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

DIVISION OF
CORPORATION FINANCE

April 4, 2023

Marc S. Gerber
Skadden, Arps, Slate, Meagher & Flom LLP

Re: Regeneron Pharmaceuticals, Inc. (the "Company")
Incoming letter dated January 24, 2023

Dear Marc S. Gerber:

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

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

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

Copies of all of the correspondence on which this response is based will be made available on our website at https://www.sec.gov/corpfin/2022-2023-shareholder-proposals-no-action.

Sincerely,

Rule 14a-8 Review Team

cc: Lauren Compere
Boston Common Asset Management

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
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BY EMAIL (shareholderproposals@sec.gov)

January 24, 2023

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Chief Counsel
100 F Street, N.E.
Washington, D.C. 20549

RE: Regeneron Pharmaceuticals, Inc. – 2023 Annual Meeting
Omission of Shareholder Proposal of
Boston Common ESG Impact U.S. Equity Fund and
co-filers[1]

Ladies and Gentlemen:

Pursuant to Rule 14a-8(j) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are writing on behalf of our client, Regeneron Pharmaceuticals, Inc., a New York corporation ("Regeneron"), to request that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") concur with Regeneron's view that, for the reasons stated below, it may exclude the shareholder proposal and supporting statement (the "Proposal") submitted by Boston Common Asset Management, on behalf of Boston Common ESG Impact US Equity Fund ("Boston Common"), and co-filers from the proxy materials to be distributed by Regeneron in connection with its 2023

[1] The following shareholders have co-filed the Proposal: Benedictine Sisters of Mount St. Scholastica, Mercy Investment Services, Inc. and Trinity Health. The co-filers' submissions and related correspondence are not relevant to this no-action request and have been omitted from the exhibits hereto but may be supplementally provided upon the Staff's request.

annual meeting of shareholders (the "2023 proxy materials"). Boston Common and the co-filers are sometimes collectively referred to as the "Proponents."

In accordance with Section C of Staff Legal Bulletin No. 14D (Nov. 7, 2008) ("SLB 14D"), we are emailing this letter and its attachments to the Staff at shareholderproposals@sec.gov. In accordance with Rule 14a-8(j), we are simultaneously sending a copy of this letter and its attachments to the Proponents as notice of Regeneron's intent to omit the Proposal from the 2023 proxy materials.

Rule 14a-8(k) and Section E of SLB 14D provide that shareholder proponents are required to send companies a copy of any correspondence that the shareholder proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to remind the Proponents that if the Proponents submit correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should concurrently be furnished to Regeneron.

I. The Proposal

The text of the resolution contained in the Proposal is set forth below:

> **RESOLVED,** that shareholders of Regeneron Pharmaceuticals Inc. ("Regeneron") 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 Regeneron's website.

II. Basis for Exclusion

We hereby respectfully request that the Staff concur with Regeneron's view that the Proposal may be excluded from the 2023 proxy materials pursuant to Rule 14a-8(i)(7) because the Proposal deals with matters relating to Regeneron's ordinary business operations.

III. Background

Regeneron received the Proposal via email on December 9, 2022, accompanied by a cover letter from Boston Common, dated December 9, 2022. On December 13, 2022, Regeneron received a letter via email from US Bank, dated December 13, 2022, verifying Boston Common's continuous ownership of at least the requisite amount of

stock for at least the requisite period preceding and including the date of submission of the Proposal. Copies of the Proposal and cover letter are attached hereto as Exhibit A.

IV. The Proposal May be Excluded Pursuant to Rule 14a-8(i)(7) Because the Proposal Deals with Matters Relating to Regeneron's Ordinary Business Operations.

Under Rule 14a-8(i)(7), a shareholder proposal may be excluded from a company's proxy materials if the proposal "deals with matters relating to the company's ordinary business operations." In Exchange Act Release No. 34-40018 (May 21, 1998) (the "1998 Release"), the Commission stated that the policy underlying the ordinary business exclusion rests on two central considerations. The first recognizes 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. The second consideration relates to the degree to which the 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. As demonstrated below, the Proposal implicates both of these two central considerations.

