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January 13, 2023

VIA ELECTRONIC MAIL

Office of the Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549
shareholderproposals@sec.gov

Re: **Amgen Inc.**
Stockholder Proposal of Mercy Investment Services
Securities Exchange Act of 1934 – Rule 14a-8

Ladies and Gentlemen:

We are filing this letter on behalf of our client, Amgen Inc., a Delaware corporation (the "***Company***"), pursuant to Rule 14a-8(j) under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), to notify the Staff of the Division of Corporation Finance (the "***Staff***") of the U.S. Securities and Exchange Commission (the "***Commission***") of the Company's intention to exclude from the Company's proxy statement and form of proxy for the Company's 2023 Annual Meeting of Stockholders (the "***2023 Proxy Materials***") a stockholder proposal and supporting statement (collectively, the "***Proposal***") received from Mercy Investment Services (the "***Proponent***"), which asks the Company's board of directors (the "***Board***") 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." Trinity Health and Dominican Sisters, Grand Rapids Michigan have co-filed the Proposal. The Company respectfully requests confirmation that the Staff will not recommend enforcement action to the Commission if the Company excludes the Proposal on the following grounds:

(i) pursuant to Rule 14a-8(i)(3), as the Proposal violates the proxy rules; and

(ii) pursuant to Rule 14a-8(i)(7), as the Proposal relates to the Company's ordinary business operations.

Pursuant to Staff Legal Bulletin 14D (Nov. 7, 2008) ("***SLB 14D***"), we are transmitting this letter by electronic mail to the Staff at shareholderproposals@sec.gov. We are also sending a copy of this letter concurrently to the Proponent. If the Proponent elects to submit any correspondence to the Commission or the Staff with respect to the Proposal, pursuant to Rule 14a-8(k) and SLB 14D, we request that a copy of that correspondence should be furnished concurrently to the Company and the undersigned. Pursuant to Rule 14a-8(j), this letter is being submitted not less than 80 days before the Company intends to file its definitive 2023 Proxy Materials with the Commission.

I. THE PROPOSAL

The Proposal requests that the Company's stockholders approve the following resolution:

> RESOLVED, that shareholders of Amgen Inc. ("Amgen") 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 Amgen's website.

The Proposal also includes a supporting statement that explains the Proponent's basis for submitting the Proposal. A copy of the Proposal, dated November 22, 2022, is attached to this letter as Exhibit A.

II. GROUNDS FOR EXCLUSION

We hereby respectfully request that the Staff concur with the Company's view that the Proposal may be excluded from the 2023 Proxy Materials for the reasons set forth below.

A. The Proposal May Be Excluded Under Rule 14a-8(i)(3) Because it is Contrary to the Proxy Rules.

Rule 14a-8(i)(3) permits exclusion of a proposal if the proposal or supporting statement is contrary to any of the Commission's proxy rules, including Rule 14a-9, which prohibits materially false or misleading statements in proxy soliciting materials. The Staff has taken the position that a stockholder proposal is excludable under Rule 14a-8(i)(3) if the proposal is so vague and indefinite that neither the stockholders voting on the proposal, nor the company in implementing the proposal (if adopted), would be able to determine with any reasonable certainty exactly what actions or measures the proposal requires. *Staff Legal Bulletin No. 14B* (Sept. 15, 2004) ("***SLB 14B***").

Under this standard, the Staff has routinely permitted exclusion of proposals that fail to define key terms, contain only general or uninformative references regarding the steps to be taken, or otherwise fail to provide sufficient clarity or guidance to enable either stockholders or the company to understand how the proposal would be implemented. For example, in *Apple Inc.* (avail. Dec. 6, 2019), the Staff permitted the company to exclude, as vague and indefinite, a proposal submitted by a proponent requesting that the company "improve guiding principles of executive compensation." The proposal did not define what it means to "improve" such guiding principles and the supporting statement did not clarify the nature of the requested "improvements." In its response, the Staff noted that "neither shareholders nor the Company would be able to determine with reasonable certainty how the Proposal seeks to "improve [the] guiding principles of executive compensation" and that the proposal therefore "lack[ed] sufficient description about the changes, actions or ideas for the Company and its shareholders to consider ...." In *Alcoa, Inc.* (avail. Dec. 24, 2002), the Staff concurred that the company could exclude as vague and indefinite a proposal calling for the full implementation of "human rights standards." In its letter to the Staff, the company pointed out that, although the supporting statement referenced a variety of International Labor Organization human rights goals, the reference to "standards" did not clarify for either stockholders or the company what standards were being referenced or precisely what actions were contemplated under the proposal. See also *Kroger Co.* (avail. Mar. 19, 2004) (concurring with the exclusion under Rule 14a-8(i)(3) of a proposal

requesting that the company prepare a sustainability report based on the Global Reporting Initiative's sustainability reporting guidelines, where the company argued that the proposal's "extremely brief and basic description of the voluminous and highly complex Guidelines" did not adequately inform the company of the actions necessary to implement the proposal).

