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

DIVISION OF
CORPORATION FINANCE

March 20, 2023

Regina M. Schlatter
Latham & Watkins LLP

Re: Amgen Inc. (the "Company")
Incoming letter dated March 17, 2023

Dear Regina M. Schlatter:

This letter is in regard to your correspondence concerning the shareholder proposal (the "Proposal") submitted to the Company by Mercy Investment Services, Inc. and co-filers (the "Proponents") for inclusion in the Company's proxy materials for its upcoming annual meeting of security holders. Your letter indicates that the Proponents withdrew the Proposal and that the Company therefore withdraws its January 13, 2023 request for a no-action letter from the Division. Because the matter is now moot, we will have no further comment.

Copies of all of the correspondence related to this matter 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: Lydia Kuykendal
Mercy Investment Services, Inc.

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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.

* * * *

LATHAM & WATKINS LLP

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/

February 6, 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 Amgen Inc. to omit proposal submitted by Mercy Investment Services and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Mercy Investment Services, Inc. and two co-filers (the "Proponents") submitted a shareholder proposal (the "Proposal") to Amgen Inc. ("Amgen" or the "Company"). The Proposal asks Amgen's board to establish and report on a process by which the impact of extended patent exclusivities on product access would be considered when deciding whether to apply for secondary and tertiary patents.

In a letter to the Division dated January 13, 2023 (the "No-Action Request"), Amgen stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2023 annual meeting of shareholders. Amgen argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(3), arguing that the Proposal is excessively vague and indefinite; and Rule 14a-8(i)(7), on the ground that the Proposal deals with Amgen's ordinary business operations. As discussed more fully below, Amgen has not met its burden of proving its entitlement to exclude the Proposal in reliance on either of those exclusions and the Proponents respectfully urge that Amgen's request for relief should be denied.

The Proposal

The Proposal states:

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.

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]

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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.

Overpatenting 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 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] As of 2020, 57 patent applications had been filed on Amgen's Enbrel, 72% of which were filed after Enbrel received FDA approval, giving Enbrel 19 additional years of market exclusivity.[12] The Proposal asks Amgen to take the impact on patient access into account when making decisions about applying for secondary and tertiary patents on its medicines.

Vagueness

Amgen argues that the Proposal is excessively vague and indefinite because it does not define "secondary and tertiary patents" with enough specificity or provide sufficient guidance regarding "[t]he type of steps that would comprise a process for consideration of the impact of exclusive patents on product access."[13] Neither of those examples is so vague that exclusion of the Proposal pursuant to Rule 14a-8(i)(3) is appropriate.

The term "secondary and tertiary patents" is defined in the Proposal as "patents applied for after the main active ingredient/molecule patent(s) and which relate to the product." That definition is clear and straightforward. Also, the Proposal's supporting statement quotes from the House Oversight Committee's report, which described secondary patents as "covering the formulations, dosing, or methods of using, administering, or manufacturing a drug." Amgen's speculation that the phrase is intended to refer to all patents other than the initial composition of matter patent[14] shows, indeed, that the term is sufficiently well-defined.

The terms secondary and tertiary patents are in widespread use in scientific and policy circles. The term "secondary patents" is used in nearly all of the media coverage cited in the following section of this response to show that the Proposal's subject transcends ordinary business. So do articles in health care and medical journals,[15] pharmaceutical industry publications,[16] and

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[8] https://www.commonwealthfund.org/publications/podcast/2022/feb/its-the-patents-stupid-why-drugs-cost-so-much-in-us

[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] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.enbrel.report-REVISED-2020-10-06.pdf, at 3.

[13] No-Action Request, at 3.

[14] No-Action Request, at 3.