A. The Proposal relates to Regeneron's ordinary business matters.

The Commission has stated that a proposal requesting the dissemination of a report is excludable under Rule 14a-8(i)(7) if the substance of the proposal involves a matter of ordinary business of the company. *See* Exchange Act Release No. 34-20091 (Aug. 16, 1983) ("[T]he staff will consider whether the subject matter of the special report or the committee involves a matter of ordinary business; where it does, the proposal will be excludable under Rule 14a-8(c)(7)."); *see also Netflix, Inc.* (Mar. 14, 2016) (permitting exclusion under Rule 14a-8(i)(7) of a proposal that requested a report describing how company management identifies, analyzes and oversees reputational risks related to offensive and inaccurate portrayals of Native Americans, American Indians and other indigenous peoples, how it mitigates these risks and how the company incorporates these risk assessment results into company policies and decision-making, noting that the proposal related to the ordinary business matter of the "nature, presentation and content of programming and film production").

In accordance with the policy considerations underlying the ordinary business exclusion, the Staff has consistently permitted exclusion under Rule 14a-8(i)(7) of shareholder proposals relating to the products and services offered for sale by a company. *See, e.g.*, *Wells Fargo & Co.* (Jan. 28, 2013, *recon. denied* Mar. 4, 2013) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company prepare a report discussing the adequacy of the company's policies in addressing the

social and financial impacts of its direct deposit advance lending service as relating to the ordinary business matter of "products and services offered for sale by the company," stating in particular that "[p]roposals concerning the sale of particular products and services are generally excludable under rule 14a-8(i)(7)"); *Pfizer Inc.* (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"); *The Walt Disney Co.* (Nov. 23, 2015) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the company's board of directors approve the release of a specific film on Blu-ray, noting that the proposal "relates to the products and services offered for sale by the company"); *FMC Corp.* (Feb. 25, 2011, *recon. denied* Mar. 16, 2011) (permitting exclusion under Rule 14a-8(i)(7) of a proposal seeking, among other things, an immediate moratorium on sales and a withdrawal from the market of a specific pesticide, as well as other certain pesticides, noting that the proposal "relates to the products offered for sale by the company"); *JPMorgan Chase & Co.* (Mar. 16, 2010) (permitting exclusion under Rule 14a-8(i)(7) of a proposal requesting that the board implement a policy mandating that the company cease its current practice of issuing refund anticipation loans, noting that the proposal related to the company's "decision to issue refund anticipation loans" and that "[p]roposals concerning the sale of particular services are generally excludable under rule 14a-8(i)(7)").

More specifically, under those same policy considerations underlying the ordinary business exclusion, 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 shareholder oversight. In *International Business Machines Corporation* (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 operations (i.e., the design, development and licensing of [the company's] software products)."

In this instance, the Proposal focuses primarily on how Regeneron decides to safeguard and protect the intellectual property rights associated with the pharmaceutical products it discovers, invents, develops and commercializes, which is an ordinary business matter. Specifically, the Proposal's resolved clause asks Regeneron's board of directors (the "Board") to establish and report on a process by which Regeneron would consider the impact of extended patent exclusivities on one particular factor—product access—in deciding whether to apply for secondary and tertiary patents. The

Proposal's supporting statement then goes into detail on aspects of Regeneron's intellectual property strategy. Read together, the Proposal's resolved clause and supporting statement clearly articulate a concern with the ordinary business matter of how Regeneron manages and protects the intellectual property rights associated with the pharmaceutical products that it discovers, invents, develops and commercializes.

Decisions with respect to how Regeneron safeguards and protects the intellectual property rights associated with the pharmaceutical products it discovers, invents, develops and commercializes are at the heart of Regeneron's business as a fully integrated biotechnology company and are so fundamental to its day-to-day operations that they cannot, as a practical matter, be subject to direct shareholder oversight. These decisions involve numerous business, scientific and legal considerations, along with the balancing of complex factors such as: whether patents meet the recognized patentability standards in the United States and other jurisdictions; Regeneron's ability to use and evaluate intellectual property rights to facilitate collaboration and enable partnerships with counterparts (including by allowing the parties to freely discuss their inventions without the risk of misappropriation); 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; and other factors and challenges unique to different countries and markets. In administering its strategy with respect to developing intellectual property and safeguarding the associated intellectual property rights, Regeneron 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 that involves extensive review and scrutiny by patent offices and substantive responses by the patent applicant. Balancing the numerous and complex factors is plainly within the ambit of management's operations of Regeneron's ordinary business. Therefore, the Proposal should be excluded under Rule 14a-8(i)(7) as relating to Regeneron's ordinary business operations.