The Proposal here requests that the Board "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." Given the Proposal's broad and all-inclusive definition of "[s]econdary and tertiary patents," which is not a concept defined in the patent laws, the requested policy and report would apply to all of the Company's patent applications except, perhaps, an initial single patent on the active ingredient or molecule (which we are interpreting to refer to a composition of matter patent). The Proposal does not, however, provide any guidance to the Company regarding what the intended "process" should look like, and if the Proposal were to be successful, the Company's Board would not know how to implement the Proposal or how to report on the requested "process."

The Proponent requests a Board-determined "process" that would be instrumental to the determination of whether to seek to obtain patent protection on the Company's products and developments. The Company's patent application and prosecution considerations, timing and strategy, however, are extremely involved and detailed, and differ based on numerous factors including, among others, (i) the subject process, machine, manufacture, composition of matter or improvement thereof[1], (ii) the applicable country's highly complex patent laws as well as international treaties, and (iii) the existing prior art. Extensive involvement by people with expertise in the relevant science, manufacturing process, medicine, and law and regulations is required in order to determine the most appropriate patent approach for each specific development. The Board is not qualified to design a process of this type, as they do not have the relevant expertise, and even if they were qualified, the Proponent does not provide any guidance regarding what the requested process should look like.

A process generally entails "a series of actions or operations conducing to an end." "process." Merriam-Webster.com. Retrieved Dec. 20, 2022, from https://www.merriam-webster.com/dictionary/process. The type of steps that would comprise a process for consideration of the impact of exclusive patents on product access is unclear, vague and ill-defined. For example, it seems that the process would be "consider the impact of obtaining a proposed patent on product access" and the impact would be that exclusive patents prevent competitors from copying the particular process, design, composition of matter, delivery method or improvement that is covered by the patent without first obtaining a license or approval from the patent holder. That is the very nature, effect and desired purpose of the patent process, which is protected by the Constitution of the United States. The Proposal is so vague and indefinite that neither the stockholders voting on the proposal, nor the Company in implementing the Proposal (if adopted), would be able to determine with any reasonable certainty exactly what actions or measures the Proposal requires.

Further, the Proponent requests not only the establishment of a process, but also a report on such process. It is unclear what would be contained in the report on the process itself, and it should also be noted that all discussions, considerations and decisions regarding the Company's patent strategy would likely be deemed confidential and highly sensitive. Again, the Board and the Company's stockholders are not able to determine with any reasonable certainty exactly what actions or measures any of the report, process or Proposal requires. Accordingly, the Company believes that it may properly exclude the Proposal from the 2023 Proxy Materials under Rule 14a-8(i)(3) as being so vague and indefinite that it violates the proxy rules.

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[1] See 35 U.S.C. § 101 – Inventions Patentable

B. The Proposal May Be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals With Matters Relating to the Company's Ordinary Business Operations.

Under Rule 14a-8(i)(7), a company may exclude a stockholder proposal from its proxy materials if "the proposal deals with a matter relating to the company's ordinary business operations." The purpose of Rule 14a-8(i)(7) is to allow companies to exclude stockholder proposals that deal with ordinary business on which "shareholders, as a group, would not be qualified to make an informed judgement…due to their lack of business expertise and their lack of intimate knowledge of the issuer's business." *SEC Release No. 34-12999* (Nov. 22, 1976). The Commission has stated that the "general underlying policy of this exclusion is consistent with the policy of most state corporate laws: 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," and identified two central considerations that underlie this policy. *Exchange Act Release No. 34-40018* (May 21, 1998) (the "***1998 Release***").

