**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**

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| CALVIN T. NAKATA, Individually and on Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>v.<br><br>ABBVIE INC., RICHARD A. GONZALEZ, ROBERT A. MICHAEL, JEFFREY R. STEWART, and MICHAEL E. SEVERINO,<br><br>Defendants. | Case No. 1:22-cv-01773<br><br>**JURY TRIAL DEMANDED** |

# CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Plaintiff Calvin T. Nakata ("Plaintiff"), by and through his counsel, alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, including the investigation of Plaintiff's counsel, which included, among other things, a review of Defendants' (defined below) United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by AbbVie Inc. ("AbbVie" or the "Company"), analyst reports and advisories about the Company, media reports concerning the Company, judicial filings and opinions, and other publicly available information. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## I. NATURE OF THE ACTION AND OVERVIEW

1. This is a securities class action on behalf of a class of all persons and entities who purchased or otherwise acquired AbbVie securities between April 30, 2021, through August 31,

2021, inclusive (the "Class Period"), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

2. AbbVie is one of the world's largest pharmaceutical companies. Its biggest drug, Humira—an anti-inflammatory drug used to treat illnesses such as Crohn's disease, ulcerative colitis, rheumatoid arthritis ("RA"), and more—was, in 2021 (aside from COVID-19 vaccines), the world's best-selling prescription drug, with net revenue of more than $20 billion in 2021. Humira accounts for more than a third of AbbVie's net revenue.

3. While patents have protected Humira's blockbuster profits for years, biosimilar drugs will be permitted to enter the market and compete directly with Humira beginning in 2023. As a result, Humira's sales are widely expected to decline significantly over the next several years—thereby undermining AbbVie's revenue and earnings.

4. Accordingly, AbbVie's future revenue and earnings depend in large part on the Company's ability to develop new sources of revenue to offset reduced Humira sales. Rinvoq—an anti-inflammatory drug manufactured by AbbVie and used to treat RA and other diseases by inhibiting Janus kinase ("JAK") enzymes—was touted as one such drug.

5. Rinvoq was initially approved in the United States to treat only moderate to severe RA. However, AbbVie was actively pursuing additional treatment indications and, in 2020, asked the U.S. Food and Drug Administration (the "FDA") to approve Rinvoq for the treatment of several other diseases, including psoriatic arthritis, ankylosing spondylitis, and atopic dermatitis.

6. As is relevant here, Rinvoq uses the same mechanism of action as other JAK inhibitor drugs, including Xeljanz and Xeljanz XR (collectively, "Xeljanz"), manufactured by Pfizer Inc. ("Pfizer"), and Olumiant, manufactured by Eli Lilly and Company ("Eli Lilly"). When the FDA approved Xeljanz in 2012 for the treatment of RA, it required an additional safety trial to

evaluate Xeljanz's risk of certain serious adverse effects compared with non-JAK inhibitor anti-inflammatory drugs. Beginning in February 2019, the FDA repeatedly warned the public that the Xeljanz safety trial indicated that certain dosages of Xeljanz were associated with elevated risks of serious heart-related issues, cancer, and other adverse events.

7. Notwithstanding the pharmacological similarities between Rinvoq and Xeljanz, during the Class Period, Defendants conditioned investors to view Rinvoq as far safer than Xeljanz while downplaying the likelihood that the FDA would take regulatory action against Rinvoq as a result of Xeljanz's problematic safety profile.

8. However, on June 25, 2021, AbbVie revealed that the FDA would not complete its review of several of the expanded treatment indications for Rinvoq by the end of June, as previously announced, due to its ongoing evaluation of safety concerns associated with Xeljanz. On this news, the price of AbbVie common stock declined $1.76 per share, or approximately 1.5%, from a close of $114.74 per share on June 24, 2021, to close at $112.98 per share on June 25, 2021.

