectively, in preliminary injunction (PI) and main infringement proceedings against us related to our commercialization of Taltz. In June 2021, the Court of Rome Intellectual Property Division dismissed Novartis' PI action. Novartis appealed the ruling and in October 2021, the panel hearing Novartis' appeal appointed a technical expert to assess the merits of the case. Both matters are ongoing. Hearings on the Italian and Swiss PI requests are scheduled for May 2022.

In June 2021, Novartis petitioned the Commercial Court of Vienna in PI proceedings and in November 2021, the Austrian court denied Novartis' request. Novartis did not appeal the ruling, and this matter is now closed.

Zyprexa Canada Patent Litigation

Beginning in the mid-2000s, several generic companies in Canada challenged the validity of our Zyprexa compound patent. In 2012, the Canadian Federal Court of Appeals denied our appeal of a lower court's decision that certain patent claims were invalid for lack of utility. In 2013, Apotex Inc. and Apotex Pharmachem Inc. (collectively, Apotex) brought claims against us in the Ontario Superior Court of Justice at Toronto for damages related to our enforcement of the Zyprexa compound patent under Canadian regulations governing patented drugs. Apotex seeks compensation based on novel legal theories under the Statute of Monopolies, Trade-Mark Act, and common law. In March 2021, the Ontario Superior Court granted our motion for summary judgement, thereby dismissing Apotex's case. Apotex appealed that ruling to the Court of Appeal for Ontario in April 2021 and a hearing occurred February 2022. We await a decision.

Product Liability Litigation

Actos® Product Liability

We are named along with Takeda Chemical Industries, Ltd. and Takeda affiliates (collectively, Takeda) as a defendant in four purported product liability class actions in Canada related to Actos, which we commercialized with Takeda in Canada until 2009, including one in Ontario filed December 2011 (*Casseres et al. v. Takeda Pharmaceutical North America, Inc., et al.*), one in Quebec filed July 2012 (*Whyte et al. v. Eli Lilly et al.*), one in Saskatchewan filed November 2017 (*Weiler v. Takeda Canada Inc. et al.*), and one in Alberta filed January 2013 (*Epp v. Takeda Canada Inc. et al.*). In general, plaintiffs in these actions alleged that Actos caused or contributed to their bladder cancer. An agreement to settle these actions became effective in May 2021. The relevant courts approved the settlement and the deadline for class members to seek settlement funds has now expired. The lawsuits have been dismissed or discontinued.

Exhibit C
[Copy of ESG Report]

Our Social Approach

Our approach to social impact starts with our medicines and our goal to expand access to quality health care. We work across global health systems to extend our reach by being part of the solution for complex challenges that disproportionately affect people living in settings with limited resources. We strive to provide an inclusive, high-performance workplace where our team members can bring their authentic selves to work every day, and grow and thrive. And in our communities, we invest our time, expertise and resources to drive social impact, with a focus on health. We also engage in targeted social issues that affect our business, our communities and employees, with an emphasis on racial justice and education.

Goals and Highlights

Access and Affordability

Reach 30 million people in resource-limited settings annually by 2030, through investments in people, medicines and health systems.

Community Engagement

Lilly employees and retirees, along with match from the Lilly Foundation, contributed $12.6 million to United Way in 2021.

Diversity and Inclusion

Increase the number of women and minority group members in leadership; increase the current representation of Black/African Americans in our U.S. workforce from approximately 10% to 13%.

Employee Safety

Achieve zero severe injuries; develop safety leadership capabilities, reduce our most significant risks that could have life-altering or fatal consequences and manage business continuity risk.

Access & Affordability

SASB Disclosures Covered:
Access to Medicines (HC-BP-240a.1, HC-BP-240a.2)
Affordability & Pricing (HC-BP-240b.2)

Management Approach

Throughout our nearly 150-year history, Lilly has pioneered many life-changing medicines – including insulin, which has helped make diabetes a manageable disease; penicillin, which greatly reduced deaths from infection; fluoxetine, which revolutionized depression care; and COVID-19 treatments, which have provided additional tools in the fight against the global pandemic. Today, over 47 million people use Lilly's medicines.

Lilly employees from across the globe come together from diverse backgrounds to harness the power of biotechnology and aim to bring relief to millions of people with serious illnesses. We invest in innovation that helps solve some of the world's most significant health challenges.

But we know that our commitment to patients and society goes beyond the medicines we make.

We are deeply committed to equitable and affordable access to our medicines so that our breakthroughs can transform more people's lives. We're also committed to expanding our impact on society by addressing complex global health challenges, with a focus on people living in communities with limited resources.

Reaching across industry boundaries, we collaborate with leading partners to reach more people and help them feel better in their daily lives. Our collective work benefits individual patients and the entire global health system.

In This Section

U.S. Access & Affordability

Pricing in the U.S.

Pricing medicines to ensure the right balance between patient access and sustained investment in life-changing treatments is complex. At Lilly, we know that pricing our medicines is one of the most important decisions we make as a company. When making pricing considerations, we use a value-based approach, taking into account the following:

- **Customer perspective** – The unmet needs that medicines can fulfill for patients and caregivers and how people can affordably access the treatment.
- **Company considerations** – The costs of research, development, manufacturing and support services for customers; business trends and other economic factors; as well as the medicine's potential market size, patent life and place within our larger portfolio of medicines.
- **Competitive landscape** – The benefits of our medicine compared to alternative medicines, where our medicine fits in treating conditions and existing contracts between payers and our competitors.
- **Other external factors** – Such as health system changes and policy guidelines.

Lilly also makes price adjustments (up or down) over a product's lifecycle that are based on the factors above as well as improvements in the clinical data supporting the drug's use.

We are committed to increasing transparency around the price of our medicines. We publish list prices for our medicines, as well as average out-of-pocket costs and financial assistance information.

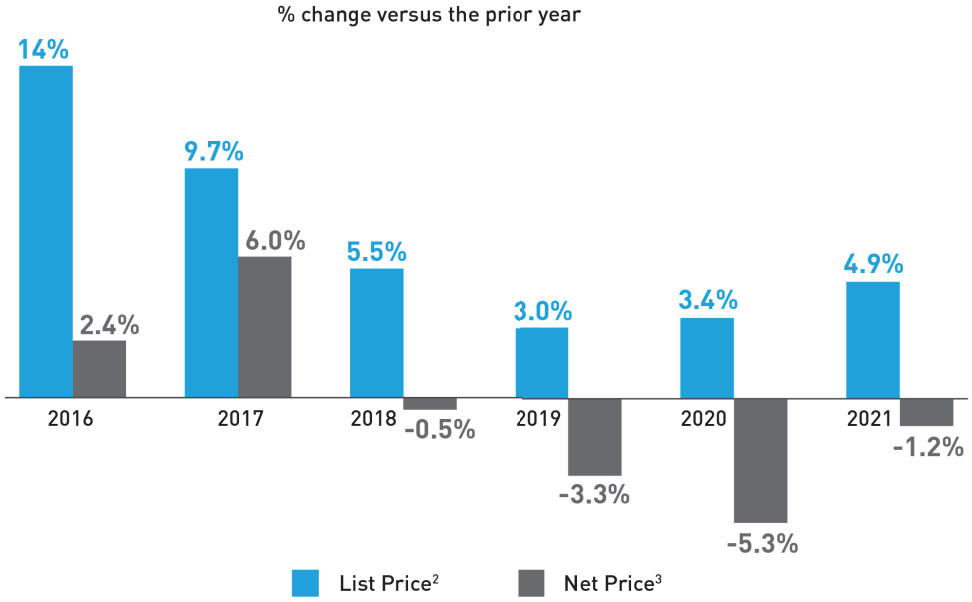
List Price vs. Net Price
Lilly sets a list price for each of our medicines using the considerations noted above.

To expand patient access, we pay rebates and other discounts to payers, pharmacy benefit managers (PBMs), providers, the U.S. and state governments and other supply chain entities such as wholesalers and distributors. After paying these rebates and discounts, the final dollar amount that Lilly ultimately receives is called the net price.

From 2016 to 2021, these rebates and discounts have continued to increase for Lilly's entire U.S. portfolio while net prices for many of our medicines have continued to decrease.