We note that a proposal may not be excluded under Rule 14a-8(i)(7) if it is determined to focus on a significant policy issue. The fact that a proposal may touch upon a significant policy issue, however, 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; Staff Legal Bulletin No. 14E (Oct. 27, 2009). The Staff has consistently permitted exclusion of shareholder proposals where the proposal focused on ordinary business matters, even though it also related to a potential significant policy issue. For example, in *PetSmart, Inc.* (Mar. 24, 2011), the proposal requested that the company's board require suppliers to certify that they had not violated certain laws regulating the treatment of animals. Those laws affected a wide

array of matters dealing with the company's ordinary business operations beyond the humane treatment of animals, which the Staff has recognized as a significant policy issue. In permitting exclusion under Rule 14a-8(i)(7), the Staff noted the company's view that "the scope of the laws covered by the proposal is 'fairly broad in nature from serious violations such as animal abuse to violations of administrative matters such as record keeping.'" *See also, e.g.*, *CIGNA Corp.* (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); *Capital One Financial Corp.* (Feb. 3, 2005) (permitting exclusion under Rule 14a-8(i)(7) when, although the proposal addressed the significant policy issue of outsourcing, it also asked the company to disclose information about how it manages its workforce, an ordinary business matter).

In this instance, even if the Proposal were to touch on a potential significant policy issue, the Proposal's overwhelming concern with how Regeneron decides to safeguard and protect the intellectual property rights associated with the pharmaceutical products it discovers, invents, develops and commercializes 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 Regeneron's product development and associated intellectual property decisions. Therefore, even if the Proposal could be viewed as touching upon a significant policy issue, its focus is on ordinary business matters.

B. The Proposal seeks to micromanage Regeneron.

The Staff has consistently agreed that shareholder proposals attempting to micromanage a company by probing too deeply into matters of a complex nature upon which shareholders, 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.* (Feb. 16, 2022); *Deere & Co.* (Jan. 3, 2022); *JPMorgan Chase & Co.* (Mar. 22, 2019); *Royal Caribbean Cruises Ltd.* (Mar. 14, 2019); *Walgreens Boots Alliance, Inc.* (Nov. 20, 2018); *RH* (May 11, 2018); *Amazon.com, Inc.* (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 Staff Legal Bulletin No. 14L (Nov. 3, 2021) ("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 Regeneron by dictating the establishment of a particular intellectual property analysis that inappropriately limits

discretion of the board and management. It does so by requesting that Regeneron establish a process by which the impact of extended patent protections on one particular factor—product access—would be considered, and reported on, in deciding whether to apply for secondary and tertiary patents. The Proposal thus seeks to direct how Regeneron develops and safeguards its intellectual property.

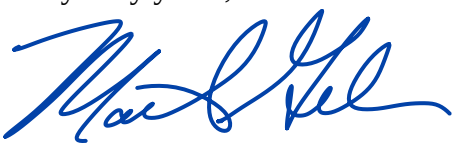
As described above, decisions concerning whether, when and how Regeneron applies for and/or obtains patents and other intellectual property protections require complex business judgments by Regeneron's management that must account for numerous factors. In making such decisions, Regeneron's management must consider and balance these factors, including the business, scientific and legal considerations discussed above. By seeking to impose a specific process on Regeneron's management of its intellectual property, the Proposal attempts to micromanage Regeneron by probing too deeply into matters of a complex nature upon which shareholders, as a group, are not in a position to make an informed judgment.

Accordingly, the Proposal should be excluded from Regeneron's 2023 proxy materials pursuant to Rule 14a-8(i)(7) as relating to its ordinary business operations.

V. Conclusion

Based upon the foregoing analysis, Regeneron respectfully requests that the Staff concur that it will take no action if Regeneron excludes the Proposal from its 2023 proxy materials. Should the Staff disagree with the conclusions set forth in this letter, or should any additional information be desired in support of Regeneron's position, we would appreciate the opportunity to confer with the Staff concerning these matters prior to the issuance of the Staff's response. Please do not hesitate to contact the undersigned at (202) 371-7233.

Very truly yours,



Marc S. Gerber

Enclosures

cc: Joseph J. LaRosa
Executive Vice President, General Counsel and Secretary
Regeneron Pharmaceuticals, Inc.

Richard Gluckselig
Vice President, Associate General Counsel and Assistant Secretary
Regeneron Pharmaceuticals, Inc.

Lauren Compere, Managing Director and Head of Stewardship & Engagement
Amy Orr, Director of US Shareholder Engagement
On behalf of Boston Common ESG Impact US Equity Fund
Boston Common Asset Management

Rose Marie Stallbaumer, OSB
Treasurer
Benedictine Sisters of Mount St. Scholastica

Lydia Kuykendal
Director of Shareholder Advocacy
Mercy Investment Services, Inc.