9. Then, on September 1, 2021, the FDA announced that final results from the Xeljanz safety trial established an increased risk of serious adverse events, even with low doses of Xeljanz. As a result, the FDA determined that it would require new and updated warnings for Xeljanz ***and Rinvoq*** because Rinvoq "share[s] similar mechanisms of action with Xeljanz" and "may have similar risks as seen in the Xeljanz safety trial." The FDA also indicated that it would further limit approved indications for Rinvoq as a result of these safety concerns. On this news, the price of AbbVie common stock declined $8.51 per share, or more than 7%, from a close of $120.78 per share on August 31, 2021, to close at $112.27 per share on September 1, 2021.

10. After the Class Period, on December 3, 2021, AbbVie announced that the FDA had updated Rinvoq's label in accordance with its September 1, 2021 decision. Specifically, AbbVie

stated that "the U.S. label for RINVOQ will now include additional information about the risks of malignancy and thrombosis, and the addition of mortality and MACE (defined as cardiovascular death, myocardial infarction and stroke) risks within the Boxed Warnings and Warnings and Precautions sections." Additionally, the label would also now state that Rinvoq "is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more" non-JAK inhibitor drugs—meaning that Rinvoq can be marketed only as an alternative option after other anti-inflammatory drugs have failed.

11. On January 11, 2022, Defendants admitted that these changes to Rinvoq's label would negatively impact sales, forcing the Company to reduce its long-term guidance for Rinvoq's sales in 2025, from greater than $8 billion, to greater than $7.5 billion.

12. This Complaint alleges that, throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts, about the Company's business and operations. Specifically, Defendants misrepresented and/or failed to disclose that: (1) safety concerns about Xeljanz extended to Rinvoq and other JAK inhibitors; (2) as a result, it was likely that the FDA would require additional safety warnings for Rinvoq and would delay the approval of additional treatment indications for Rinvoq; and (3) therefore, Defendants' statements about the Company's business, operations, and prospects lacked a reasonable basis.

13. As a result of Defendants' wrongful acts and omissions, and the significant decline in the market value of the Company's securities when the truth was revealed, Plaintiff and other members of the Class have suffered significant damages.

## II. JURISDICTION AND VENUE

14. Plaintiff's claims arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

15. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

16. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), because AbbVie is headquartered in this District and many of the acts and conduct that constitute the violations of law complained of herein, including the dissemination to the public of materially false and misleading information, occurred in this District.

17. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mails, interstate telephone communications, and the facilities of the national securities markets.

## III. PARTIES

18. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased AbbVie securities at artificially inflated prices during the Class Period and has been damaged thereby.

19. Defendant AbbVie is a Delaware corporation with principal executive offices at 1 North Waukegan Road, North Chicago, Illinois 60064.

20. Defendant Richard A. Gonzalez ("Gonzalez") is and was the Company's Chairman of the Board and Chief Executive Officer at all relevant times.

21. Defendant Robert A. Michael ("Michael") is and was the Company's Chief Financial Officer at all relevant times.

22. Defendant Jeffrey R. Stewart ("Stewart") is and was the Company's Chief Commercial Officer at all relevant times.

23. Defendant Michael E. Severino ("Severino") is and was the Company's Vice Chairman and President at all relevant times.

24. Defendants Gonzalez, Michael, Stewart, and Severino are collectively referred to herein as the "Individual Defendants."

25. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of AbbVie's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, i.e., the market. Each Individual Defendant was provided with copies of the Company's reports alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and/or were being concealed from, the public, and that the positive representations that were being made were then materially false and/or misleading.

26. AbbVie and the Individual Defendants are collectively referred to herein as "Defendants."

## IV. SUBSTANTIVE ALLEGATIONS

### A. Background

27. AbbVie, a Delaware corporation with principal executive offices in North Chicago, Illinois, is one of the world's largest pharmaceutical companies. Its biggest drug, Humira—an

anti-inflammatory drug used to treat illnesses such as Crohn's disease, ulcerative colitis, RA, and more—was, in 2021 (aside from COVID-19 vaccines), the world's best-selling prescription drug, with net revenues of more than $20 billion in 2021. In 2021, sales of Humira accounted for approximately 37% of AbbVie's total net revenue—with AbbVie's next-best-selling drug, Imbruvica, accounting for less than 10% of AbbVie's net revenue.