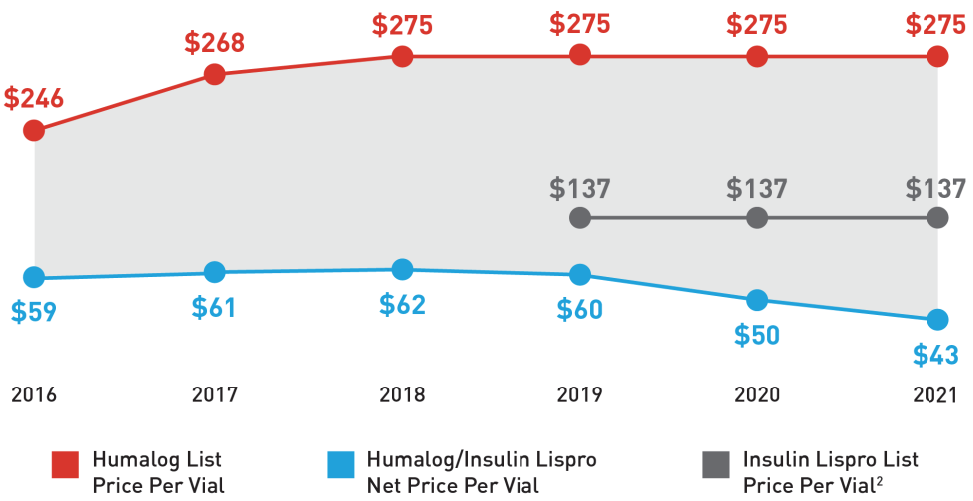
Changes in Lilly's Net Price: 2016-2021

Comparison of Lilly List And Net Price Changes For U.S. Product Portfolio[1]



[1] U.S. Product Portfolio includes all human pharmaceutical products marketed in the U.S. for which Lilly is the holder of the new drug application (NDA). Bamlanivamab and etesevimab are not included because they are not currently marketed commercially. The U.S. Product Portfolio represents approximately 87% of our total U.S. human pharmaceutical revenue.
[2] List Price represents the weighted average year-over-year change in the wholesale acquisition cost (WAC).
[3] Net Price represents weighted average year-over-year change in net price, which is WAC minus rebates, discounts and channel costs.

Humalog® List And Net Price Per Vial[1]



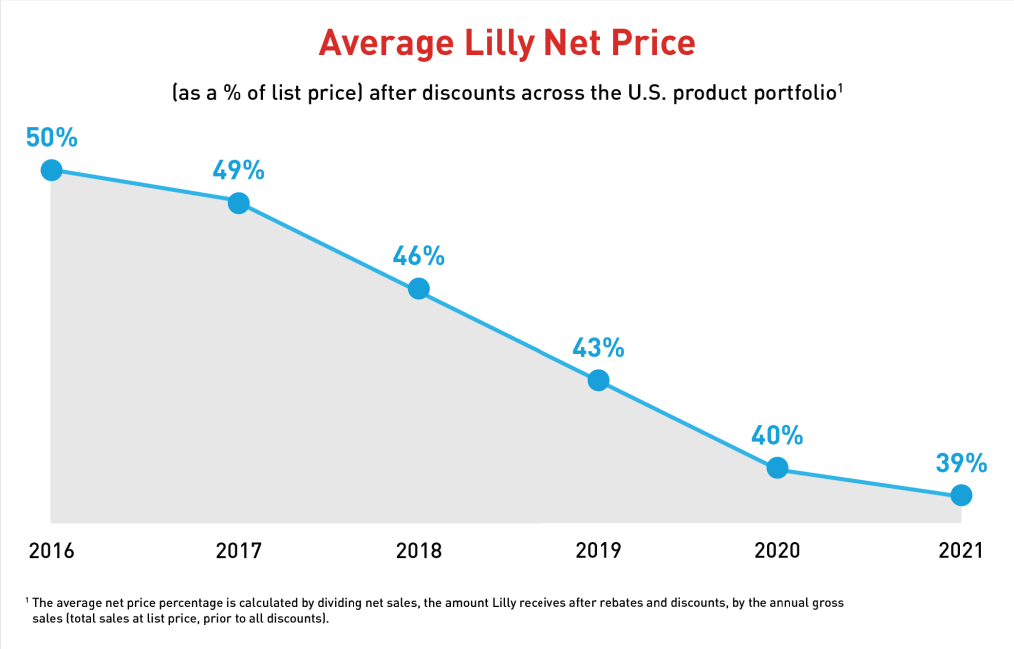
Anyone is eligible to buy their monthly prescription of Lilly insulin for $35 or less if they use commercial insurance, Medicare Part D[3], Medicaid or have no insurance at all.

The last list price increase for Humalog vial was May 2017. List Price represents the weighted average wholesale acquisition cost (WAC). Net Price represents the weighted average net price, which is WAC minus rebates, discounts and channel costs.

[1] The average net price per vial, the amount Lilly receives after rebates and discounts, is calculated by dividing the total net vial sales (Humalog and Insulin Lispro vials), by the total vials sold.

[2] The new list price for Insulin Lispro per vial, $82.41, went into effect in January 2022.

[3] Medicare Part D participants must be enrolled in a plan in the Senior Savings Model.



Lilly Affordability Solutions

Discovering new medicines that make life better for people around the world drives our company and our employees. Innovative medicines play a crucial role in reducing the burden of disease, improving lives and ultimately bringing down health care costs.

Changes in the U.S. health care system have created greater consumer cost-sharing and exposed a growing number of people to a medicine's full list price.

We actively advocate for and participate in the process of driving systematic changes. We support the restructuring of financial incentives for the entire pharmaceutical supply chain to ensure patients directly benefit from rebates and discounts we provide at their point of purchase. We are also taking important steps within our own control to increase access to Lilly medicines today.

Lilly offers a variety of affordability solutions through patient support programs and copay assistance across the major products of our portfolio, including medicines for diabetes, migraine, immunology diseases and cancer. For migraine and immunology, we've designed copay assistance programs to bring eligible patients' monthly out-of-pocket costs to as little as $25 or lower. For cancer, we have created a Lilly Oncology Support Center that assists eligible patients in identifying affordability options related to their Lilly treatment.

Insulin Affordability

For millions of people with diabetes, insulin is a life-saving medicine. Over the last century, this medical miracle has improved and extended countless lives around the world. Lilly takes its role as a leading diabetes company seriously – and that includes ensuring people have affordable access to treatments.

While many people in the U.S. have insurance coverage with affordable copays, others struggle to afford their out-of-pocket costs for insulin. Some people have large deductibles they must satisfy before insurance will cover their medicines, while others have no insurance at all. And, for many people, insulin is just one of several interventions used to control diabetes, such as blood glucose monitoring devices and supplies, and other medicines.

In recent years, we've taken numerous steps to help ensure people can afford their insulin at retail pharmacies regardless of their personal circumstances – including establishing automatic discounts at retail pharmacies and launching non-branded insulins with lower list prices.

Today, anyone is eligible to obtain their monthly prescription of Lilly insulin for $35 or less – regardless of the number of vials or pens – whether they are uninsured or use commercial insurance, Medicaid or a participating Medicare Part D plan.

This follows the introduction of several affordability options including:

- **Lilly Insulin Value Program** – In April 2020, Lilly unveiled the Lilly Insulin Value Program, a new co-pay card that allows anyone with commercial insurance, or no insurance at all, to obtain their monthly prescription of Lilly insulin for $35 at retail pharmacies. In September 2020, we announced our long-term commitment to this program.
- **Medicare Part D Senior Savings Model** – We also participate in the Medicare Part D Senior Savings Model, a federal government program that allows seniors enrolled in participating Medicare Part D plans to purchase their monthly prescription of Lilly insulin for $35 during all phases of their Part D coverage – including deductibles, the coverage gap and co-pays. Lilly has committed all of our insulins to the Savings Model program, which went into effect in January 2021.

Insulin Lispro – Lilly's non-branded insulin was first introduced in 2019 at half the list price of branded Humalog. On January 1, 2022, we lowered the list price of Insulin Lispro by an additional 40 percent, making its list price 70 percent lower than Humalog. Approximately one in three prescriptions for Lilly's U-100 mealtime insulin – Lilly's most commonly used insulin formulation – is for Insulin Lispro.

All of these programs are making an impact and helping at least 20,000 people each month better afford their insulin. Importantly, despite rising insurance deductibles, the average monthly out-of-pocket cost for Lilly insulin has dropped 44 percent, to $21.80, over the past five years.