The first consideration relates to the subject matter of a proposal, recognizing that "certain tasks are so fundamental to management's ability to run a company on a day-to-day basis that they could not, as a practical matter, be subject to direct shareholder oversight." 1998 Release. Examples of the tasks cited by the Commission include "management of the workforce, such as the hiring, promotion, and termination of employees, decisions on production quality and quantity, and the retention of suppliers." 1998 Release.

The second consideration relates to "the degree to which a proposal seeks to 'micro-manage' 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. In Staff Legal Bulletin 14L, the Commission explained that in assessing "whether a proposal probes matters 'too complex' for shareholders, as a group, to make an informed judgment, [the Commission] may consider the sophistication of investors generally on the matter, the availability of data, and the robustness of public discussion and analysis on the topic." *Staff Legal Bulletin No. 14L* (Nov. 3, 2021) ("***SLB 14L***")

The Staff has also provided guidance as to when a proposal requesting the preparation of a report is excludable under 14a-8(i)(7), stating that it may be excludable "if the subject matter of the special report . . . involves a matter of ordinary business." Exchange Act Release No. 34-20091 (Aug. 16, 1983) (the "***1983 Release***"); *Duke Energy Corp.* (avail. Feb. 24, 2012); *PepsiCo* (avail. Mar. 3, 2011); *FedEx Corp.* (avail. Jul. 14, 2009); *The Coca-Cola Co*. (avail. Jan. 21, 2009).

1. The Proposal relates to the Company's ordinary business matters.

In accordance with the policy considerations underlying the ordinary business exclusion, the Staff has consistently permitted exclusion under Rule 14a-8(i)(7) of stockholder proposals relating to the products and services offered for sale by a company. For example, in *DENTSPLY Int'l Inc.* (avail. 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)." See also, *Pfizer Inc.* (avail. Mar. 1, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report describing the steps the company has taken to prevent the sale of its medicines to prisons for the purpose of aiding executions, noting that the proposal "relates to the sale or distribution of [the company's] products"). In *The TJX Companies, Inc.* (avail. Apr. 16, 2018), the proposal requested that the board of directors adopt "a new universal and comprehensive animal welfare policy applying to all of [its] stores, merchandise and suppliers." The proposal was preceded by a supporting statement which largely focused on the company's sale of products containing fur in certain of its retail

stores. The company argued that the supporting statement demonstrated that the proposal's thrust and focus concerned "specific products the [c]ompany offers for sale in certain of its retail stores," and the Staff concurred with exclusion of the proposal under Rule 14a-8(i)(7), noting that "the [p]roposal relates to the products and services offered for sale by the [c]ompany." See also, *Wells Fargo & Co.* (avail. Jan. 28, 2013, recon. denied Mar. 4, 2013) ("[p]roposals concerning the sale of particular products and services are generally excludable under rule 14a-8(i)(7)"). In this instance, it is clear that the ability to provide patent protection for the Company's products and services directly impacts the development, sale and distribution of the specific products the Company develops. In fact, the thrust and focus of the Proponent in the supporting statement is entirely on the sale, distribution and patent portfolio of the Company's product Enbrel®, and as such, the Proposal should be excludable under Rule 14a-8(i)(7) as relating to the products offered for sale by the Company.

Further, and more specifically, the Staff has recognized that decisions regarding intellectual property matters are fundamental to a company's day-to-day operations and cannot, as a practical matter, be subject to direct stockholder oversight. In *International Business Machines Corp.* (avail. Jan. 22, 2009), for example, the proposal requested that the company take steps to further the advancement of open source software, which the company noted allows recipients to "freely copy, modify and distribute the program source code without paying a royalty fee." In permitting exclusion under Rule 14a-8(i)(7), the Staff noted that the proposal related to the company's "ordinary business (i.e., the design, development and licensing of [the company's] software products)." Relatedly, the Staff has also recognized that decisions relating to a company's research and development activities are excludable as relating to ordinary business matters. See *Pfizer Inc.* (avail. Jan. 25, 2004) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company establish procedures to provide information to study participants when their participation is terminated, noting that the proposal relates to the company's "ordinary business operations (i.e., product research, development and testing))."

In this instance, the Proposal focuses primarily on how, when and whether the Company should safeguard and protect the intellectual property rights associated with the products and improvements it develops, manufactures and sells, which is an ordinary business matter. The Proposal suggests that there is only one type of patent that is valuable and appropriate, and that all other patents and patent approaches require a special process established by the Board and reporting to stockholders. In effect, every patent, other than, perhaps, an initial patent for the active ingredient or molecule (composition of matter), would be subject to the process and reporting requested by the Proposal.