Catherine Rowan
Director, Socially Responsible Investments
Trinity Health

EXHIBIT A
(see attached)

Boston Common
Asset Management

200 State Street, 7th Floor | Boston, MA 02109

December 9, 2022

Regeneron Pharmaceuticals, Inc. ("Regeneron")
777 Old Saw Mill River Road
Tarrytown, New York 10591-6707

Attn: Corporate Secretary

Dear Corporate Secretary,

Boston Common Asset Management is a global investment manager that specializes in sustainable and responsible global equity strategies. Boston Common urges the companies we invest in to improve their sustainable business practices and to promote transparency, accountability, and inclusivity in the way they conduct business with their employees, customers, suppliers, and other partners. The Boston Common ESG Impact US Equity Fund, a long-term investor, is currently the beneficial owner of shares of Regeneron Pharmaceuticals, Corp. ("the Company", "Regeneron").

As long-term investors in Regeneron, Boston Common appreciates our ongoing dialogue focused on access to medicines and health equity. Not only are these systemic issues that impact Regeneron's business model but there is an escalating and widespread public debate in the US focused on costly specialty drugs. Given this, there are many healthcare companies receiving shareholder proposals on topic. We believe that excessive patenting, and secondary patent extensions, are contributing to these outsized drug prices and cause reputational risks to Regeneron. We are filing this proposal to gain greater clarity on how Regeneron is addressing the issue and remain a part of the dialogue.

We are concerned about some of the recent comments made this week by Regeneron's co-founder and chief scientific officer at the Future of Health Summit ***"You can't deliver a vaccine until you have a vaccine. You can't deliver a treatment until you have it. So these are secondary problems. I'm sorry, but think about how ludicrous your point is."*** In contrast to this view, we believe that an integrated approach to access and equity is about intentionally thinking about how to pay for it during the R&D process.

Boston Common Asset Management is the lead filer for the enclosed proposal for inclusion in the 2023 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. The Boston Common ESG Impact US Equity Fund has been a shareholder continuously holding at least $25,000 in market value for the last year and a day as

of the filing date and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. The verification of ownership by our custodian will be sent as a follow-up to this correspondence. A representative from Boston Common will attend the Annual Meeting to present the resolution as required by SEC rules.

We hope that Regeneron is open to setting commitments aligned with the resolution asks. We would be happy to schedule a call in the coming weeks to discuss this more. Per SEC requirements, we are available to meet with the company via teleconference at the following times: January 9th at 3 PM ET or January 10th at 10 AM ET.

Sincerely,

Lauren Compere, Managing Director and Head of Stewardship & Engagement
[redacted]

Amy Orr, Director of US Shareholder Engagement
[redacted]

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

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

This high level of concern has driven policy responses. The Inflation Reduction Act empowers the federal government to negotiate some drug prices.[3] State measures, including drug price transparency legislation and Medicaid purchasing programs, have also been adopted.[4] The House Committee on Oversight and Reform (the "Committee") launched an 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" granted after the drug's primary patent, covering its main active ingredient or molecule, has been granted.[6] The U.S. Patent and Trademark Office, partly in response to a letter from six U.S. Senators requesting measures to address patent thickets,[7] recently issued a request for public comment on initiatives to "adequately protect[] innovation while not unnecessarily delaying generic and biosimilar competition."[8]

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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.
7 www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf
8 www.govinfo.gov/content/pkg/FR-2022-10-04/pdf/2022-21481.pdf

Regeneron markets Eylea, which treats eye disorders. According to I-MAK, of the 135 patent applications filed on Eylea, 65% were filed after the drug was approved by the Food and Drug Administration.[9] According to I-MAK, such post-approval filings "indicat[e] an attempt to prolong existing exclusivity."[10]

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

[9] www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 6.
[10] www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 6.

Boston Common
Asset Management

200 State Street, 7th Floor | Boston, MA 02109

February 17, 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 Regeneron Pharmaceuticals Inc. to omit proposal submitted by Boston Common Asset Management and co-filers

Ladies and Gentlemen,

In a letter to the Division dated January 24, 2023 (the "No-Action Request"), Regeneron 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. Regeneron argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), on the ground that the Proposal deals with Regeneron's ordinary business operations. As discussed more fully below, Regeneron has not met its burden of proving its entitlement to exclude the Proposal on that basis, and the Proponents respectfully request that Regeneron's request for relief be denied.

