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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<sup>1</sup>

#### 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

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)



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 cofounder 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 9<sup>th</sup> at 3 PM ET or January 10<sup>th</sup> at 10 AM ET.

Sincerely,

Lauren Compere, Managing Director and Head of Stewardship & Engagement

Amy Orr, Director of US Shareholder Engagement

**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. The Kaiser Family Foundation has "consistently found prescription drug costs to be an important health policy area of public interest and public concern."

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

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. The U.S. Patent and Trademark Office, partly in response to a letter from six U.S. Senators requesting measures to address patent thickets, recently issued a request for public comment on initiatives to "adequately protect[] innovation while not unnecessarily delaying generic and biosimilar competition."

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

<sup>&</sup>lt;sup>2</sup> www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

<sup>&</sup>lt;sup>3</sup> www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

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

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

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

<sup>&</sup>lt;sup>7</sup> www.leahy.senate.gov/imo/media/doc/20220608%20Letter%20to%20PTO%20on%20repetitive%20patents.pdf

<sup>8</sup> 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. According to I-MAK, such post-approval filings "indicat[e] an attempt to prolong existing exclusivity." Prolong existing exclusivity.

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.

 $<sup>^9\</sup> www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 6.$ 

<sup>&</sup>lt;sup>10</sup> www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf, at 6.