[15] E.g., C. Scott Hemphill & Bhaven Sampat, "Drug Patents at the Supreme Court," Science, Mar. 22, 2013) ("The Court's ruling promises to reset the innovation/access balance for drugs, whatever the result. We explain the stakes of the case, and how settlements of 'secondary' patents affect that balance."); Tahir Amin & Aaron Kesselheim, "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could be Extended for Decades," Health Affairs, Oct. 2012 (https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2012.0107); Maria Jose Abud et al., "An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile," PLoS One, Apr. 27, 2015 (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0124257)

[16] E.g., Zachary Brennan, "Secondary patents prove to be key in biosimilar blocking strategies, researchers find," Endpoints News, Jan. 19, 2022 ("Researchers are now uncovering the extent to which secondary patents (i.e., not the ones covering the active ingredient) have played a major role in stunting the growth of the biosimilars industry.")

papers by economists and health policy experts.[17] Despite Amgen's protestation that patent law does not refer to secondary or tertiary patents, law review articles use the terms as well.[18] Patent policy expert organization Initiative for Medicines, Access and Knowledge (I-MAK) analyzes the impact of secondary patents on affordability and has issued a report on Amgen's medicine Enbrel. That report notes that although Enbrel's primary patent expired in 2010, patents filed after Enbrel received FDA approval extend exclusivity through 2029, and it recommends reforms to address the excessive number of secondary patents granted in the U.S.[19]

Amgen's objection that the requested process is too undefined rests in part on a disingenuous claim that the impact of obtaining a secondary or tertiary patent on product access is "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."[20] In other words, patents provide protection from others who wish to copy your invention. The Proposal makes clear, however, through references to drug prices and co-pay caps, that the requested process should analyze the impact on patient access, making it unlikely that shareholders or Amgen would be confused on that point.

Amgen complains that the Proposal does not spell out the steps that should be included in the process. That is not Proponents' proper role, however, given that they are not experts in patent law or the scientific considerations that go into decisions about patent applications. Proponents have identified a factor they believe should be part of the analysis and have left it to Amgen's board to specify other factors and assign appropriate weights. According to Amgen, its board is "not qualified to design a process" of the kind sought by the Proposal. Nothing in the Proposal would preclude the board from overseeing the process' development and drawing on subject-matter experts from Amgen's staff to formulate its more technical aspects. More important, neither that objection nor the purported complexity of decisions regarding patents[21] supports Amgen's vagueness argument. Instead, those arguments are reasons Amgen believes shareholders shouldn't support the Proposal and, as such, are appropriately raised in Amgen's statement in opposition.

Unlike the Proposal, the proposals in the determinations cited by Amgen sought nonspecific changes involving broad subjects without providing shareholders or the companies with sufficient guidance regarding implementation. In Apple, Inc.,[22] the Staff concurred that a request to "improve guiding principles of compensation" was excessively vague, remarking that "[a] proposal that described the nature of improvements that the company could consider, without prescribing the particular result, would be less likely to be viewed as vague and indefinite." Although the supporting

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[17] E.g., Bhaven N. Sampat & Kenneth C. Shadlen, "Secondary Pharmaceutical Patenting: A Global Perspective," National Bureau of Economic Research Working Paper 23114, Jan. 2017 (https://www.nber.org/papers/w23114); Theo Bourgeron & Susi Geiger, "(De-) assetizing pharmaceutical patents: Patent contestations behind a blockbuster drug," Economy & Society, pp. 23-45, 2022 (https://www.tandfonline.com/doi/full/10.1080/03085147.2022.1987752) ("As drug development advances into the later stages, additional patents are then filed pertaining to other aspects of the active ingredients, such as different dosages, formulations, or production methods. Such patents are referred to as secondary patents.")

[18] E.g., Christopher M. Holman, "In Defense of Secondary Pharmaceutical Patents: A Response to the UN's *Guidelines for Pharmaceutical Patent Examination*," 50 Ind. L. Rev. 759 (2016-2017); S. Sean Tu & Mark A. Lemley, "What Litigators Can Teach the Patent Office About Pharmaceutical Patents," 99 Wash. U. L. Rev. 1673 (2021-2022) ("Most litigated patents (90%) are "secondary" patents—minor alterations to an existing drug rather than a patent on a new chemical.")

[19] https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.enbrel.report-REVISED-2020-10-06.pdf

[20] No-Action Request, at 3.