The Proposal

The Proposal states:

> RESOLVED**,** that shareholders of Regeneron Pharmaceuticals Inc. ("Regeneron") 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 Regeneron'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]

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

Ordinary Business

Regeneron 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

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1 https://www.gao.gov/prescription-drug-spending

2 https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 2 (citing Charles Roehrig and Ani Turner, Projections of the Non-Retail Prescription Drug Share of National Health Expenditures Report, Altarum, July 2022).

3 https://www.healthaffairs.org/do/10.1377/forefront.20181106.217086/full/

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

5 https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs--What-Does-It-Mean-.pdf

6 A tertiary patent applies to a drug-device combination, such as the EpiPen. https://blog.petrieflom.law.harvard.edu/2018/04/30/tertiary-patents-an-emerging-phenomenon/

7 See https://sgp.fas.org/crs/misc/R46221.pdf, at 1-2. Secondary patents may address matters such as manufacturing methods, dosing, and methods of administering the drug. https://sgp.fas.org/crs/misc/R46221.pdf, at 9.

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

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

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

The Division generally regards a company's product offerings and choices about IP protections, without more, as ordinary business matters. However, the fact that a proposal implicates 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. For that reason, Regeneron's blanket statements that "the Staff has consistently permitted exclusion under Rule 14a-8(i)(7) of shareholder proposals relating to the products and services offered for sale by a company" and "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 shareholder oversight"[12] are simplistic and inaccurate.

Last season, the Staff considered and rejected arguments much like those Regeneron 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 Regeneron does here, JNJ argued that the proposal's subject was the distribution of the company's products, the licensing of its technologies, and/or decisions about safeguarding its IP, all of which JNJ urged were ordinary business.[13] The proponent framed the proposal's topic as "whether companies should pursue profits in a manner that degrades critical environmental and social systems, with a focus on the Company's approach to guarding intellectual property involving COVID-19 vaccine technology." The Staff declined to grant relief.

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

Although the pandemic gave additional urgency to the issue of access to vaccines and COVID-19 therapeutics, that context is not necessary to avoid exclusion because the Staff has previously found that access to medicines and drug pricing are significant policy issues, even absent a pandemic. As far back as the 1990s, the Staff has declined to allow exclusion on ordinary business grounds of proposals addressing drug pricing and access.[15] Last year's JNJ, Pfizer and Moderna determinations reinforce that a proposal will not be deemed excludable simply because it implicates products or IP, so long as the primary concern is patient access. The Proposal fits that description as well.

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[12] See No-Action Request, at 3-4.
[13] Johnson & Johnson (Feb. 8, 2022)
[14] Pfizer, Inc. (Feb. 23, 2022); Moderna, Inc. (Feb. 8, 2022).
[15] See Eli Lilly and Company (Feb. 25, 1993); Bristol-Myers Squibb Company (Feb. 21, 2000); Warner Lambert Company (Feb. 21, 2000).

In the third set of determinations, the Staff declined to allow two pharmaceutical companies to exclude proposals dealing with anticompetitive practices on ordinary business grounds. The proposals asked the companies to report to shareholders on how their boards oversee risks related to anticompetitive practices. The supporting statements discussed patent thickets as well as other practices. The companies claimed that the proposals addressed the ordinary business matters of legal compliance and/or management of IP. The proponents urged that the proposals dealt with the significant social policy issue of "the strategic, reputational, and public policy risks created by anticompetitive practices."[16] Although the proposals addressed anticompetitive practices other than patent thickets, these determinations illustrate that addressing IP does not doom a proposal.

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[17] 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,[18] the Staff did not concur with the company's claim that a proposal asking it to sell at least 10% cage-free eggs by volume was excludable because it implicated the sale of particular products, siding with the proponent's characterization of the proposal's subject as the significant policy issue of "[r]educing cruel confinement conditions for egg-laying hens" (i.e., animal cruelty).

Significant Social Policy Issue Analysis

In November 2021, the Staff shifted its approach to deciding whether a proposal's subject is a significant social policy issue. In Staff Legal Bulletin ("SLB") 14L,[19] the Staff announced that it would no longer focus on the significance of an issue to a particular company, but rather would analyze whether the proposal "raises issues with a broad societal impact, such that they transcend the ordinary business of the company." The Proponents believe that the Proposal's subject would have qualified as a significant policy issue under the previous approach, but the new focus on societal impact strengthens the case significantly. 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.[20]

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[21] ("Twelve of the drugs that Medicare spends the most on are protected by more than 600