Decisions with respect to how, when and whether to safeguard and protect the intellectual property rights associated with the products the Company develops, manufactures and sells are at the heart of the Company's business as a global, research-based biotechnology company and are so fundamental to its day-to day operations that they cannot, as a practical matter, be subject to direct stockholder oversight. The Company invests heavily in research and development to advance numerous potential new medicines at all stages in its pipeline of potential products. The Company currently has approximately 42 pipeline programs in mid- and late-stage development, well in excess of 100 research collaborations, and has invested $4 billion in research and development from September 2021 through September 2022, with three quarters of the molecules in the Company's pipeline representing potential first-in-class medicines targeting diseases for which there remains a huge need for new and better treatments. Throughout this extensive research and development process, the Company must make critical decisions regarding how best to safeguard and protect its intellectual property rights with respect to these new and potential products, including how, when and whether to patent its products, processes, components, formulations or improvements thereof, including when to apply for patents and what such patents should cover. Such decisions, including the scope of and which patents to file for and when to file for them, are inherently complex and confidential, involve expert analysis and opinion and are not made lightly, and are made to ensure assets are protected and value is

created. These decisions involve a multitude of scientific, legal and operational considerations, along with the balancing of numerous complex factors, such as: whether patents meet the recognized standards of novelty, non-obviousness or inventive step and utility; whether to maintain all or a portion of the invention as a trade secret; the Company's ability to use intellectual property rights to facilitate collaboration and enable partnerships with counterparts; the Company's ability to better ensure supply chain quality and monitor for counterfeit products; laws and regulations relating to effective and fair competition; the potential for patent disputes and related legal, market and business uncertainty; economic incentives to continue to innovate and develop new treatments, cures and vaccines; and socio-economic challenges unique to different countries and markets. In administering its strategy with respect to developing intellectual property and safeguarding the associated intellectual property rights, the Company also must consider the timeframe and its future plans, since obtaining a patent often takes several years and requires passing through a robust and thorough process involving extensive review by patent examiners, substantive responses by the patent applicant and third-party challenges through administrative proceedings. Balancing these numerous and complex factors is plainly within the ambit of management's operations of the Company's ordinary business. The Proposal also implicates the Company's collaboration, license and similar agreements, pursuant to which the Company commits to research, develop, manufacture or commercialize potential products with other biopharmaceutical companies or collaborators. The Proposal would impair the Company's ability to satisfy these commitments. The Proposal probes matters regarding intellectual property protection availability, coverage and value that are too complex for stockholders as a group to make an informed decision. Stockholders lack the technical, business and legal experience and lack intimate knowledge of the Company's business, patent portfolio, agreements, developments and operations to make an informed judgment. Moreover, decisions regarding how, when and whether the Company manages and protects the intellectual property rights associated with the products that it develops and sells are inherently based on confidential, competitively sensitive and proprietary information, underscoring that these decisions are fundamental to management's ability to run the company on a day-to-day basis and inappropriate for stockholder oversight.

Not only is the subject matter of the Proposal inappropriate for stockholder oversight, but it is also inappropriate for detailed decision making by the Board through the establishment of a policy, given the complexity of intellectual property-related decisions. Neither stockholders nor the Board as a whole have the specific expertise necessary to understand the process and requirements for obtaining, or the extent of exclusivity provided by, various existing and proposed patents, nor the technical or medical value provided by the various patents, and thus are not qualified to establish or review any process or report that attempts to evaluate the complexities involved with the potential impact of patent exclusivities on product access. Stockholders do not have sufficient expertise or knowledge of the Company's business or technologies to make an informed decision about the Proposal, or even to understand what they are voting on and what the implications of the Proposal would be. Stockholder review of this process would involve stockholders scrutinizing a variety of daily decisions made by the Company in managing its patent strategy for a multitude of products and product candidates. The Company's stockholders, as a group, and even the Company's Board, do not have the specific expertise necessary and are not as familiar with the myriad of factors and potential risks, benefits and alternatives the Company must take into consideration when making decisions of this type, and they are not in a position to make an informed decision on such issues.