28. While AbbVie has protected Humira's blockbuster profits for years with a "patent thicket" of more than 100 patents, certain biosimilar drugs—that is, direct competitors to Humira—will be permitted to enter the market beginning in 2023 under agreements settling patent litigation between AbbVie and other pharmaceutical companies.[1] Because profits for brand name drugs (like Humira) typically plummet when biosimilar or generic versions enter the market, AbbVie's revenue and earnings are expected to decline significantly when Humira loses complete patent protection. Indeed, during an earnings call on February 2, 2022, Defendant Gonzalez warned that the Company expected to see "45% erosion, plus or minus 10%," in Humira sales following the introduction of biosimilar competitors in 2023. As such, industry analysts and experts have reported that AbbVie is looking to its other drugs—including Rinvoq, another type of anti-inflammatory drug—to make up for declining Humira sales.[2]

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[1] *See, e.g.*, Zachary Brennan, *AbbVie settles one of its final Humira biosimilar suits for another mid-2023 delayed entry*, ENDPOINTS NEWS (Mar. 9, 2022), https://endpts.com/abbvie-settles-one-of-its-final-humira-biosimilar-suits-for-another-mid-2023-delayed-entry/ (noting that "as many as 10 biosimilars" may launch in 2023 pursuant to settlement agreements with AbbVie).

[2] *See, e.g.*, Noah Higgins-Dunn, *AbbVie's Rinvoq marches toward blockbuster ulcerative colitis nod even as JAK delays drag on*, FIERCE PHARMA (June 29, 2021), https://www.fiercepharma.com/pharma/abbvie-s-rinvoq-continues-march-toward-ulcerative-colitis-nod-even-as-fda-jak-delays-loom ("AbbVie has pegged much of its post-Humira hopes on its next-gen immunology med Rinvoq."); Michael Gibney, *AbbVie nurtures deep drug pipeline to replace heavy US Humira sales loss in 2023*, S&P GLOBAL MARKET INTELLIGENCE (Feb. 2, 2022), https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/abbvie-nurtures-deep-drug-pipeline-to-replace-heavy-us-humira-sales-loss-in-2023-68707010 ("To fill

29. However, Rinvoq currently accounts for only a small portion of AbbVie's revenues—approximately $1.7 billion in 2021, or just under 3% of AbbVie's total net revenue. Notably, Rinvoq was initially approved in the United States to treat only moderate to severe RA, and its revenues were expected to increase substantially if the FDA approved Rinvoq for the treatment of additional diseases. The FDA's approval of additional treatment indications for Rinvoq was and is therefore critical to the Company's ability to offset lost Humira sales. In 2020, prior to the Class Period, AbbVie submitted a series of supplemental New Drug Applications seeking the FDA's approval of Rinvoq for the treatment of psoriatic arthritis, ankylosing spondylitis, and atopic dermatitis (collectively, the "sNDAs").

30. As is relevant here, Rinvoq treats disease by inhibiting JAK enzymes. Rinvoq uses the same mechanism of action as several other JAK inhibitor drugs, including Pfizer's Xeljanz and Eli Lilly's Olumiant.

31. When the FDA approved Xeljanz for the treatment of RA in 2012, it required Pfizer to conduct an additional safety trial (the "ORAL Surveillance Trial") to evaluate Xeljanz's risk of serious heart-related events and cancer when compared with other anti-inflammatory drugs that were not JAK inhibitors. In February 2019, the FDA alerted the public that, according to interim data from the ongoing ORAL Surveillance Trial, RA patients taking 10 mg twice daily doses of Xeljanz were subject to increased risks of blood clots in the lungs, and of death, compared to patients treated with smaller doses of Xeljanz or with a non-JAK inhibitor drug. Several months later, in July 2019, the FDA further warned the public that ulcerative colitis patients taking 10 mg

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[Humira's] void in the immunology business, AbbVie is looking to its newer drugs with different modalities to Humira's TNF blocking agent[, including] the JAK inhibitor Rinvoq.").

twice daily doses of Xeljanz were also subject to increased risks of blood clots in the lungs and of death.