Our suite of affordability programs is available on insulinaffordability.com and through the Lilly Diabetes Solution Center at (833) 808-1234. The Solution Center is a call center staffed with experts who can help guide individuals to the affordability solution that best matches their needs, including connecting people with diabetes to charitable organizations that provide free Lilly insulin. Additionally, we are a financial supporter of getinsulin.org, a tool launched in 2020 by the patient advocacy group, Beyond Type 1, that helps people easily find the most affordable insulin options in their area – regardless of brand or manufacturer. Both web- and app-based, getinsulin.org is a convenient one-stop shop for people who use insulin and is available in both English and Spanish.

These solutions are only helpful if people know about them, and Lilly has worked diligently to make people aware of their options. We published full-page advertisements printed in dozens of top English and Spanish-language newspapers to inform the public how they can lower their insulin costs. We have also published sponsored content and ads online, and participated in radio station interviews about Lilly's affordability solutions in markets throughout the U.S.

Lilly Cares Foundation

In addition to the Lilly insulin affordability solutions noted above, Lilly also donates medicines to the Lilly Cares Foundation, a separate nonprofit organization that provides Lilly medications for free to qualifying patients in the United States. Eligibility is determined by the Lilly Cares Foundation.

Value vs Volume: Linking Cost to Patient Outcomes

When a patient seeks medical care, the health care system's top goal should be to improve their health. Medical interventions, including medicines, should be evaluated based on how well the patient's health may improve. This seems obvious, but it's not how our current payment system works.

Under the existing fee-for-service model that is common in the U.S., payments are based on the number of treatments or services provided, not whether a patient sees improvements in their health. However, as health care costs and rates of chronic disease continue to rise, there has been increased urgency to deliver care that brings greater value to both the patient and the health care system as a whole.

We believe that innovative value-based arrangements (VBAs) are an important part of the solution. VBAs allow Lilly to stand behind the health outcomes we expect our medicines to deliver when the medicines are used appropriately. Such arrangements are designed to link the cost of our medicine more directly to patient outcomes.

A VBA includes predefined patient health outcomes and/or associated performance metrics base he observed impact of a particular medicine on the person taking it. Such metrics can include favorable test results, improved medication adherence, reduced re-hospitalization rates or reduction in overall disease management costs. This approach can transform the health care system to one that is about delivering value versus one about the volume of medicines purchased.

Lilly has been committed to driving VBAs since 2014 and in the U.S., more than 50% of revenue flowing through our access-based contracts has a value-based component – a goal we met in 2021, two years ahead of schedule. In addition, we have alternative access contracts in other global markets, many of which are value-based. We use each VBA as an opportunity to learn more about the real-world data we need to gather to make these arrangements more effective.

In many cases, VBAs improve access to a medicine for eligible patients and many patients may also get more personalized care, given medicines in these arrangements are generally made available based on how well they work in specific subpopulations. For payers, VBAs can help them better maintain affordability in novel ways and pay for medicines that deliver outcomes. For companies like Lilly, these arrangements can increase access to their medicines and reinforce data from clinical studies with real-world evidence. And over the long term, the results from these arrangements may help inform and improve future research and development efforts.

We believe VBAs have the potential to improve patient outcomes while lowering costs for the entire health care system, but they require increased collaboration between payers, health systems, employers, patients and industry to be successful. At Lilly, we continue to advocate for legislative and regulatory changes that support this transition. We believe this is one of the most important long-term changes we can make as an industry.

Long Term Policy Solutions

Lilly is actively working with other stakeholders throughout the health care system, including Congress, to seek common-sense policy solutions to address gaps. Some of these include:

Rebate Pass-Through – We continue to advocate for insurers to pass through our negotiated rebates directly to consumers at the point of purchase.

First Dollar Coverage – We support efforts to exempt certain health care services for chronic conditions, including medicines such as insulin, from insurance plan deductibles.

Insulin Out-of-Pocket Caps – We support legislation to cap out-of-pocket costs for Medicare Part D and privately insured patients. We believe a cap could provide a critical financial safeguard for patients and support the $35 copay cap for insulin.

We believe these long-term, much-needed reforms could provide lasting relief to those who struggle to afford their medicines. In the meantime, Lilly intends to continue providing affordability solutions to people who need them.

Large Employers Doing Their Part: Making Health Care More Affordable for Employees

Employers are spending more than ever to provide health benefits to their workers in the U.S. Yet many, especially those with chronic illnesses, struggle with affordability and access to the care they need.

If more employers – especially large employers – reduce cost-sharing for high-value therapies, they could change the insurance market in ways that could improve health and productivity while constraining costs.

Like all employers, Lilly works every year to minimize the rising costs of health care for our organization. For more than a decade, we've offered exclusively high-deductible plans to our employees. But we take certain steps to make sure our high deductibles don't lead our people to skip or ration the care they need.

We fund our employees' health savings accounts all at once at the beginning of the year. It shouldn't matter if someone gets sick around New Year's Day or Thanksgiving Day – we believe they should have money to help cover their health care costs.

We exempt preventive and chronic disease medications from our health plan deductibles. This means Lilly employees, retirees and their families pay only 10% to 20% of these medicines' prices instead of the full retail price.

For all medicines, Lilly's health plan has lowered costs by passing through rebates to patients at the point of sale. Sharing these rebates helped over 9,000 of our health plan members save $260 on average in 2021 – or about $2.4 million collectively.

- Employees and their eligible family members with diabetes can receive a free connected glucose meter and related supplies, along with real-time support from trained diabetes educators.

As we've expanded these cost-saving policies, both company-paid and employee-paid premiums for our plans have grown an average of just 3% annually – half as fast as the trend among all U.S. employers.

We believe corporate leaders across the U.S. can make longer-term decisions and trade-offs to more effectively manage health benefits. Working together, employers can advance good ideas and help provide a better way to make U.S. health care and health insurance work for all Americans.

Improving Global Access and Health

Medicines play an important role in making life better for people. When used appropriately, medications can help us live longer and healthier, slow the progression of disease, improve management of chronic conditions, enhance our quality of life and prevent or minimize complications– or even potentially eliminate the need for costly hospitalizations and surgeries. But medicines can often be out of reach for those who need them the most. Ensuring access to medicines is an important component of investing in health and well-being.

Our commitment to tackle complex global health challenges takes many forms. We work to develop and scale sustainable solutions while focusing on diseases where we have deep technical expertise.

Pricing Around the World

We sell medicines in about 120 countries around the world. Each country values medications and innovation differently, and each must balance competing demands for finite resources, including other health care products and services, as well as meeting other social needs, such as education or infrastructure. At Lilly, we consider country-specific conditions when pricing medicines on a market-by-market basis to help ensure patients have affordable access to the innovative medications we develop. We support public policies to meet this same end. We strive to price our medicines to enable affordable access for appropriate patients, reflecting the value provided to patients, providers, payers, caregivers, the health system and society as a whole.

We explore new pricing and reimbursement models in different markets, and we advocate for policy changes that help increase access to medicines while protecting innovation and enabling development of new medicines. Value-based and outcomes-based reimbursement models are examples of approaches that can deliver greater health and economic value to health systems.

As a global company, we are particularly aware of the social and economic circumstances in many developing countries that may make access to medicines difficult. In response, Lilly is researching alternative business models, recognizing lower ability to pay in lower-income countries. We also support efforts to decrease the final price of medicines to patients, such as minimizing taxes and limiting markups applied in the supply chain.

COVID-19 Antibody Pricing and Allocation

We believe cost should not be a barrier to access – including for patients who need Lilly's COVID-19 antibody therapies. Wherever possible, we negotiated contracts with governments to set patient out-of-pocket costs for our COVID-19 therapies at $0. For instance, the U.S. government has committed that patients will have no out of-pocket costs for Lilly's antibody therapies, although health care facilities may charge a fee for the product's administration. We pursued tiered pricing arrangements for government purchases of our antibody therapies, based on the World Bank's gross national income (GNI) per capita data. The price we charge governments for bamlanivimab and etesevimab is $2,100 per dose for wealthy countries, with lower prices for countries with less ability to pay. Furthermore, we provided more than 100,000 doses of our bamlanivimab and etesevimab COVID-19 therapies at no cost to Direct Relief for use in eight low-income to lower-middle-income countries.