The Proposal asks that the Company's patent strategy serve one purpose: product access. However, such high-value complex decisions must take into account the concerns of all stockholders and stakeholders, and the responsibilities of management, the Board and the Company to its stockholders. The Company has a duty to its stockholders to protect and employ its assets and to promote long-term value creation. Most companies could not manufacture and deliver existing medicines to patients or discover and develop potential new medicines for patients, let alone generate profits for its stockholders, without a successful patent strategy. In addition, because the Proposal's requested process and report focuses on one

particular factor—product access—and requires Board involvement, vetting and public disclosure, the Proposal gives this one particular factor priority in the Company's decision of how, when and whether to patent its products, processes, formulas, delivery methods or improvements thereof, and interferes with management's conduct of ordinary business operations and decisions. The Company operates in an extremely competitive environment, and decisions regarding how, when and to what extent the Company should safeguard its intellectual property rights, and what factors to consider and their relative importance, are matters that are fundamental to management's ability to run the Company on a day-to-day basis, impact its ability to compete and its ability to fund its extensive research and development efforts, and are of the type that, as a practical matter, should not be subject to direct stockholder oversight.

Not only does the Proposal relate to the Company's sale of its products and its ability to safeguard its intellectual property rights and assets, but it also directly relates to the pricing of the Company's products. This is made abundantly clear in the Proposal's supporting statement, which discusses product pricing at length and asserts a tie between the Company's price increases on Enbrel® and the intellectual property protections the Company has obtained on Enbrel® since its launch. The Proposal requests that the Company consider foregoing the legal protections and exclusive rights on its products, innovations and developments, which effectively seeks to limit and control the pricing it can obtain for its products, and particularly Enbrel®. The pricing of the Company's products is fundamental to the Company's ability to run its business on a day-to-day basis and directly impacts it ability to fund future research and development initiatives and to develop new and improved products.

The Staff has consistently permitted exclusion of stockholder proposals under Rule 14a-8(i)(7) when those proposals relate to how a company makes specific pricing decisions regarding certain of its products. For example, in *Amgen Inc.* (avail. Feb. 10, 2017), the Staff determined that a proposal, submitted by the Proponent and other members of the same group supporting this Proposal, requesting a report on the "rationale and criteria for price increases of the company's top ten selling branded prescription drugs in the last six years" related to the Company's ordinary business, and was excludable under Rule 14a-8(i)(7). And, in *Johnson & Johnson* (avail. Jan. 12, 2004), the Staff permitted exclusion under Rule l4a-8(i)(7) of a proposal requesting that the board review pricing and marketing policies and prepare a report on how the company will respond to regulatory, legislative and public pressure to increase access to prescription drugs as relating to the company's ordinary business operations. *See also, e.g.*, *Equity LifeStyle Properties, Inc.* (avail. Feb. 6, 2013) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on, among other things, "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," noting 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"); *Verizon Communications Inc.* (avail. Jan. 29, 2019) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company offer its stockholders 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'"; *Western Union Co.* (avail. Mar. 7, 2007) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board review, among other things, the effect of the company's remittance practices on the communities served and compare the company's fees, exchange rates, and pricing structures with other companies in its industry, noting that the proposal related to the company's "ordinary business operations (i.e., the prices charged by the company)"); *Prime Computer Inc.* (avail. Feb. 10, 1986) (permitting exclusion under Rule 14a-8(i)(7) of a proposal relating to altering the company's policies with respect to license fees, noting that the proposal relates to the Company's "ordinary business operations (i.e., the determination of appropriate fees for Company products and services").

Moreover, in the Proposal's supporting statement, the Proponent tries to justify the Proposal due to the asserted "reputation risks and potential regulatory blowback resulting from high drug prices and

perceptions about abusive patent practices." The Staff, however, has consistently excluded proposals concerning evaluation of risks as being related to the "company's ordinary business operations." For example, in *Amgen Inc.* (avail. Feb. 10, 2017), the Proponent requested a report on the "rationale and criteria for price increases of the company's top ten selling branded prescription drugs… and an assessment of the legislative, regulatory, reputational and financial risks they represent" and the Staff determined that the Proposal related to the Company's ordinary business operations and was excludable under Rule 14a-8(i)(7). See also, *Abbott Laboratories* (avail. Mar. 9, 2006) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a review of the economic effects of the HIV/AIDS, tuberculosis and malaria pandemics on the company's business strategies and initiatives where the proposal related to the "company's ordinary business operations (i.e., evaluation of risk)." See also *Pfizer Inc.* (avail. Jan. 24, 2006) (same); *Marathon Oil Corp.* (avail. Jan. 23, 2006) (same); *American International Group, Inc.* (avail. Feb. 19, 2004) (same); *Texas Instruments, Inc.* (avail. Jan. 28, 2005) (same).