[21] See No-Action Request, at 3.

[22] Apple, Inc. (Dec. 6, 2019).

statement critiqued pay levels at Apple and across the S&P 500, it did not identify specific "guiding principles" that would address the proponent's concerns. In Kroger,[23] the Staff granted relief on vagueness grounds where a proposal requesting a sustainability report specified that it should be prepared in accordance with the Global Reporting Initiative's sustainability reporting guidelines but did not adequately describe the contents of those extensive guidelines.

Amgen also cites Alcoa,[24] where the proposal opened with several "whereas" clauses discussing human rights principles and various International Labor Organization conventions ,then asked the company to commit to the "full implementation of these human rights standards by its international suppliers and in its own international production facilities." Alcoa argued that the proposal was excessively vague, since it did not make clear what "these human rights standards" are and, if the proposal intended to encompass the standards mentioned in the whereas clauses, did not describe or summarize them for shareholders or the company. The Staff concurred and granted relief.

An argument much like the one Amgen advances was rejected at Northrop Grumman Corp.,[25] where the proposal asked the company to publish a report with the results of "human rights impact assessments examining the actual and potential human rights impacts associated with high-risk products and services, including those in conflict-affected areas." Northrop Grumman argued that the proposal was excessively vague because "high-risk" and "conflict-affected areas" were not defined, leaving "significant room for interpretation." The Proponents responded that although the proposal did not formally define those terms, their meanings were clear in the context of the proposal. The Staff denied relief.

Similarly, in Comcast Corp.,[26] the proposal asked the company to adopt a policy, and amend its governance documents as necessary, requiring that the chair of the board be an independent director. Comcast claimed that the absence of a definition for "independent," a "critical concept," rendered the proposal excessively vague. The Staff did not grant the requested relief.

Both Amgen and its shareholders can discern what the Proposal is asking Amgen to do. The Proposal requests that Amgen incorporate the impact on patient access, a well-understood concept in the pharmaceutical industry, into its decisions whether to apply for secondary and tertiary patents on its medicines. Secondary and tertiary patents are defined in the Proposal, and the term is commonly used in discussing how the pharmaceutical industry erects patent "thickets" or "fortresses" to protect top-selling branded drugs. Accordingly, Amgen has not showed that it is entitled to exclude the Proposal on vagueness grounds.

Ordinary Business

Amgen 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, pricing, and how Amgen safeguards its intellectual property ("IP"). Amgen also claims that the Proposal would micromanage it. Neither argument has merit.

The Division generally regards a company's product offerings, choices about IP protections, and pricing decisions, without more, as ordinary business matters. However, the fact that a proposal

[23] Kroger Co. (Mar. 19, 2004).
[24] Alcoa, Inc. (Dec. 24, 2002).
[25] Northrop Grumman Corporation (Mar. 13, 2020).
[26] Comcast Corporation (Feb. 8, 2016)

implicates one of those subjects does not support exclusion on ordinary business grounds if it focuses on a significant social policy issue, which is the case with the Proposal.

Last season, the Staff considered and rejected arguments much like those Amgen 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 Amgen 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.[27] 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 Amgen'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.[28] The proponent countered that the proposal's topic, ensuring equitable access to vaccines and the role of IP protections in maintaining 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.[29] 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."[30]

Similar outcomes have been reached on other proposals involving pharmaceutical companies' products where a significant policy issue was implicated. The Staff did not agree with JNJ's 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. And Gilead[31] unsuccessfully argued that a proposal seeking a report on risks related to rising pressures to contain specialty drug prices was excludable on ordinary business grounds, pointing to the focus on its products and pricing decisions. In Denny's,[32] 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).