Lilly's Support of Universal Health Care Principles

In 2019, Lilly participated in the first-ever high-level meeting of the United Nations (UN) General Assembly focused exclusively on universal health coverage (UHC). The meeting featured heads of state, global health leaders and

We support the principles of UHC and its importance in fulfilling the 2030 Agenda for Sustainable Development, which provides a framework for member countries, the private sector and non-governmental organizations to work together toward achieving peace and prosperity for people and our planet by realizing the UN's Sustainable Development Goals. UHC means that all individuals and communities have access to quality health care services, where and when they need them, without risk of financial hardship. Pharmaceutical companies are part of a much larger health ecosystem composed of public and private providers, health care professionals, hospitals and clinics, laboratories, supply chain operators and health insurers, and we recognize that no single organization or sector can achieve UHC on its own. We believe the private sector is well-positioned to contribute to UHC goals as we provide products and services to improve lives for many millions of people across the globe.

Intellectual Property

Intellectual property protections play a central role in driving innovations that result in better patient outcomes. For example, decades-long investments made by biopharmaceutical companies in new technologies, research and treatments helped prepare the industry to pivot quickly and develop therapies and vaccines in response to the COVID-19 pandemic. Sustaining a dependable intellectual propriety environment enhances the industry's ability to respond quickly to future public health challenges, promotes the pursuit of breakthroughs in areas of unmet need, like Alzheimer's disease and antimicrobial resistance, and emboldens investor confidence in keeping the engines of innovation operating at full speed.

Intellectual property improves patient access by expanding the innovation base. Lilly supports the removal of regulatory or pricing, reimbursement and access restrictions for generics and biosimilars when intellectual property protections expire. In addition, Lilly has a long-standing practice of not seeking or enforcing patents for medicines in least developed countries, as defined by the United Nations.

Lilly 30x30

Through investments in people, medicines and health systems, we aim to improve access to quality health care for 30 million people living in settings with limited resources annually by 2030. We call this global effort Lilly 30x30. To achieve our goal, we are leveraging the company's resources and working with leading health organizations to increase access to Lilly medicines and address complex global health challenges. Our bold Lilly 30x30 goal will advance health equity across three areas of impact: our pipeline and external pipelines we help support, programs to increase access to Lilly medicines, and partnerships. In each of these areas, we are working to develop high-impact, scalable solutions.

Governance of 30x30

To embed accountability throughout the company, Lilly 30x30 is governed by a steering committee of six Executive Committee members and the head of Social Impact. Reporting to the CEO, this committee oversees management of key priorities and operational milestones to measure our progress and ensures the Lilly 30x30 program is strategically aligned with our business.

In 2021, Lilly created a new senior role within our Lilly International business unit to accelerate Lilly 30x30 activities. This role will help identify and implement new opportunities, including solutions to improve access to insulins in low- and middle-income countries.

Measuring Patient Reach

To track our progress, we developed a measurement framework that allows us to estimate the number of people we reach through the full Lilly 30x30 portfolio. This includes a proportion of people we reach with our marketed products, people we reach via product donations, and the estimated number of people reached by the implementing organizations of our global health partnerships. We continue to develop new initiatives with broad reach to achieve our 2030 goal. In 2021, our estimated Lilly 30x30 reach was approximately 11.6 million people, an increase of about 6.6 million since 2015.

Pipeline

In 2021, we continued to explore the repositioning and repurposing of internal assets and engaging with external organizations that develop innovation for diseases disproportionately affecting people living in settings with limited resources. Our research efforts remained focused on our current and legacy products, and mid- to late-phase assets. We also engaged external groups to explore potential opportunities and business development models that further support the development of our Lilly 30x30 pipeline.

Drug Development and Repurposing
Not every Lilly scientific discovery will go on to become a marketed medicine, but some could still yield value in other ways. For example, in response to the coronavirus pandemic, our Lilly 30x30 drug repurposing efforts uncovered an antibody previously studied in cancer that could be evaluated against new disease targets. Other examples include:

- **Lilly Collaboration with NIDA** - Lilly has entered into a collaboration with NIDA to explore the potential of some early-phase therapies that might be repurposed for the treatment of opioid use disorder (OUD). Although there are three drugs approved by the U.S. Food and Drug Administration for the treatment of opioid dependence, misuse of opioids remains a significant public health concern, and there is a high unmet need to develop new and effective treatments for opioid and other addictive disorders. Opioid and other addictive disorders disproportionately affect people with limited resources.

  Lilly has provided NIDA with samples of four specific molecules that we initially studied for psychiatric disorders and diabetes. There is evidence to suggest these investigational therapies may hold the potential for other indications.

  Lilly's own initial data, along with scientific review literature, show that these molecules may have effects on the brain-reward pathway by decreasing anxiety, improving mood, increasing satiation or dampening the rewarding effects of drugs of abuse.

- **Antimicrobial Resistance (AMR) Action Fund** - In 2020, the Antimicrobial Resistance (AMR) Action Fund was launched by over 20 leading biopharmaceutical companies, including Lilly. Joining forces with global charitable organizations and development banks, the AMR Action Fund aims to accelerate antibiotic development with the goal to deliver 2-4 new antibiotics by 2030. To launch the AMR Action Fund, Lilly loaned one of our finance executives to serve as interim CEO, underscoring our commitment to strengthening and accelerating antibiotic development. Lilly continues to be a top-tier investor, with $100 million commitment over the life of the Fund.

- **PASTEUR Act** - To further support AMR efforts, Lilly extended our support in 2021 to the bipartisan Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act. The bill seeks to advance needed reforms to encourage innovative drug development targeting the most threatening infections, improve the appropriate use of antibiotics and ensure domestic availability when needed.

Programs

Through Lilly 30x30, we are strengthening our existing programs and developing new approaches to improve access to Lilly products and services for people living in settings with limited resources. These efforts include exploring alternative business models and expanding access strategies and patient support programs.

Patient Support Programs
Lilly offers more than 125 patient support programs across 40 countries that reach nearly 1.5 million people annually. These programs, including strengthened insulin affordability efforts in the U.S., support people who take Lilly medicines as well as their caregivers and loved ones.

Our patient support programs fall into three categories:

- Supporting patients through reimbursement and product access issues
- Answering questions related to living with disease and managing health
- Providing information on Lilly medicines and training on Lilly devices.

To help expand access to our medicines, some of our support programs take a patient's income level and ability to pay into consideration.

Alternative Access Programs
Lilly offers alternative access programs in addition to standard pricing, reimbursement and access models. Our alternative programs facilitate appropriate patient access to Lilly medicines by addressing specific challenges faced by institutional payers, patients or channel partners.

We are also exploring manufacturing and public-private, partnership-based solutions to expand access to our products in the countries where Lilly currently has no or limited presence.

Partnerships

Through strategic partnerships and collaborations, Lilly and the Lilly Foundation work to strengthen local health care systems and improve access to care. In conjunction with other organizations, Lilly uses its technology and expertise to find innovative, sustainable and scalable solutions to help address pressing global health concerns, especially diabetes care. We work to establish cross-industry collaborations and develop and test models of care to reach as many people as possible.

Our global health work is largely focused on noncommunicable diseases (NCDs), which disproportionately affect people living in settings with limited resources. According to the World Health Organization, more than three quarters of NCD deaths annually – 31.4 million – occur in low- and middle-income countries. Even in the U.S., NCDs have a greater impact on underserved communities. It's not uncommon for someone in the U.S. with limited resources to live 10 to 15 years less than someone in the U.S. with more resources living just 10 miles away.

Through our partnerships, we share data and lessons learned to help inform policy and advocate for the scale-up and replication of proven, cost-effective solutions.

Notable Partnerships

- **Africa Health Worker Training Initiative** – In early 2020, we joined four other health care companies and the Bill & Melinda Gates Foundation to launch a new fund to increase access to community-based primary health care for nearly 1.7 million people in up to six African countries by 2022. Led by nonprofit partners Last Mile Health and Living Goods, who have worked through networks in Kenya, Uganda, Liberia, Ethiopia and Malawi, the initiative has supported or digitally enabled more than 16,000 Community Health Workers (CHWs) to date, with new partnerships developing in Sierra Leone and Burkina Faso. Following the onset of the COVID-19 pandemic, both organizations quickly adapted their programming to support government-led response efforts focused on training and equipping CHWs to safely interrupt virus transmission while also maintaining essential health services. The COVID-19 pandemic helped validate the important role of CHWs, increased demand for digital health solutions and accelerated efforts for community health systems strengthening.