[16] AbbVie, Inc. (Mar. 11, 2022); Pfizer, Inc. (Mar. 8, 2022).
[17] Gilead Sciences Inc. (Feb. 23, 2015).
[18] Denny's Inc. (Mar. 17, 2009)
[19] Staff Legal Bulletin 14L (Nov. 3, 2021)
[20] See, e.g., www.sec.gov/interps/legal/cfslb14a.htm.
[21] https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html

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.")
- Editorial Board, "How Big Pharma plays games with drug patents and how to combat it," USA Today, Jan. 18, 2019[22] ("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[23]
- Berkeley Lovelace Jr., "'Gaming' of U.S. patent system is keeping drug prices sky high, report says," NBCNews.com, Sept. 15, 2022[24]
- "Biden Drug Price Pressure on Patent Office Draws Skeptics," Bloomberg, Sept. 21, 2021[25] ("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[26]
- Matthew Lane, "The Key to Lowering Drug Prices is Improving Patent Quality," Techdirt, July 21, 2021[27] ("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[28] ("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').")

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[22] https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/

[23] https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/

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

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

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

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

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

- Joe Cahill, "Humira Patent Strategy Makes the Case for Reform," Crain's Chicago Business, May 20, 2019[29]
- Gunjan Sinha, "How Patent Extensions Keep Some Drug Costs High," Undark, June 16, 2021[30]
- 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[31]
- Ryan Chatelain, "House committee report blasts drug pricing strategies as 'troubling,'" NY1, Dec. 10, 2021[32]
- 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[33]
- Matthew Lane, "To rein in Big Pharma over high drug prices, start with patent reform," Roll Call, Jan. 17, 2020[34] ("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[35] ("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[36] ("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[37]
- "Congress takes aim again at pharmaceutical giant over patent-stacking for brand-name drugs," The Examiner (Washington, DC), May 20, 2021

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[29] https://www.chicagobusiness.com/joe-cahill-business/humira-patent-strategy-makes-case-reform
[30] https://undark.org/2021/06/16/how-patent-extensions-keep-some-drug-costs-high/
[31] https://www.politico.com/tipsheets/prescription-pulse/2017/07/17/fda-to-examine-anticompetitive-practices-by-drug-industry-221368
[32] https://www.ny1.com/nyc/all-boroughs/politics/2021/12/10/house-committee-report-blasts-drug-pricing-strategies-as--troubling-
[33] https://www.chicagotribune.com/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html
[34] https://www.rollcall.com/2020/01/17/to-rein-in-big-pharma-over-high-drug-prices-start-with-patent-reform/
[35] https://www.cnn.com/2019/09/12/perspectives/drug-patents-abuse/index.html
[36] https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation
[37] https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html

- Robert Pearl, "Why Patent Protection in the Drug Industry is Out of Control," Forbes, Jan. 19, 2017[38]
- Ahmed Aboulenein, "Consumer group says drugmakers abuse U.S. patent system to keep prices high," Reuters, Sept. 16, 2022[39]
- Sarah Jane Tribble, "Drugmakers Play the Patent Game to Ward Off Competitors," NBCNews.com, Oct. 2, 2018[40]

Legislators and regulators have also focused on the impact of IP protections—and secondary and tertiary patents in particular—on access. Although attention shifted to the COVID-19 pandemic in 2020, policy initiatives proliferated both before and after that year.

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.[41] 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.[42] The Second Look at Drug Patents Act would have required publication of patents filed after approval of a new drug or abbreviated new drug application by the FDA in order to facilitate validity challenges.[43] The Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019[44] 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.[45] 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

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[38] https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control/?sh=73fa684178ca

[39] https://www.reuters.com/business/healthcare-pharmaceuticals/consumer-group-says-drugmakers-abuse-us-patent-system-keep-prices-high-2022-09-16/

[40] https://www.nbcnews.com/health/health-news/drugmakers-play-patent-game-ward-competitors-n915911

[41] 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.

[42] https://www.congress.gov/bill/116th-congress/house-bill/3199/text

[43] https://www.congress.gov/bill/116th-congress/senate-bill/1617

[44] https://www.congress.gov/bill/116th-congress/house-bill/3991

[45] https://www.congress.gov/bill/117th-congress/house-bill/2873

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.[46]

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.[47]

The House Judiciary Antitrust Subcommittee held a hearing in April 2021 on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."[48] Experts on drug companies' anticompetitive practices testified, including Professor Robin Feldman, who discussed the relationship between secondary patents and product-hopping.[49]

The House Committee on Energy and Commerce's Subcommittee on Health held a hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition" in March 2019.[50] 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.[51]

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

[47] https://www.judiciary.senate.gov/imo/media/doc/Testimony%20-%20July%2013%202021_Rachel_Moodie.pdf

[48] https://oversight.house.gov/news/press-releases/house-judiciary-antitrust-subcommittee-to-hold-hearing-on-anticompetitive

[49] https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-FeldmanR-20210429.pdf, at 3-4

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

[51] 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.").