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[27] Johnson & Johnson (Feb. 8, 2022)
[28] Pfizer, Inc. (Feb. 23, 2022); Moderna, Inc. (Feb. 8, 2022).
[29] See Eli Lilly and Company (Feb. 25, 1993); Bristol-Myers Squibb Company (Feb. 21, 2000); Warner Lambert Company (Feb. 21, 2000).
[30] AbbVie, Inc. (Mar. 11, 2022); Pfizer, Inc. (Mar. 8, 2022).
[31] Gilead Sciences Inc. (Feb. 23, 2015).
[32] Denny's Inc. (Mar. 17, 2009)

Finally, Amgen's assertion that "[t]he Staff . . . has consistently excluded proposals concerning evaluation of risks as being related to the 'company's ordinary business operations'"[33] is flatly wrong. In Staff Legal Bulletin ("SLB") 14E,[34] the Staff announced that it would shift from allowing exclusion if a proposal "relate[s] to the company engaging in an evaluation of risk" to focusing on the "subject matter to which the risk pertains or that gives rise to the risk." Going forward, if that subject matter raised significant policy issues, exclusion would not be warranted simply because a proposal referred to risk. All but one of the determinations Amgen cites on page 8 of the No-Action Request pre-date SLB 14E and thus reflect the earlier methodology; the remaining determination involved a proposal whose subject the Staff deemed not to transcend ordinary business., which supports exclusion under the current approach.

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.[35]

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

- Editorial Board, "Save America's Patent System," The New York Times, Apr. 17, 2022[36] ("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.")
- Rebecca Robbins, "How a Drug Company Made $114 Billion By Gaming the U.S. Patent System," The New York Times, Jan. 28, 2023 ("AbbVie orchestrated the delay [in loss of exclusivity, by six years] by building a formidable wall of intellectual property protection and suing would-be competitors before settling with them to delay their product launches until this year. The strategy has been a gold mine for AbbVie, at the expense of patients and taxpayers. . . . Following AbbVie's footsteps, Amgen has piled up patents for its anti-inflammatory drug Enbrel, delaying a copycat version by an expected 13 years after it won regulatory approval. ")
- Editorial Board, "How Big Pharma plays games with drug patents and how to combat it," USA Today, Jan. 18, 2019[37] ("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[38]

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[33] No-Action Request, at 8.
[34] Staff Legal Bulletin 14E (Oct. 27, 2009).
[35] See, e.g., www.sec.gov/interps/legal/cfslb14a.htm.
[36] https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html
[37] https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/
[38] https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/

- Berkeley Lovelace Jr., "'Gaming' of U.S. patent system is keeping drug prices sky high, report says," NBCNews.com, Sept. 15, 2022[39]
- "Biden Drug Price Pressure on Patent Office Draws Skeptics," Bloomberg, Sept. 21, 2021[40] ("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[41]
- Matthew Lane, "The Key to Lowering Drug Prices is Improving Patent Quality," Techdirt, July 21, 2021[42] ("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[43] ("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[44]
- Gunjan Sinha, "How Patent Extensions Keep Some Drug Costs High," Undark, June 16, 2021[45]
- 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[46]
- Ryan Chatelain, "House committee report blasts drug pricing strategies as 'troubling,'" NY1, Dec. 10, 2021[47]
- 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[48]

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[39] https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507

[40] https://news.bloomberglaw.com/health-law-and-business/biden-drug-price-pressure-on-patent-office-draws-skeptics

[41] https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

[42] https://www.techdirt.com/2021/07/21/key-to-lowering-drug-prices-is-improving-patent-quality/

[43] https://prospect.org/health/its-time-for-public-pharma/

[44] https://www.chicagobusiness.com/joe-cahill-business/humira-patent-strategy-makes-case-reform

[45] https://undark.org/2021/06/16/how-patent-extensions-keep-some-drug-costs-high/

[46] https://www.politico.com/tipsheets/prescription-pulse/2017/07/17/fda-to-examine-anticompetitive-practices-by-drug-industry-221368

[47] https://www.ny1.com/nyc/all-boroughs/politics/2021/12/10/house-committee-report-blasts-drug-pricing-strategies-as--troubling-