32. Then, in February 2021, the FDA issued an alert warning that preliminary results from the now-complete ORAL Surveillance Trial "show an increased risk of serious heart-related problems and cancer with [Xeljanz] compared to another type of medicine called tumor necrosis factor (TNF) inhibitors."

**B. Defendants' False and Misleading Statements**

33. The Class Period begins on April 30, 2021, to coincide with AbbVie's announcement of its first quarter 2021 financial results. During an earnings conference call with analysts that same day, an analyst from BMO Capital Markets asked whether physicians were "switching patients from Xeljanz to Rinvoq in RA if there's a perceived safety benefit with Rinvoq as a more selective JAK." In response, Defendant Stewart assured the market that "we clearly see that [the risks being studied in the ORAL Surveillance Trial are] ***perceived as a Xeljanz issue***."[3] Stewart further explained that, as a result, "you may see people take their foot off the gas on" prescribing new patients to Xeljanz, compared to other JAK inhibitor drugs such as Rinvoq.

34. During the April 30, 2021 earnings call, Defendant Gonzalez also explained that AbbVie expected approval of "expanded indications for Rinvoq in psoriatic arthritis, ankylosing spondylitis and atopic dermatitis" in 2021. More specifically, Defendant Severino represented that the Company "***expect[ed] approval decisions for psoriatic arthritis [and ankylosing spondylitis] in June and for atopic dermatitis in July***."

35. The following month, during the UBS Global Healthcare Virtual Conference on May 25, 2021, Defendants discussed the importance of additional approvals for Rinvoq. For

[3] All emphasis is added.

example, Stewart stated that the atopic dermatitis market is "very dynamic" and "very significant," and touted AbbVie's market prospects, highlighting that the Company anticipated "lots of dynamic growth in the market" and "very strong positioning of Rinvoq as a new agent into that space."

36. During the May 25, 2021 conference, Defendants also assured investors that the Company was confident in the safety of Rinvoq, despite the preliminary results of the ORAL Surveillance Trial. Specifically, when a UBS analyst observed that "everyone's now waiting for how the label plays out" and "whether or not there is an [FDA Advisory Committee meeting] for JAKs," and asked Defendants to "help us think through what the different scenarios might be for what the [Rinvoq] label could look like," Defendant Severino explained:

> With respect to the label, I think it's early to speculate, we don't know what Xeljanz labeling will look like and that is obviously a key component of the story. But what I would say is, ***we remain very confident in the data that we've generated for Rinvoq***. We have a very large data set, more than 10,000 patient years of follow-up. We have long-term randomized data, and we know that those randomized data, controlled data are the most impactful, with the agency when looking at safety questions like the ones that they're examining, we have 3-year data in RA. We have 1-year data in psoriatic arthritis. We have large safety databases across all of the indications that we are pursuing.
>
> ***And those data have not shown a signal with our agent, with Rinvoq, for the adverse experiences that are being evaluated with Xeljanz and with others***. Specifically, we've not seen increased rates of VTE or PE. We've not seen increased rates of cardiovascular events or MACE events, and we've not seen increased risk for malignancy. And if you look at the track record here, ***we've been very successful in getting our data into the label so they're well understood by prescribing physicians***.
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> And if [one] looks at the RA launch, ***we had our data in the label for RA, both our efficacy and our safety data. I think they well characterize the benefit risk of the molecule in that launch.*** Performed very well. In fact, it exceeded our expectations, ***so we feel good about the opportunities that are in front of us for psoriatic arthritis, for atopic dermatitis and ankylosing spondylitis***, which are the indications that are under review. And of course, we

> have more indications that are still in Phase III and we feel confident in those as well.