The Company notes that a proposal may not be excluded under Rule 14a-8(i)(7) if it is determined to focus on a significant policy issue. However, the fact that a proposal may touch upon a significant policy issue does not preclude exclusion under Rule 14a-8(i)(7). Instead, the question is whether the proposal focuses primarily on a matter of broad public policy versus matters related to the company's ordinary business operations. *See* 1998 Release and Staff Legal Bulletin 14E (Oct. 27, 2009).

The Staff has consistently permitted exclusion of stockholder proposals where the proposal focused on ordinary business matters, even though it also related to a potential significant policy issue, and particularly the policy issue of product access and affordable healthcare. *See UnitedHealth Group Inc.* (avail. Mar. 16, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a board report on how the company is responding to regulatory, legislative, and public pressures relating to pricing policies or price increases to ensure affordable health care coverage and the measures the company is taking to contain price increases of health insurance premiums as relating to the company's ordinary business operations); *Johnson & Johnson* (avail. Jan. 12, 2004) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board review pricing and marketing policies and prepare a report on how the company will respond to regulatory, legislative and public pressure to increase access to prescription drugs as relating to the company's ordinary business operations); *CIGNA Corp.* (avail. Feb. 23, 2011) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the potential significant policy issue of access to affordable health care, it also asked the company to report on expense management, an ordinary business matter); *Amgen Inc.* (avail. Feb. 10, 2017) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the potential significant policy issue of "access to life-saving medicines, particularly for economically challenged patients," it also asked the company to report on the rationale and criteria for price increases, an ordinary business matter).

The Company recognizes that the Staff recently changed its approach to how it evaluates significant social policy issues, explaining in SLB 14L that 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) on that basis. 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. This shift in approach by the Staff does not, however, mean that whenever a policy issue is raised the proposal cannot be excluded. 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.* (avail. 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*. (avail. Apr. 8, 2022) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting a report on information about the distribution of stock-based incentives to employees, including data about EEO-1 employee classification, despite declarations in the supporting statement that the intention was for the proposal to address a significant social policy issue); *Repligen Corp.* (avail. Apr. 1, 2022) (same).

In this instance, even if the Proposal were to touch on a potential significant policy issue, the Proposal's overwhelming concern with the products offered for sale by the Company, how the Company decides to safeguard and protect the intellectual property rights associated with the products it develops and sells, how the Company determines pricing for its products and its risk analysis resulting from these decisions demonstrates that the Proposal's focus is on ordinary business matters. In particular, the Proposal's supporting statement demonstrates this focus by highlighting the economic effects of the Company's product development and associated intellectual property decisions. By trying to influence the Company's decisions regarding how, when and whether to patent its products, processes, components, delivery methods, or any new and useful improvement thereof, and requesting the implementation of a required Board process regarding the impact of such patents on product access, the Proposal seeks to control the development, design, timing, marketing, distribution, pricing and protection of the Company's products and assets – all of which are intertwined with the Company's ordinary day-to-day business operations. As a result, even if the Proposal could be viewed as touching upon a significant policy issue, its focus is on ordinary business matters. Accordingly, the Company believes that it may properly exclude the Proposal from the Company's 2023 Proxy Materials pursuant to Rule 14a-8(i)(7) as relating to its ordinary business operations.

2. The Proposal seeks to micromanage the Company.

The Staff has consistently agreed that stockholder proposals attempting to micromanage a company by probing too deeply into matters of a complex nature upon which stockholders, as a group, are not in a position to make an informed judgment are excludable under Rule 14a-8(i)(7). See 1998 Release; see also, e.g., *The Coca-Cola Co.* (avail. Feb. 16, 2022); *Deere & Co.* (avail. Jan. 3, 2022); *JPMorgan Chase & Co.* (avail. Mar. 22, 2019); *Royal Caribbean Cruises Ltd.* (avail. Mar. 14, 2019); *Walgreens Boots Alliance, Inc.* (avail. Nov. 20, 2018); *RH* (avail. May 11, 2018); *Amazon.com, Inc.* (avail. Jan. 18, 2018). As the Commission has explained, a proposal may probe too deeply into matters of a complex nature if it "involves intricate detail, or seeks to impose specific time-frames or methods for implementing complex policies." See 1998 Release. Recently, in SLB 14L, the Staff explained that a proposal can be excluded on the basis of micromanagement based "on the level of granularity sought in the proposal and whether and to what extent it inappropriately limits discretion of the board or management."