[48] https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html

- Matthew Lane, "To rein in Big Pharma over high drug prices, start with patent reform," Roll Call, Jan. 17, 2020[49] ("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[50] ("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.")
- David Blumenthal, "The U.S. Can Lower Drug Prices Without Sacrificing Innovation," Harvard Business Review, Oct. 1, 2021[51] ("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[52]
- "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[53]
- Ahmed Aboulenein, "Consumer group says drugmakers abuse U.S. patent system to keep prices high," Reuters, Sept. 16, 2022[54]
- Sarah Jane Tribble, "Drugmakers Play the Patent Game to Ward Off Competitors," NBCNews.com, Oct. 2, 2018[55]

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.[56] 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.[57] The Second Look at Drug Patents Act would have required publication of patents filed after

[49] https://www.rollcall.com/2020/01/17/to-rein-in-big-pharma-over-high-drug-prices-start-with-patent-reform/
[50] https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html
[51] https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation
[52] https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html
[53] https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/?sh=73fa684178ca
[54] https://www.reuters.com/business/healthcare-pharmaceuticals/consumer-group-says-drugmakers-abuse-us-patent-system-keep-prices-high-2022-09-16/
[55] https://www.nbcnews.com/health/health-news/drugmakers-play-patent-game-ward-competitors-n915911
[56] 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.
[57] https://www.congress.gov/bill/116th-congress/house-bill/3199/text

approval of a new drug or abbreviated new drug application by the FDA in order to facilitate validity challenges.[58] The Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019[59] 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.[60] Product hopping occurs when branded drug 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.[61]

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.[62]

The House Judiciary Antitrust Subcommittee held a hearing in April 2021 on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."[63] Experts on drug companies' anticompetitive practices testified, including Professor Robin Feldman, who discussed the relationship between secondary patents and product-hopping.[64]

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

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[58] https://www.congress.gov/bill/116th-congress/senate-bill/1617
[59] https://www.congress.gov/bill/116th-congress/house-bill/3991
[60] https://www.congress.gov/bill/117th-congress/house-bill/2873
[61] www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf
[62] https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf
[63] https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive
[64] https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-FeldmanR-20210429.pdf, at 3-4

2019.[65] 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 trends. Too often, the primary goal of these tactics is to leverage the law to stifle competition, rather than to protect meaningful clinical advancements.[66]

The House Oversight Committee initiated a sweeping investigation in 2019 into "pricing and business practices in the pharmaceutical industry."[67] 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."[68] 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."[69] 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."[70] 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."[71]

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

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[65] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to

[66] 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.").

[67] 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.

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

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

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

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

provide new drugs."[72] 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 standpoint. So, we may be lavishing rewards without getting the innovation that we desperately need."[73] Another witness identified patent thickets as key to high drug prices.[74]

The Senate Finance Committee held a hearing on "Drug Pricing in America: A Prescription for Change, Part I"[75] 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.[76]

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.[77] In addition to the general problem posed by patent thickets, Kesselheim explained how secondary patents facilitate product hopping.[78]

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."[79] The E.O. also directed the Secretary of Health and Human Services to take various steps to "promote generic drug and biosimilar

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[72] https://www.youtube.com/watch?v=aA3cDgRp37s (at 3:15).
[73] https://www.youtube.com/watch?v=aA3cDgRp37s (at 10:09).
[74] https://www.youtube.com/watch?v=aA3cDgRp37s (at 20:22).
[75] https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i
[76] https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf
[77] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf
[78] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf, at 6-7.
[79] 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).

competition." Pursuant to the E.O., the FDA and PTO are collaborating to implement strategies to lower drug prices,[80] which Amgen mentions in its most recent 10-K filing.[81]

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."[82] 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."[83] 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.[84] 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."[85]

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.[86]

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."[87] 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."[88]

In 2022, Priti Krishtel, co-founder and co-executive director of patent watchdog group 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

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[80] https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf
[81] Amgen Inc. Filing on Form 10-K filed on Feb. 16, 2022, at 32 (hereinafter, "2022 10-K").
[82] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf
[83] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf
[84] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf
[85] https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-MeierM-20170727.pdf
[86] https://www.ag.state.mn.us/Office/Initiatives/PharmaceuticalDrugPrices/Taskforce.asp
[87] https://about.kaiserpermanente.org/news/want-to-lower-drug-prices-reform-the-us-patent-system
[88] https://www.ahip.org/news/press-releases/new-research-big-pharma-companies-earn-big-revenues-through-patent-gaming