37. Several days later, at the Sanford C. Bernstein Strategic Decisions Conference (Virtual) on June 2, 2021, Defendants were asked again whether physicians were "moving towards Rinvoq away from Xeljanz as a result of the heightened safety concern around Xeljanz." In response, Defendant Severino assured analysts and investors that "the Xeljanz issue seems to be viewed by the prescribing community as ***specific to Xeljanz***," and that "you see a change in the Xeljanz performance, but Rinvoq's performance has continued." Additionally, Severino engaged in an extended discussion with an analyst regarding Rinvoq's sNDA for atopic dermatitis, and assured the market that the Company was on track to achieve that approval in July 2021:

> [ANALYST:] Can you, a, remind us sort of the timeline for you guys to be able to comment? And two, there has been a discussion about potential AdCom for all the JAK1s before a decision is—will take place. You and some of the other companies were saying, no, our time line is driven by our—by the delays of the dates that FDA comes on [the Prescription Drug User Fee Act ("PDUFA")]. But can we be confident that, that is not going to all be delayed by the need for some sort of an AdCom on the overall safety of the class?
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> [SEVERINO:] So the PDUFA date for the atopic derm indication, which is I assume the indication that you're referring to, had been April and it moved 3 months so it's now in July. So early in the third quarter. ***And we feel like we are making appropriate progress with the—our ability to provide answers to the FDA, provide them the data that they have requested, and we feel good about the overall progress we're making there***. And we feel very confident in that overall profile and our ability to gain an approval in that indication.
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> . . .
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> If you look at the Rinvoq RA application, that was in review at the time that the baricitinib, DVT, PE issue came to light. And there was speculation at that time that there would be an AdCom before they could act on the RA application. And there was not. The FDA made their decision based on the data that we provided them and based on their own review of those data. ***And the outcome there***

> ***was a good one and the label that we achieved was a good one***. And it supported the very robust launch in RA that quite frankly exceeded our expectations and I think exceeded expectations broadly speaking.
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> [ANALYST:] Okay. So the obvious question is, are we at the—is there still a go, a back-and-forth in things like the label language? Is the overall review still progressing with the exception of that question of the safety profile of the class? Or is this kind of done and that's the last gating factor? Or is everything delayed and will we start somewhere in June? Can I—can you give us a little bit more color on this?
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> [SEVERINO:] I would say that the review of the file is progressing in a way that's very consistent with our expectations. We—we're asked in April to supply some additional data. We supplied those data. ***We viewed the data as supportive of our overall application and very consistent with everything that we've said about product safety and efficacy. And I would say that the file is progressing as we would have expected***.
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> [ANALYST:] A kind of like label discussion at this point or close enough to closing the last gaps in what needs to get done before approval. Is that kind of like the overall picture?
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> [SEVERINO:] Yes. I mean we usually don't comment on the specifics of exact label discussions until they're finalized. But I would say we're making the progress that we would expect and we believe ***we're on track for an approval on the new PDUFA date***.

38. Similarly, during the Goldman Sachs Global Healthcare Conference (Virtual) on June 8, 2021, an analyst from Goldman Sachs observed that "the regulatory environment for the JAK class here in the U.S." is "top of mind," and asked Defendants about "potential [JAK inhibitor] class label changes the FDA might be considering," as well as "how generalizable the Xeljanz data is to other JAK" drugs, like Rinvoq. In response, Severino stated:

> Well, ***we certainly have seen differences in JAKs with respect to performance and with respect to a number of safety issues***, if you look across the class. And while people talk about the JAK class in aggregate, ***there are very significant differences in specificity for JAK type, and those can drive real differences in performance,***