- **UNICEF** – In early 2022, Lilly and UNICEF announced a collaboration to help improve health for 10 million children and adolescents living with or at risk of chronic, non-communicable diseases (NCDs) through 2025. Lilly has committed $14.4 million in support of UNICEF's life-saving work to address NCD risk factors, strengthen health systems, and enhance the ability of health care workers to care for patients in Bangladesh, Malawi, Nepal, the Philippines and Zimbabwe. The countries were selected based on the potential to strengthen country-level health systems and models that provide care and support for children and adolescents with chronic conditions. This four-year commitment reflects the respective efforts of Lilly and UNICEF to work toward the UN Sustainable Development Goals. Donations from Lilly will go directly to the U.S. Fund for UNICEF, a tax-exempt organization that supports UNICEF's global work.

- **Expanding Successful AMPATH Model** – Lilly and the Lilly Foundation have each provided support related to AMPATH, which has been working for 30 years in western Kenya to improve health for people with limited resources. Lilly's product donations related to the support of AMPATH Kenya total $215 million – including $36 million in medicines in 2021 – and are helping people living with cancer, diabetes and mental health disorders. Lilly and the Lilly Foundation provided support related to AMPATH's efforts to establish new health sites in Puebla, Mexico and Tamale, Ghana, with the potential to reach more than 7 million people by 2030. Lilly has committed support of more than $2.8 million related to helping establish AMPATH in Puebla. The Lilly Foundation awarded $600,000 related to support efforts to provide additional personnel in Ghana and $520,000 to support the IU Center for Global Health's role as the coordinating secretariat of the global AMPATH Consortium.

- **Diabetes Impact Project in Indianapolis Neighborhoods (DIP-IN)** – In 2021, Lilly announced expansion of our support of DIP-IN, committing an additional $5 million to the project with the Richard M. Fairbanks School of Public Health at Indiana University and other community partners. Initially launched in 2018, the goal of this effort is to drive long-term improvements in diabetes diagnosis and care in three Indianapolis neighborhoods where residents are predominantly people of color and there are high rates of diabetes. The program employs a holistic approach to diabetes prevention and control that includes residents, and neighborhood and clinic-based community health workers who help identify people with or at risk for developing diabetes and connect them with quality care. The pilot has the potential to scale to health systems in Indiana and across the U.S. and could reach more than 250,000 people by 2030.

- **Type 2 Diabetes in Mexico** – Lilly is working with Mexico's Consejo de Salubridad General (National Health Council) and the Fundación México-Estados Unidos para la Ciencia (FUMEC) to strengthen the Mexican health care system and the treatment of chronic diseases, starting with type 2 diabetes. Launched in 2020, this project is developing information tools for better decision-making and engagement between patients and health care providers. The project uses an epidemiological surveillance system, called SANENT (National System for Analysis of Non-Communicable Diseases), which has the potential to benefit more than 5.7 million people by 2030.

Through the collaboration, we are working to find a less expensive and better way to perform an oral glucose tolerance test to screen for gestational diabetes and help women who test positive avoid complications throughout their pregnancy. The partnership has delivered a number of important outcomes, including documenting the prevalence of gestational diabetes in Mexico – 13% – for the first time at the national level, and developing a simpler version of the oral glucose tolerance test.

- **Expanding One-Stop-Shop Diabetes Care Model across Mexico and Latin America** – Lilly is working with Clinicas del Azúcar (Sugar Clinics) and MIT on a four-year effort to validate and then help expand a "one-stop-shop" diabetes care model and related efforts that engage people in improving their health over the long term. Through the validation project, the efficacy of the model has been proven. Clinicas del Azucar plans to significantly expand the number of clinics and people served across Mexico in the coming years.

- **Training for metabolic diseases management in primary care in China** – Lilly is collaborating with Shanghai Medicine and Development Foundation to qualify trainers at provincial level sites, who will cascade training to 1,600 primary care level providers to improve treatment outcomes for patients with metabolic diseases nationwide, especially in resource-limited areas. Launched in 2021, this partnership is expected to improve metabolic outcomes for millions of patients by 2030.

Multi-Stakeholder Collaborations to Advance the U.N. Sustainable Development Goals

We are members of several multi-stakeholder collaborations focused on tackling global health challenges including:

- Access Accelerated – A first-of-its-kind, multi-stakeholder collaboration focused on improving non-communicable disease (NCD) care globally. NCDs include cardiovascular diseases, cancer, chronic respiratory diseases, diabetes and mental illness

- NCD Alliance – A global thought leader on policy and practice related to NCDs

- Shared Value Initiative – A global community of organizations committed to driving the adoption and implementation of shared value strategies among leading companies, civil society and government organizations

Product Donations

In 2021, Lilly provided more than $3 billion in medicines to charitable organizations that offer free Lilly medicines to qualifying patients*, including through the efforts described below.

- **Life for a Child** – Since 2009, Lilly has donated more than 3.2 million vials and cartridges of insulin related to support of the Life for a Child (LFAC) program. LFAC provides diabetes support to children and youth with type 1 diabetes in settings with limited resources. That support includes insulin, delivery devices, monitoring supplies, medical care, diabetes education, and complications screening and management.

  In 2021, Life for a Child and Lilly announced plans to expand our support of LFAC to increase access to care to approximately 150,000 youth annually over the next 10 years. To facilitate the expanded support, we will increase donations of mealtime and basal insulins and reusable pens, as well as financial support for the costs associated with arranging, packing and shipping to countries in conjunction with Direct Relief.

- **Partnering with Relief Agencies to Increase Access to Insulin** – As part of Lilly's commitment to identify gaps in the U.S. health care system and find solutions to help people with diabetes live healthier lives, we announced in early 2020 that we would donate at least 200,000 KwikPens® to Direct Relief, Americares and Dispensary of Hope to stock insulin at nearly 300 U.S. free clinics through 2022. These donations will directly support people with limited resources living with diabetes who qualify for free clinic services. Separately, Lilly is donating $2 million to fund grants available through two relief organizations: Direct Relief and Americares. These agencies will distribute grant funds to a wide range of eligible free clinics to increase access in underserved communities. Learn more about our commitment.

  Over the past five years, Lilly has donated more than 10 million insulin vials® and pens to U.S. charitable organizations, including Americares, Direct Relief, Dispensary of Hope and the Lilly Cares® Foundation.

Patient Assistance Programs

We also work with organizations who provide patient assistance programs, including:

- **Lilly Cares® Foundation Patient Assistance Program** – Lilly donates medications to the Lilly Cares Foundation, a separate nonprofit organization. Lilly Cares' Patient Assistance Program provides qualifying patients in the U.S. with significant financial need prescribed Lilly medications at no cost. In 2021, Lilly Cares helped more than 172,000 people obtain prescribed medications across the therapeutic areas of diabetes, immunology, neuroscience, cancer, pain, endocrinology, cardiovascular and bone, muscle and joint. Over the past 20 years, Lilly Cares has helped more than one million patients with financial need receive medicines donated by Lilly.

China Primary Health Care Foundation – In China, Lilly offers patient assistance programs for oncology and osteoporosis patients through the China Primary Health Care Foundation. In 2021, more than 5,000 new patients were registered and more than 20,000 patients were helped through the foundation's support programs.

**Includes value of Lilly medicines provided to separate charitable organizations that offer free Lilly medicines to qualifying patients. Products valued at wholesale acquisition cost, or WAC.*

Global Health Highlights

47 Million+
people around the world use Lilly medicines in 2021

$7 Billion+
investments in research and development in 2021

30 Million
people in resource-limited settings who Lilly aims to reach, each year, by 2030

$3 Billion+
in medicines provided to charitable organizations that provide free Lilly medicines, including more than $250 million in COVID-19 therapies[1]

$285 Million+
committed to global health 2016-2030[2]

3.2 Million
insulin vials and cartridges donated for the Life for a Child program since 2009

[1] Includes value of Lilly medicines provided to separate charitable organizations that offer free Lilly medicines to qualifying patients. Products valued at wholesale acquisition cost, or WAC.
[2] Includes financial commitments from Lilly and $13.5 million from the Eli Lilly and Company Foundation, a separate nonprofit organization, commonly referred to as the Lilly Foundation.