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."[89]

The existence of a significant social policy issue, then, distinguishes the Proposal from those analyzed in the determinations Amgen cites on pages 4-5 of the No-Action Request. In Wells Fargo,[90] the proposal 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 proposal 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 Amgen relies, the proponents unsuccessfully argued that the proposals' subjects—the use of the company's products for lethal injection, phasing out mercury from the company's products, 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,[91] 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.

Amgen points to two determinations as standing for the proposition that proposals addressing drug pricing do not transcend ordinary business. But those determinations are the exceptions, not the rule. One[92] involved a proposal that sought detailed data on price increases for the 10 best-selling drugs over the past six years, as well as the risks associated with those decisions, which the company urged would interfere with the company's day-to-day operations. In the other,[93] the proposal asked the company to review its "pricing and marketing policies"; although proposals on drug pricing had previously been found to implicate a significant policy issue, the addition of marketing introduced an ordinary business element. Proposals on drug pricing that do not request excessive detail and that focus on patient access, however, have generally been found to transcend ordinary business.[94]

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89 https://www.macfound.org/fellows/class-of-2022/priti-krishtel#searchresults
90 Wells Fargo & Co. (Jan. 28, 2013, *recon. denied* Mar. 4, 2013).
91 International Business Machines Corp. (Jan. 22, 2009).
92 Amgen, Inc. (Feb. 10, 2017).
93 Johnson & Johnson (Jan. 12, 2004).
94 See Gilead Sciences Inc. (Feb. 23, 2015); Celgene Corporation (Mar. 19, 2015); Vertex Pharmaceuticals Inc. (Feb. 25, 2015); Eli Lilly and Company (Feb. 25, 1993); Bristol-Myers Squibb Company (Feb. 21, 2000); Warner Lambert Company (Feb. 21, 2000).

The Proposal does not focus on ordinary business matters despite "touch[ing] on" a significant policy issue, as Amgen claims.[95] Instead, access to Amgen'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 Amgen cites involved proposals that addressed a significant policy issue but then grafted on an additional element that implicated day-to-day management. For example, The proposal in CIGNA[96] asked the company to report on how it was "responding to regulatory, legislative and public pressures to ensure affordable health care coverage" as well as "the measures our company is taking to contain the price increases of health insurance premiums." CIGNA argued that the second part of the resolved clause focused on the ordinary business matter of expense management, rather than health care reform, as shown by the supporting statement's discussion of the relationship between administrative costs and premiums. The Staff concurred with CIGNA's view that the proposal was excludable because it addressed "the manner in which the company manages its expenses."

In the 2021 proxy season, JNJ[97] unsuccessfully advanced an argument similar to the one Amgen 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 Amgen. SLB 14L recently clarified the Staff's approach to micromanagement claims. It states that the Staff will analyze "the level of granularity sought in the proposal and to what extent it inappropriately limits the discretion of the board or management."[98] 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.

Amgen argues that the Proposal would micromanage because it would "dictat[e] the establishment of a particular intellectual property analysis and process that inappropriately limits discretion of the Board and management."[99] The Proposal simply suggests a factor to be considered and does not specify any details around implementation. It urges that Amgen consider the impact on

[95] No-Action Request, at 9.
[96] CIGNA Corporation (Feb. 23, 2015).
[97] Johnson & Johnson (Feb. 12, 2021).
[98] Staff Legal Bulletin 14L (Nov. 3, 2021).
[99] No-Action Request, at 9.

access when making decisions regarding seeking secondary and tertiary patents, but does not prescribe the weight to be accorded to access considerations, dictate how they should be balanced against other factors, or specify how the impact on access should be measured. The Proposal "afford[s] discretion to management as to how to achieve" the requested outcome, in the words of SLB 14L.