> ***both from a safety and an efficacy perspective***. And we've consistently had very strong data in both perspectives.
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> Obviously, most of the attention now comes after the results of the Xeljanz Oral Surveillance study and the results that were demonstrated there on MACE and malignancy. So failing to clear their safety boundary for those 2 events in a study that was a post-marketing requirement, going way back to their original approval.
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> What I would say there is we've looked for those events very carefully within our program. We have a large database. We have more than 10,000-patient years' experience in our clinical trials database that we have examined for these events. We adjudicate these events. We have very rigorous methods to try to make sure that we are capturing all events that are occurring. And those databases have not shown a signal for increased risk. And that's true whether you look compared to baseline rates or within the controlled portions of those programs where you have long-term control data against Humira, principally, and other agents as well. We've not shown evidence of increased risk for MACE, for malignancy, for DVT and PE. ***So we feel confident in the profile that we've described***.
>
> And I think it's challenging to predict how they will come down on labeling across each member of the class. But what I would say is ***we have been successful in making sure that our data are reflected in our label, and that's been well understood by prescribing physicians***. And if you go back, as an analogy, if you will, to the RA approval, which occurred right around the time that the DVT and PE issue was the focus for baricitinib, we had data in our label that described our experience. Those data were well understood by physicians, and the uptake has been very robust in that indication. And so I think we're in a very similar position here.

39. The above statements identified in ¶¶ 33-38 were materially false and misleading, and failed to disclose material adverse facts, about the Company's business and operations. Specifically, Defendants misrepresented and/or failed to disclose that: (1) safety concerns about Xeljanz extended to Rinvoq and other JAK inhibitors; (2) as a result, it was likely that the FDA would require additional safety warnings for Rinvoq and would delay the approval of additional

treatment indications for Rinvoq; and (3) therefore, Defendants' statements about the Company's business, operations, and prospects lacked a reasonable basis.

**C. The Truth Emerges**

40. On June 25, 2021, AbbVie announced that the FDA would not complete its review of the sNDAs regarding psoriatic arthritis and ankylosing spondylitis in June, as Defendants had represented. Defendants revealed that the FDA had, in explaining the delay, "cited its ongoing review of Pfizer's post-marketing study, ORAL Surveillance."

41. On this news, the price of AbbVie common stock declined $1.76 per share, or approximately 1.5%, from a close of $114.74 per share on June 24, 2021, to close at $112.98 per share on June 25, 2021.

42. Several weeks later, on July 16, 2021, AbbVie announced that the FDA had also extended its review of the sNDA regarding atopic dermatitis, again citing the Oral Surveillance Trial.

43. Despite these developments, Defendants continued to assure investors that Rinvoq's safety data was strong. For example, during the Company's quarterly earnings call on July 30, 2021, Severino represented that—despite the FDA's delay—"[w]e remain confident in the benefit risk profile for Rinvoq across all indications." Stewart also reiterated that AbbVie's data on Rinvoq was "very significant[ly] differentiated" from the problematic data on Xeljanz. Moreover, Gonzalez touted the Company's guidance for future Rinvoq revenue, stating that the Company projected $8 billion in Rinvoq sales in 2025.

44. However, on September 1, 2021, the FDA announced that the final results of the ORAL Surveillance Trial showed "an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death" even with lower doses of Xeljanz. Accordingly, the FDA further stated that it would require "new and updated warnings" not only for Xeljanz, ***but***

***also for both Rinvoq and Olumiant***. The FDA explained that, "since they share mechanisms of action with Xeljanz, [the] FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial." Moreover, the FDA also revealed that it would further limit approved uses of Rinvoq, Xeljanz, and Olumiant, permitting these drugs to be prescribed only for "certain patients who have not responded [to] or cannot tolerate one or more TNF blockers."

45. On this news, the price of AbbVie common stock declined $8.51 per share, or more than 7%, from a close of $120.78 per share on August 31, 2021, to close at $112.27 per share on September 1, 2021.

46. As analysts and industry experts noted, the FDA's announcement affected AbbVie's prospects particularly strongly, given AbbVie's reliance on Rinvoq to provide much more substantial profits in the future. For example, *Bloomberg* noted that "AbbVie's stock was hit particularly hard [from this news] as Rinvoq is supposed to be the company's next big drug" after Humira loses its patent-protected monopoly. Similarly, analysts from SVB Leerink and Bernstein warned that the FDA's label changes—particularly the new restrictions on approved uses—would likely reduce future Rinvoq sales by billions of dollars.