The House Oversight Committee initiated a sweeping investigation in 2019 into "pricing and business practices in the pharmaceutical industry."[52] 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."[53] 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."[54] 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."[55] 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."[56]

The House Ways and Means Committee's Subcommittee on Health held a hearing in March 2019 on the cost of drugs to the Medicare program. In his opening statement, Subcommittee Chairman Doggett noted that "[o]ver the last decade, 74 percent of all pharmaceutical patent applications were not for new innovative cures, but were for modifying existing drugs, which often took the form of what's referred to as evergreening, simply to protect monopoly pricing, not to provide new drugs."[57] 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."[58] Another witness identified patent thickets as key to high drug prices.[59]

The Senate Finance Committee held a hearing on "Drug Pricing in America: A Prescription for Change, Part I"[60] in January 2019, at which the Committee heard testimony on drug makers'

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[52] 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.

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

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

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

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

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

[58] https://www.youtube.com/watch?v=aA3cDgRp37s (at 10:09).

[59] https://www.youtube.com/watch?v=aA3cDgRp37s (at 20:22).

[60] https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i

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.[61]

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.[62] In addition to the general problem posed by patent thickets, Kesselheim explained how secondary patents facilitate product hopping.[63]

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."[64] The E.O. also directed the Secretary of Health and Human Services to take various steps to "promote generic drug and biosimilar competition." Pursuant to the E.O., the FDA and PTO are collaborating to implement strategies to lower drug prices.[65]

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."[66] 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

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61 https://www.finance.senate.gov/imo/media/doc/29JAN2019MILLERSTMNT.pdf

62 https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf

63 https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf, at 6-7.

64 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).

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

66 https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf

on the circumstances) inappropriately hinder generic competition."[67] 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.[68] 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."[69]

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.[70]

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."[71] 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."[72]

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 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."[73]

The existence of a significant social policy issue, then, distinguishes the Proposal from those analyzed in the determinations Regeneron cites on pages 3-4 of the No-Action Request. In Wells Fargo[74] and JPMorgan Chase,[75] the proposals focused on specific products that the proponents argued were forms of predatory lending, which had previously been found to transcend ordinary business. The Staff granted relief, characterizing the proposals as relating to the ordinary business

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67 https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf
68 https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12641.pdf
69 https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-MeierM-20170727.pdf
70 https://www.ag.state.mn.us/Office/Initiatives/PharmaceuticalDrugPrices/Taskforce.asp
71 https://about.kaiserpermanente.org/news/want-to-lower-drug-prices-reform-the-us-patent-system
72 https://www.ahip.org/news/press-releases/new-research-big-pharma-companies-earn-big-revenues-through-patent-gaming
73 https://www.macfound.org/fellows/class-of-2022/priti-krishtel#searchresults
74 Wells Fargo & Co. (Jan. 28, 2013, *recon. denied* Mar. 4, 2013).
75 JPMorgan Chase & Co. (Mar. 16, 2010).

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 Regeneron relies, the proponents unsuccessfully argued that the proposals' subjects—the use of the company's products for lethal injection, the controversy over releasing the film "Song of the South" on Blu-ray, and a product environmental stewardship program--were significant social policy issues. The proponent did not even respond to the company's no-action request in IBM,[76] 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 2022 determinations dealing with IP, discussed above, have more persuasive power than IBM, given how long ago that determination was issued.

The Proposal is not excludable because it focuses on ordinary business matters and "touch[es] upon" a significant policy issue, as Regeneron claims.[77] Regeneron gets it exactly backward: If a proposal's subject qualifies as a significant social policy issue, the fact that it involves ordinary business matters is irrelevant. The Commission articulated this clearly in its 1998 release:

> 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. Examples include the management of the workforce, such as the hiring, promotion, and termination of employees, decisions on production quality and quantity, and the retention of suppliers. <u>However, proposals relating to such matters but focusing on sufficiently significant social policy issues (e.g., significant discrimination matters) generally would not be considered to be excludable</u>, because the proposals would transcend the day-to-day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote.[78] (emphasis added)