Amgen also urges that "stockholders, as a group, are not in a position to make an informed judgment" about the Proposal's subject.[100] But Amgen's 10-K includes many discussions of patents, presumably because Amgen believes this is valuable information for shareholders. There is an extensive discussion of patent litigation and a list of products and their patents.[101] The 10-K identifies the loss of patent protection as a material risk, stating "Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates."[102]

Given the centrality of patent protection to Amgen's business model, it is a stretch to suggest that the Proposal is too difficult for shareholders to understand. The fact that one of Amgen's key disclosure documents treats the subject in detail suggests that Amgen 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 related to patents in order to form a view about the desirability of considering access when making decisions about them.

The determinations cited on page 9 of the No-Action Request are inapposite because the proposals requested an excessive amount of detail or sought to control details of the companies' day-to-day operations. It is important to note that all but two of the determinations were issued prior to the issuance of SLB 14L, which limits their persuasive power. The proposal submitted to Coca-Cola[103] would have required shareholder approval for any political statement by the company, which Coca-Cola successfully argued would have substituted shareholders' judgments for those of management on day-to-day matters. Likewise, the Royal Caribbean[104] and Walgreens[105] proposals sought to require shareholder approval of all share repurchase programs. In RH,[106] the proposal requested a policy prohibiting the sale of down products. The Deere[107] resolution asked the company to disclose, each year, all employee-training materials offered to any subset of employees, including material conveyed orally, and the Staff concurred with Deere that the proposal micromanaged, stating that it sought disclosure of "intricate details" regarding employment and training practices. The Amazon[108] proposal tried to dictate the placement of a specific showerhead in search results as well as the information provided about it.

The Proposal does not specify any details around implementation. Amgen's assertion that the Proposal "asks that the Company's patent strategy serve one purpose: product access" is contradicted by the Proposal's language, which clearly requests that access be considered in the secondary/tertiary patent review process but 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

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100 No-Action Request, at 10.
101 2022 10-K, at 37-38.
102 2022 10-K, at 37.
103 The Coca-Cola Company (Feb. 16, 2022).
104 Royal Caribbean Cruises Ltd. (Mar. 14, 2019).
105 Walgreens Boots Alliance, Inc. (Young) (Nov. 20, 2018).
106 RH (May 11, 2018).
107 Deere & Company (Jan. 3, 2022).
108 Amazon.com, Inc. (Jan. 18, 2018).

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 Amgen's process, as the Deere proposal would have done.

In its no-action request submitted last season, Moderna made an argument very similar to Amgen'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, Amgen 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. Amgen's inclusion of 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 Amgen's management nor requests intricate detail, it would not micromanage Amgen.

* * *

For the reasons set forth above, Amgen has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(3) or 14a-8(i)(7). The Proponents thus respectfully request that Amgen'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 (317) 910-8581.

Sincerely,

Lydia Kuykendal
Director of Shareholder Advocacy
Mercy Investment Services, Inc

cc: Regina M. Schlatter
Latham & Watkins LLP
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LATHAM & WATKINS LLP

March 17, 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

To the addressee set forth above:

On January 13, 2023, we submitted a letter on behalf of Amgen Inc. (the "***Company***") requesting that the staff of the Division of Corporation Finance (the "***Staff***") concur that the Company could exclude a stockholder proposal and supporting statement (the "***Proposal***") received from Mercy Investment Services (the "***Proponent***"), and co-filed by Trinity Health and Dominican Sisters, Grand Rapids Michigan (collectively, the "***Co-Filers***"), from the Company's proxy statement for its 2023 Annual Meeting of Stockholders.

Pursuant to a withdrawal agreement entered into on March 16, 2023, the Proponent withdrew the Proposal on behalf of itself and the Co-Filers. Based on the withdrawal of the Proposal, the Company hereby informs the Staff that the Company is withdrawing its no-action request of January 13, 2023 relating to the Proposal.

Please contact the undersigned at (714) 755-8261 to discuss any questions you may have regarding this matter.

Very truly yours,

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.