47. After the Class Period, on December 3, 2021, AbbVie revealed that the FDA had updated Rinvoq's label in accordance with the FDA's September 1, 2021 announcement. Specifically, AbbVie stated that "the U.S. label for RINVOQ will now include additional information about the risks of malignancy and thrombosis, and the addition of mortality and MACE (defined as cardiovascular death, myocardial infarction and stroke) risks within the Boxed Warnings and Warnings and Precautions sections." The label would also state that Rinvoq "is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers"—meaning that

Rinvoq can be marketed only as an alternative after other anti-inflammatory drugs have already failed.

48. Defendants have admitted that these label changes will negatively impact sales of Rinvoq. For example, on January 11, 2022, the Company lowered its guidance for Rinvoq, stating that AbbVie "now expects 2025 risk-adjusted sales of greater than $7.5 billion for Rinvoq" (compared to the Company's prior guidance of greater than $8 billion). Accordingly, it is clear that the FDA's safety concerns about Rinvoq—which Defendants misleadingly downplayed during the Class Period—will have a lasting, negative effect on a critical Company revenue source.

## V. CLASS ACTION ALLEGATIONS

49. Plaintiff brings this class action under Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired AbbVie securities during the Class Period (the "Class"). Excluded from the Class are Defendants, their agents, directors and officers of AbbVie, and their families and affiliates.

50. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

51. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether Defendants violated the Exchange Act;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the prices of AbbVie securities were artificially inflated; and

f. The extent of damage sustained by members of the Class and the appropriate measure of damages.

52. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

53. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in securities class actions. Plaintiff has no interests that conflict with those of the Class.

54. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all Class members is impracticable.

## VI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

55. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's securities traded in an efficient market;

d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

e. Plaintiff and the Class purchased AbbVie securities between the time the Company and the Individual Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

56. At all relevant times, the market for the Company's securities was efficient because: (1) as a regulated issuer, the Company filed periodic public reports with the SEC; and (2) the Company regularly communicated with public investors using established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services.

## VII. NO SAFE HARBOR

57. Defendants' "Safe Harbor" warnings accompanying any forward-looking statements issued during the Class Period were ineffective to shield those statements from liability. Defendants are liable for any false and/or misleading forward-looking statements pleaded because, at the time each forward-looking statement was made, the speaker knew the forward-looking statement was false or misleading and the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that the forward-looking statement was false. None of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

## VIII. LOSS CAUSATION/ECONOMIC LOSS

58. Defendants' wrongful conduct directly and proximately caused the economic loss suffered by Plaintiff and the Class. The prices of Company securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses. As a result of their purchases of AbbVie securities during the Class Period, Plaintiff and the Class suffered economic loss, i.e., damages, under the federal securities laws.

## IX. SCIENTER ALLEGATIONS

59. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of Company securities during the Class Period.

## X. CLAIMS AGAINST DEFENDANTS

### COUNT I

**Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder Against All Defendants**

60. Plaintiff incorporates by reference the allegations in the preceding paragraphs.

61. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiff and the Class; and (2) cause Plaintiff and the Class to purchase Company securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Defendants, and each of them, took the actions set forth herein.

62. Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact and/or omitted material facts necessary to make the statements not misleading; and (3) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices thereof in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5.

63. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class suffered damages in connection with their respective purchases of the Company's securities during the Class Period.

## COUNT II

### Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

64. Plaintiff incorporates by reference the allegations in the preceding paragraphs.

65. The Individual Defendants acted as controlling persons of AbbVie within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control—and did influence and control, directly or indirectly—the decision-making of the Company, including the content and dissemination of the various false and/or misleading statements. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

66. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular accounting practices giving rise to the securities violations as alleged herein, and exercised the same.

67. As described above, the Company and the Individual Defendants each violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable under Section 20(a) of the Exchange Act. As a direct and proximate result of this wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of Company securities during the Class Period.

## XI. PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

a. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

b. Awarding compensatory damages and equitable relief in favor of Plaintiff and other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

c. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

d. Such other and further relief as the Court may deem just and proper.

## XII. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: April 6, 2022