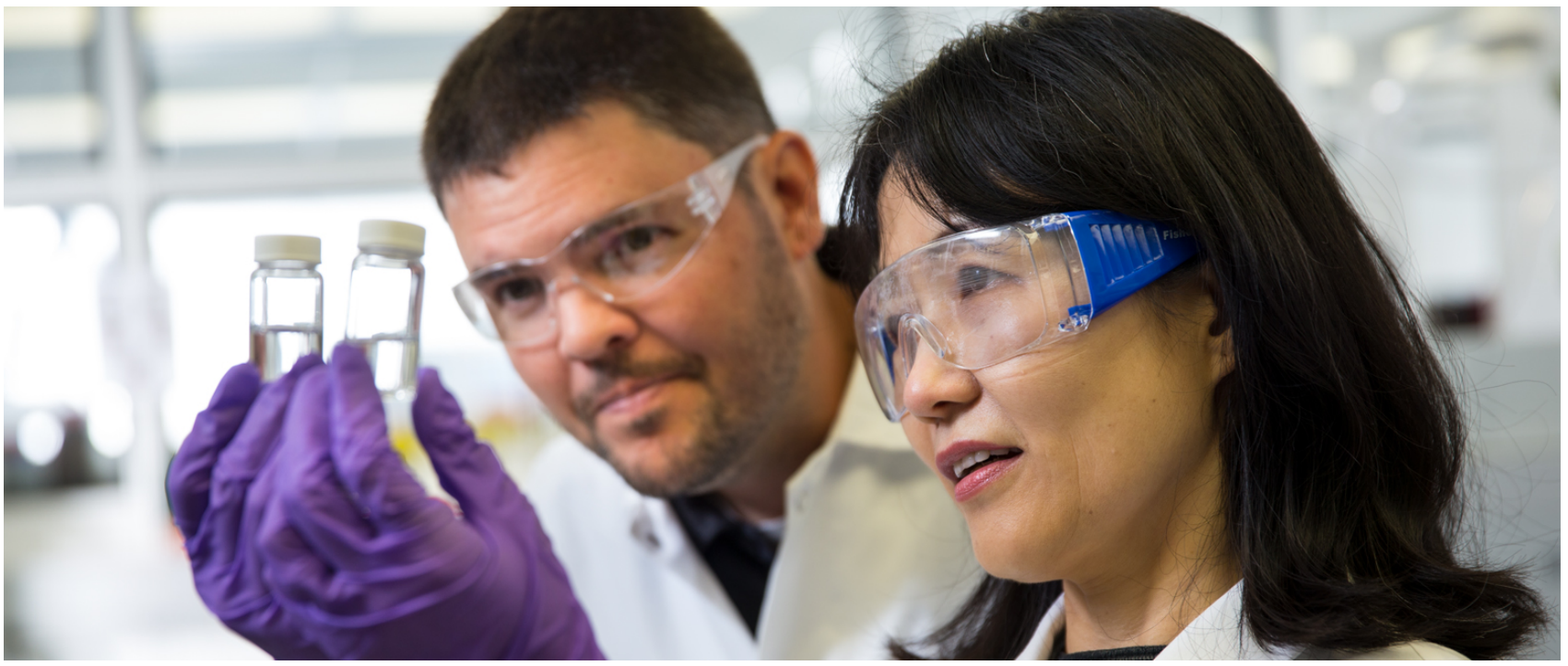
Exhibit D

[Copy of IP PACT]

A New Commitment to Patients on World IP Day

April 26, 2021 Posted by: Shawn O'Neail

Innovation | Policy



World IP Day is a day to recognize the benefits that intellectual property (IP) brings to society, like innovative new medicines that make life better for people around the world.

At Lilly, our scientists harness the power of biotechnology to urgently advance new discoveries with the potential to radically transform diabetes care, slow the progression of Alzheimer's, leverage the body's immune system to relieve suffering, and turn ha to-treat cancers from fatal to manageable.

Strong IP protections are essential to our ability to innovate and develop new treatments and cures.

This World IP Day, Lilly is announcing our participation in the IP PACT (IP Principles for Advancing Cures and Therapies). IP PACT new company-led initiative affirming the biopharmaceutical industry's commitment to innovation and keeping patients at the hea our efforts.

The IP PACT framework includes these principles:

- Patient and societal benefit will guide our approach to IP.
- We'll support initiatives to ensure patent quality, which help advance biopharmaceutical innovation.
- We'll use IP rights to facilitate collaboration and enable partnerships that advance global health.
- We believe that accessible patent information promotes scientific progress and helps improve the procurement of medicines, we support voluntary initiatives that advance these goals.
- We'll act responsibility and professionally in our patent proceedings, and seek timely resolutions to enhance certainty for all stakeholders.
- We believe that generic and biosimilar medicines are important for sustainable health systems, and that certain activities relat to seeking regulatory approval should be exempt from patent infringement.
- We believe that a meaningful, and well-defined experimental use exemption is consistent with the goals of the patent system.
- We believe that advancing public health depends on robust IP, rights as well as collaboration among stakeholders, and may ca tailored uses of our IP where these add value for patients.
- We'll approach IP in the world's poorest countries in ways that considers their unique socio-economic challenges.

The principles aren't new concepts, but today's announcement is a way for our industry to communicate how we approach IP protections to balance the needs of patients, society and our business to further health care innovation and help patients live long healthier lives.

IP PACT principles will help deliver even more scientific breakthroughs for patients around the world in the years to come.

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January 20, 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 Eli Lilly and Company to omit proposal submitted by Trinity Health and co-filers

Ladies and Gentlemen,

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

In a letter to the Division dated December 23, 2022 (the "No-Action Request"), Lilly stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the 2023 annual meeting of shareholders. Lilly argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), on the ground that the Proposal relates to Lilly's ordinary business operations, and Rule 14a-8(i)(10), as substantially implemented by the Company. The Proposal deals with the significant social policy issue of the impact of intellectual property ("IP") protections on patient access and gives Lilly's management discretion over implementation, and Lilly's existing practices and disclosures do not substantially implement the Proposal. Accordingly, Lilly has not met its burden of proving its entitlement to exclude the Proposal on either basis, and the Proponents respectfully ask that its request for relief be denied.

The Proposal

The Proposal states:

RESOLVED, that shareholders of Eli Lilly & Co. ("Lilly") 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 Lilly'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]

Over-patenting 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] The Proposal asks Lilly to take the impact on patient access into account when making decisions about applying for secondary and tertiary patents on its medicines.

Ordinary Business

Lilly 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 Lilly decides "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."[12] Lilly 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, without more, as ordinary business matters. However, the fact that a proposal implicates a company's products or IP does not support exclusion on ordinary business grounds if it focuses on a significant social policy issue, which is the case here.

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

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

[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] No-Action Request, at 5.
[13] Johnson & Johnson (Feb. 8, 2022)
[14] Pfizer, Inc. (Feb. 23, 2022); Moderna, Inc. (Feb. 8, 2022).

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.[15] Last year's JNJ, Pfizer and Moderna determinations reinforce that a proposal will not be deemed excludable simply because it implicates products or IP, so long as the primary concern is 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."[16]

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

- The Staff did not agree with JNJ's[17] claim that a proposal asking the company to establish and implement standards of response to the HIV/AIDS pandemic in developing countries could be excluded in reliance on the ordinary business exclusion because it addressed product development, research and testing; the proponent had urged that the proposal addressed the significant policy issue of the HIV/AIDS pandemic.
- Gilead's[18] argument that a proposal seeking a report on risks related to rising pressures to contain specialty drug prices was excludable on ordinary business grounds was not persuasive, even though Gilead pointed to the focus on its products and pricing decisions. The Gilead determination also undermines Lilly's contention that implicating a company's "core business model"[19] militates in favor of exclusion; in denying Gilead's request, the Staff explained that "the proposal focuses on Gilead's fundamental business strategy with respect to its pricing policies for pharmaceutical products."[20]

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

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

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

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

[19] No-Action Request, at 5.

[20] Gilead Sciences Corp. (Feb. 23, 2015).

- In Denny's,[21] the Staff did not concur with the company's claim that a proposal asking it to sell at least 10% cage-free eggs by volume was excludable because it implicated the sale of particular products, siding with the proponent's characterization of the proposal's subject as the significant policy issue of "[r]educing cruel confinement conditions for egg-laying hens" (i.e., animal cruelty).