In this instance, the Proposal seeks to micromanage the Company by dictating the establishment of a particular intellectual property analysis and process that inappropriately limits discretion of the Board and management. It does so by requesting that the Company establish a process by which the impact of patent protections on one particular factor—product access—would be considered, and reported on, in deciding how, when and whether to patent its products or components thereof, including when to file patent applications The Proposal thus seeks to direct whether the Company should protect its assets, how it develops and safeguards its intellectual property, and how it prices its products.

As described above, decisions concerning whether, when and how the Company applies for patents require complex business, legal and technical judgments by the Company's management that must account for a myriad of factors. In making such decisions, the Company's management must consider and balance this multitude of complex factors, including the costs incurred in developing intellectual property, compliance and risk considerations, legal and regulatory factors, existing prior art and the characteristics

of the Company's products, among other matters. By seeking to impose a specific process on the Company's management of its intellectual property strategy, the Proposal attempts to micromanage the Company by probing too deeply into matters of a complex nature upon which stockholders, as a group, are not in a position to make an informed judgment.

Accordingly, the Company believes that it may properly exclude the Proposal from the 2023 Proxy Materials pursuant to Rule 14a-8(i)(7) as relating to its ordinary business operations.

III. CONCLUSION

Based upon the foregoing analysis, we hereby respectfully request that the Staff confirm that it will not recommend enforcement action if the Proposal is excluded from the Company's 2023 Proxy Materials (i) pursuant to Rule 14a-8(i)(3) because it violates the proxy rules and (ii) pursuant to Rule 14a-8(i)(7) because it deals with a matter relating to the Company's ordinary business operations.

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We would be pleased to provide any additional information and answer any questions that the Staff may have regarding this submission. If the Staff does not concur with the Company's position, we would appreciate an opportunity to confer with the Staff concerning this matter prior to the determination of the Staff's final position. In addition, the Company requests that the Proponent copy the undersigned on any response it may choose to make to the Staff, pursuant to Rule 14a-8(k).

If we can be of any further assistance in this matter, please do not hesitate to contact me at 714-755-8261. Please acknowledge receipt of this letter by return electronic mail. Thank you for your attention to this matter.

Sincerely,

Regina M. Schlatter
of LATHAM & WATKINS LLP

cc: Andrea A. Robinson, Vice President, Law, Governance and Securities & Assistant Secretary
Amgen Inc.

Lydia Kuykendal
Mercy Investment Services, Inc.

Catherine Rowan
Trinity Health

Christina Dorett
Seventh Generation Interfaith Inc.

LATHAM & WATKINS LLP

Exhibit A

RESOLVED, that shareholders of Amgen Inc. ("Amgen") 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 Amgen's website.

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

This high level of concern has driven policy responses. The Inflation Reduction Act empowers the federal government to negotiate some drug prices.[3] State measures, including drug price transparency legislation, copay caps, and Medicaid purchasing programs, have also been adopted.[4] The House Committee on Oversight and Reform (the "Committee") launched a far-reaching investigation into drug pricing in January 2019.[5]

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

Among the abuses described by the Committee's December 2021 report is construction of a "patent thicket," which consists of many "secondary patents covering the formulations, dosing, or methods of using, administering, or manufacturing a drug"; they are granted after the drug's primary patent, covering its main active ingredient or molecule, has been granted.[6] In June 2022, citing the impact of patent thickets on drug prices, a bipartisan group of Senators urged the U.S. Patent and Trademark Office to "take regulatory steps to . . . eliminate large collections of patents on a single invention."

Amgen markets Enbrel, a drug that treats auto-immune conditions. According to the Committee's report, 39 patents have been granted on Enbrel, whose price has been raised over

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1 www.rand.org/news/press/2021/01/28.html

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

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

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

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

6 oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf, at 79.

28 times since launch.[7] Those patents potentially give Amgen an additional 27 years of exclusivity.[8] A different analysis puts the number of Enbrel's granted patents at 68.[9]

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

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

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

9 www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/