Access to Regeneron'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 Regeneron cites in support of this argument involved proposals that addressed a significant policy issue but then grafted on an additional element that implicated day-to-day management. In PetSmart,[79] the proposal asked the company to require its suppliers to attest that they had not violated certain laws related to animal cruelty. PetSmart urged that the laws in question governed not only animal cruelty, a significant policy issue, but also mundane matters such as record keeping. The Staff concurred and granted relief, citing the breadth of the laws referenced in the proposal. Importantly, however, the Staff did not concur with PetSmart's more sweeping argument, which is similar to the one Regeneron makes here: that even if animal cruelty is a significant social policy issue, the selection of suppliers is an ordinary business matter, essentially negating significant social policy issue status.

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[76] International Business Machines Corp. (Jan. 22, 2009).
[77] No-Action Request, at 5.
[78] Exchange Act Release No. 40018 (May 21, 1998).
[79] PetSmart, Inc. (Mar. 24, 2011).

The proposal in CIGNA[80] 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." And Capital One[81] successfully argued that a proposal went beyond addressing the arguably significant policy issue of outsourcing to include several ordinary business matters such as "estimated or anticipated cost savings associated with job elimination actions taken by the company over the past five years."

In the 2021 proxy season, JNJ[82] unsuccessfully advanced an argument similar to the one Regeneron 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 Regeneron. 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."[83] 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.

Regeneron argues that the Proposal would micromanage by "dictating the establishment of a particular intellectual property analysis that inappropriately limits discretion of the board and management."[84] But that overstates the Proposal's ambitions. The Proposal simply suggests a factor to be considered when making decisions regarding seeking secondary and tertiary patents and does not specify any details around implementation. It does not prescribe the weight to be accorded to access considerations, dictate how they should be balanced against other factors, or 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.

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80 CIGNA Corporation (Feb. 23, 2015).
81 Capital One Financial Corp. (Feb. 3, 2005).
82 Johnson & Johnson (Feb. 12, 2021).
83 Staff Legal Bulletin 14L (Nov. 3, 2021).
84 No-Action Request, at 6-7.

Regeneron also urges that "shareholders, as a group, are not in a position to make an informed judgment" about the Proposal's subject.[85] But Regeneron's 10-K includes many discussions of patents, presumably because the Company believes this is valuable information for shareholders. The 10-K includes a section in the description of the Company's business entitled "Patents, Trademarks, and Trade Secrets," which discusses the importance of patents and uncertainties associated with their validity and enforceability; it even mentions secondary patents (though without using that term), stating, "We continue to pursue additional patents and patent term extensions in the United States and other jurisdictions covering various aspects of our products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table below."[86] A list of patents and their expiration dates appears on pages 24-27. The 10-K identifies the loss of patent protection as a material risk, stating "If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed."[87]

Given the centrality of patent protection to Regeneron's business model, it is a stretch to suggest that the Proposal is too difficult for shareholders to understand. The fact that one of Regeneron's key disclosure documents treats the subject in detail suggests that the Company 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 6 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, unlike the Proposal. It is important to note that all but two of these determinations were issued prior to the issuance of SLB 14L, which limits their applicability. The proposal submitted to Coca-Cola[88] 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[89] and Walgreens[90] proposals sought to require shareholder approval of all share repurchase programs. In RH,[91] the proposal requested a policy prohibiting the sale of down products. The Deere[92] 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[93] proposal tried to dictate the placement of a specific showerhead in search results as well as the information provided about it.

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85 No-Action Request, at 7.
86 Regeneron Pharmaceuticals Inc., Filing on Form 10-K filed on Feb. 6, 2023, at 24 (hereinafter, "2023 10-K").
87 2023 10-K, at 54.
88 The Coca-Cola Company (Feb. 16, 2022).
89 Royal Caribbean Cruises Ltd. (Mar. 14, 2019).
90 Walgreens Boots Alliance, Inc. (Young) (Nov. 20, 2018).
91 RH (May 11, 2018).
92 Deere & Company (Jan. 3, 2022).
93 Amazon.com, Inc. (Jan. 18, 2018).

And the proposal submitted to JPMorgan Chase[94] sought to prohibit equity-based compensation awards from vesting if an executive resigned to enter government service.

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

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For the reasons set forth above, Regeneron has not satisfied its burden of showing that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7). The Proponents thus respectfully request that Regeneron'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 us via email (contact information below).

Sincerely,

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[94] JPMorgan Chase & Co. (Mar. 22, 2019).