Significant Social Policy Issue Analysis

The role of IP protections in keeping drug prices high and limiting patient access is a subject of consistent and widespread public debate, the standard applied in determining whether a proposal's subject transcends ordinary business operations.[22]

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

- Editorial Board, "Save America's Patent System," The New York Times, Apr. 17, 2022[23] ("Twelve of the drugs that Medicare spends the most on are protected by more than 600 patents in total, according to the committee. Many of those patents contain little that's truly new. But the thickets they create have the potential to extend product monopolies for decades. In so doing, they promise to add billions to the nation's soaring health care costs -- and to pharmaceutical coffers.")
- Editorial Board, "How Big Pharma plays games with drug patents and how to combat it," USA Today, Jan. 18, 2019[24] ("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[25]
- Berkeley Lovelace Jr., "'Gaming' of U.S. patent system is keeping drug prices sky high, report says," NBCNews.com, Sept. 15, 2022[26]
- "Biden Drug Price Pressure on Patent Office Draws Skeptics," Bloomberg, Sept. 21, 2021[27] ("Patents—viewed by some as an obstacle to greater competition in pharmaceuticals—have seized the spotlight in a wide-ranging government effort to get at high drug costs.")
- Cynthia Koons, "This Shield of Patents Protects the World's Best-selling Drug," Bloomberg Businessweek, Sept. 7, 2017[28]

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[21] Denny's Inc. (Mar. 17, 2009)
[22] See, e.g., www.sec.gov/interps/legal/cfslb14a.htm.
[23] https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html
[24] https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/
[25] https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/
[26] https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507
[27] https://news.bloomberglaw.com/health-law-and-business/biden-drug-price-pressure-on-patent-office-draws-skeptics
[28] https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

- Matthew Lane, "The Key to Lowering Drug Prices is Improving Patent Quality," Techdirt, July 21, 2021[29] ("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[30] ("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[31]
- Gunjan Sinha, "How Patent Extensions Keep Some Drug Costs High," Undark, June 16, 2021[32]
- 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[33]
- Ryan Chatelain, "House committee report blasts drug pricing strategies as 'troubling,'" NY1, Dec. 10, 2021[34]
- 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[35]
- Matthew Lane, "To rein in Big Pharma over high drug prices, start with patent reform," Roll Call, Jan. 17, 2020[36] ("A significant reason for the skyrocketing price of prescription drugs is that major pharmaceutical companies have enjoyed an effective open season on raising drug prices. Armed with government-sponsored monopolies obtained through shameless abuse of the patent system, Big Pharma has been free to raise prices at their leisure.")
- Garrett Johnson and Wayne T. Brough, "Big pharma is abusing patents, and it's hurting America," CNN, Sept. 13, 2019[37] ("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.")

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[29] https://www.techdirt.com/2021/07/21/key-to-lowering-drug-prices-is-improving-patent-quality/
[30] https://prospect.org/health/its-time-for-public-pharma/
[31] https://www.chicagobusiness.com/joe-cahill-business/humira-patent-strategy-makes-case-reform
[32] https://undark.org/2021/06/16/how-patent-extensions-keep-some-drug-costs-high/
[33] https://www.politico.com/tipsheets/prescription-pulse/2017/07/17/fda-to-examine-anticompetitive-practices-by-drug-industry-221368
[34] https://www.ny1.com/nyc/all-boroughs/politics/2021/12/10/house-committee-report-blasts-drug-pricing-strategies-as--troubling-
[35] https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html
[36] https://www.rollcall.com/2020/01/17/to-rein-in-big-pharma-over-high-drug-prices-start-with-patent-reform/
[37] https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html

- David Blumenthal, "The U.S. Can Lower Drug Prices Without Sacrificing Innovation," Harvard Business Review, Oct. 1, 2021[38] ("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[39]
- "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[40]
- Ahmed Aboulenein, "Consumer group says drugmakers abuse U.S. patent system to keep prices high," Reuters, Sept. 16, 2022[41]
- Sarah Jane Tribble, "Drugmakers Play the Patent Game to Ward Off Competitors," NBCNews.com, Oct. 2, 2018[42]

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

Bipartisan legislation addressing patent thickets has been introduced in Congress. The REMEDY Act introduced in 2019 provided that a generic manufacturer could enter the market after primary patent expiration without having to litigate the validity of secondary patents.[43] 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.[44] The Second Look at Drug Patents Act would have required publication of patents filed after approval of a new drug or abbreviated new drug application by the FDA in order to facilitate validity challenges.[45] The Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019[46] 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.[47] Product hopping occurs when branded drug

[38] https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation
[39] https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html
[40] https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/?sh=73fa684178ca
[41] https://www.reuters.com/business/healthcare-pharmaceuticals/consumer-group-says-drugmakers-abuse-us-patent-system-keep-prices-high-2022-09-16/
[42] https://www.nbcnews.com/health/health-news/drugmakers-play-patent-game-ward-competitors-n915911
[43] 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.
[44] https://www.congress.gov/bill/116th-congress/house-bill/3199/text
[45] https://www.congress.gov/bill/116th-congress/senate-bill/1617
[46] https://www.congress.gov/bill/116th-congress/house-bill/3991
[47] https://www.congress.gov/bill/117th-congress/house-bill/2873

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.[48]

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.[49]

The House Judiciary Antitrust Subcommittee held a hearing in April 2021 on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."[50] Experts on drug companies' anticompetitive practices testified, including Professor Robin Feldman, who discussed the relationship between secondary patents and product-hopping.[51]

The House Committee on Energy and Commerce's Subcommittee on Health held a hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition" in March 2019.[52] 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

[48] www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf
[49] https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf
[50] https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive
[51] https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-FeldmanR-20210429.pdf, at 3-4
[52] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to

trends. Too often, the primary goal of these tactics is to leverage the law to stifle competition, rather than to protect meaningful clinical advancements.[53]

The House Oversight Committee initiated a sweeping investigation in 2019 into "pricing and business practices in the pharmaceutical industry."[54] 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."[55] 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."[56] 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."[57] 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."[58]

The House Ways and Means Committee's Subcommittee on Health held a hearing in March 2019 on the cost of drugs to the Medicare program. In his opening statement, Subcommittee Chairman Doggett noted that "[o]ver the last decade, 74 percent of all pharmaceutical patent applications were not for new innovative cures, but were for modifying existing drugs, which often took the form of what's referred to as evergreening, simply to protect monopoly pricing, not to provide new drugs."[59] 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

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[53] 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.").

[54] 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.

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

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

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

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

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

standpoint. So, we may be lavishing rewards without getting the innovation that we desperately need."[60] Another witness identified patent thickets as key to high drug prices.[61]

The Senate Finance Committee held a hearing on "Drug Pricing in America: A Prescription for Change, Part I"[62] 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.[63]

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.[64] In addition to the general problem posed by patent thickets, Kesselheim explained how secondary patents facilitate product hopping.[65]

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."[66] The E.O. also directed the Secretary of Health and Human Services to take various steps to "promote generic drug and biosimilar competition." Pursuant to the E.O., the FDA and PTO are collaborating to implement strategies to lower drug prices.[67]

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[60] https://www.youtube.com/watch?v=aA3cDgRp37s (at 10:09).
[61] https://www.youtube.com/watch?v=aA3cDgRp37s (at 20:22).
[62] https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i
[63] https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf
[64] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf
[65] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf, at 6-7.
[66] 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).
[67] https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

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."[68] 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."[69] 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.[70] 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."[71]

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.[72]

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."[73] 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."[74]

In 2022, Priti Krishtel, co-founder and co-executive director of patent watchdog group the Initiative for Medicines, Access and Knowledge (I-MAK) was selected to receive a MacArthur Fellowship (sometimes referred to as the "genius grant"). When announcing her selection, the program described I-MAK's work on patent reform and the impact of secondary patents on access: "Patents are intended to incentivize innovation by ensuring that only the patent holder can sell and profit from the product for a fixed time. However, many pharmaceutical companies seek to extend their monopolies by filing multiple patents on small changes (such as changes in dosage) to existing drugs over several years. This stifles competition, delays generic production, and keeps medicines out of the hands of people who need them the most."[75]

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[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://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf
[71] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-MeierM-20170727.pdf
[72] https://www.ag.state.mn.us/Office/Initiatives/PharmaceuticalDrugPrices/Taskforce.asp
[73] https://about.kaiserpermanente.org/news/want-to-lower-drug-prices-reform-the-us-patent-system
[74] https://www.ahip.org/news/press-releases/new-research-big-pharma-companies-earn-big-revenues-through-patent-gaming
[75] https://www.macfound.org/fellows/class-of-2022/priti-krishtel#searchresults

The existence of a significant social policy issue, then, distinguishes the Proposal from those analyzed in the determinations Lilly cites on pages 4-5 of the No-Action Request. 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.

In the other determinations on which Lilly relies, the proponents unsuccessfully argued that the proposals' subjects—the use of the company's products for lethal injection, the controversy over releasing the film "Song of the South" on Blu-ray, shareholder product discounts, and an animal welfare policy applicable not only to the company but also its suppliers--were significant social policy issues. The proponent did not even respond to the company's no-action request in IBM,[78] where the proposal asked the company to assume a greater role in promoting open source software. Thus, IBM's characterization of the proposal's subject as the marketing, delivery and support of its software products went unchallenged. In any event, the determinations from last proxy season dealing with IP discussed above have more persuasive power than IBM, given how long ago it was issued.

The Proposal does not focus on ordinary business matters despite "contain[ing] references to" a significant policy issue, as Lilly claims.[79] Instead, access to Lilly'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 Lilly cites involved proposals addressing the core ordinary business matter of management of the workforce and whose proponents were simply unsuccessful in convincing the Staff that their proposals transcended ordinary business.

In the 2021 proxy season, JNJ[80] unsuccessfully advanced an argument similar to the one Lilly 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 Lilly. Staff Legal Bulletin ("SLB") 14L recently clarified the Staff's approach to micromanagement claims. It states that the Staff will analyze "the

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[76] Wells Fargo & Co. (Jan. 28, 2013, *recon. denied* Mar. 4, 2013).
[77] JPMorgan Chase & Co. (Mar. 16, 2010).
[78] International Business Machines Corp. (Jan. 22, 2009).
[79] No-Action Request, at 6.
[80] Johnson & Johnson (Feb. 12, 2021).

level of granularity sought in the proposal and to what extent it inappropriately limits the discretion of the board or management."[81] SLB 14L indicated that climate change proposals that "suggest targets or timelines so long as the proposals afford discretion to management as to how to achieve such goals" will not be deemed excludable on micromanagement grounds. Thus, a proposal can ask a company to change its behavior, even to set a specific objective like an emissions reduction target, as long as it doesn't instruct management or the board on exactly how to implement the change.

Lilly argues that the Proposal would micromanage because it "seeks to provide shareholder oversight on a complex topic that is outside the knowledge and expertise of shareholders, and therefore inappropriate for such oversight and vote."[82] But Lilly's 10-K includes many discussions of patents, presumably because Lilly believes this is valuable information for shareholders. There is a section entitled "Patents, Trademarks, and Other Intellectual Property Rights," which describes the concepts of patent term restoration and adjustment, the retention of exclusivity following expiration of a primary patent through "later-expiring patents on manufacturing processes, methods of use or formulations" (i.e., secondary patents), pediatric exclusivity, and orphan drug designation. That section sets forth patent and data protections for various products. Patent litigation, including litigation under the Biologics Price Competition and Innovation Act and *inter partes* review, is also covered.[83] Other sections of the 10-K--the "Risk Factors,"[84] Management's Discussion and Analysis,[85] and Financial Statements[86] sections—also address patents and patent litigation. Lilly's 10-K identifies the loss of patent protection as a material risk, stating "Our long-term success depends on intellectual property protection; if our intellectual property rights are invalidated, circumvented, or weakened, our business will be adversely affected."[87]

Given the centrality of patent protection to Lilly's business model, it is a stretch to suggest that the Proposal is too difficult for shareholders to understand. The fact that one of Lilly's key disclosure documents treats the subject in detail suggests that Lilly 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 like novelty and non-obviousness, which do not appear in the Company's 10-K, in order to form a view about the desirability of considering access when making decisions about patents.

The determinations cited on page 7 of the No-Action Request are inapposite because the proposals requested an extensive amount of detail on the companies' management of their workforces. Those proposals, which were submitted to Deere,[88] Verizon,[89] and American Express,[90] asked the companies to disclose, each year, <u>all</u> employee-training materials offered to any subset of employees, including material conveyed orally. The Verizon and American Express proposals' resolved clauses also included an alternate action for the companies to take, performing an audit "analyzing the company's impacts, including the impacts arising from company-sponsored or -

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81 Staff Legal Bulletin 14L (Nov. 3, 2021).
82 No-Action Request, at 7.
83 Eli Lilly and Company Filing on Form 10-K, filed on Feb. 23, 2022 ("2022 10-K"), at 9-12.
84 2022 10-K, at 24-26.
85 2022 10-K, at 39-40.
86 2022 10-K, at 101-102.
87 2022 10-K, at 25.
88 Deere & Company (Jan. 3, 2022).
89 Verizon Communications, Inc. (Mar. 17, 2022).
90 American Express (Mar. 11, 2022).

promoted employee training, on civil rights and non-discrimination in the workplace, and the impacts of those issues on the company's business." Thus, implementation of the proposals would likely have required the disclosure of substantial amounts of material on an annual basis in order to allow shareholders to "gauge executives' responses to and management" of risks related to "controversial or toxic" racist DE&I training materials. The Staff concurred with the companies that the proposals micromanaged, stating 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 to achieve" that outcome, in the words of SLB 14L. Nor would it require disclosure of intricate detail regarding Lilly'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 Lilly'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, Lilly 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. Lilly's inclusion of detailed 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 Lilly's management nor requests intricate detail, it would not micromanage Lilly.

Substantial Implementation

Lilly urges that the Proposal is excludable pursuant to Rule 14a-8(i)(10) because the Company "already publicly discloses the factors it considers during its patent application evaluation process, including access and affordability concerns at a domestic and international level for all patents."[91]

Lilly points first[92] to its "participation" in the IP Principles for Advancing Cures and Therapies (the "Principles"), an initiative among pharmaceutical firms setting forth "principles that guide [their] approach to IP."[93] But none of the Principles commits a participating company to

[91] No-Action Request, at 9.
[92] No-Action Request, at 10.
[93] https://www.interpat.org/ip-pact/

consider pricing or access in making decisions about patents; indeed, the Principles seem, on the whole, designed to emphasize the value of IP protection. Although Principle 1 states that "[p]atient and societal benefit guide our approach to Intellectual Property," the explanatory text makes clear that the benefit in question is discovering new medicines: "As innovative biopharmaceutical companies, it is **our mission** to make a positive contribution to patients' lives and advance modern medicine by researching, inventing, developing and delivering innovative medicines and vaccines to all patients who need them." (emphasis in original) That oblique reference to "delivering" medicines to "all patients who need them" is the Principles' only mention of patients, and it falls far short of committing participants in the Principles to considering patient access when making decisions about applying for new patents.

Next, Lilly points to language from its ESG Report stating that the Company "supports the removal of regulatory or pricing, reimbursement and access restrictions for generics and biosimilars when intellectual property protections expire. In addition, Lilly has a long-standing practice of not seeking or enforcing patents for medicines in least developed countries, as defined by the United Nations."[94] Removing restrictions when IP protections expire, however, has nothing to do with seeking secondary patent protections in the first place. A "long-standing practice" does not rise to the level of a process in which the role of various factors, including access, is formalized. And Lilly's practice in the subset of "least developed countries" says nothing about whether and how access is considered more generally.

Lilly's empty claim that "intellectual property improves patient access by expanding the innovation base" requires acceptance of two propositions that are demonstrably false. First, studies show that longer periods of market exclusivity enabled by extended IP protections keep prices high and impede patient access. According to I-MAK, anti-competitive practices enabled by patent thickets "delay or block lower-cost drugs from entering the market, at substantial cost to the public."[95] Second, Lilly's claim only makes logical sense if one distorts the meaning of "patient access" beyond recognition. "Access" does not mean the same thing as having more medication choices, especially when those choices are unaffordable. Lilly's 10-K does mention IP protections (as the Proponents note above),[96] but none of those discussions are responsive to the Proposal.

All told, none of the disclosures touted by Lilly respond to the core request of the Proposal—adopting and disclosing a process by which access is considered when deciding whether to apply for secondary and tertiary patents and several of them twist the meaning of "access" into a synonym for more choices of costly IP-protected medications, which runs contrary to the letter and spirit of the Proposal. For that reason, even taken together, they do not support a finding of substantial implementation.

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[94] No-Action Request, at 11.
[95] https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf
[96] See No-Action Request, at 11.

For the reasons set forth above, Lilly has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7)) or Rule 14a-8(i)(10). The Proponents thus respectfully request that Lilly'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 (718) 8222-0820.

Sincerely,

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