

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

MELVIN GROSS,)
)
)
 Plaintiff,)
)
 v.) C.A. No. 2020-0096-PAF
)
 BIOGEN INC.,)
 a Delaware corporation,)
)
 Defendant.)
)

MEMORANDUM OPINION

Date Submitted: January 11, 2021
Date Decided: April 14, 2021

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FIORAVANTI, Vice Chancellor

I. INTRODUCTION

Plaintiff Melvin Gross seeks an order to compel inspection of books and records of Biogen Inc. (“Biogen” or the “Company”) pursuant to Section 220 of the Delaware General Corporation Law (“DGCL”). Plaintiff aims to investigate, among other things, potential corporate wrongdoing and mismanagement arising from a federal investigation and a former employee’s allegations in a wrongful termination suit. In this post-trial Memorandum Opinion, I conclude that Plaintiff is entitled to inspect some, but not all, of the categories of books and records sought in his demand for inspection.

II. FACTUAL BACKGROUND

The following facts were either stipulated or proven at trial by a preponderance of the evidence.

A. The Company

Biogen is a Delaware corporation with its headquarters in Cambridge, Massachusetts.¹ Biogen is a global pharmaceutical company that develops drug therapies to treat neurological and neurodegenerative diseases.² Among the

¹ Pre-Trial Stipulation and Order (“PTO”) ¶ 1.

² *Id.* ¶ 2.

Company’s drug therapies are Tysabri and Zinbryta, both of which are used to treat multiple sclerosis (MS).³

Biogen operates in a heavily regulated industry, and its governance documents recognize that risk oversight is paramount. Under Biogen’s Governance Principles, its board of directors (the “Board”) is responsible for, among other things, “[r]eviewing, approving and monitoring . . . material government and other investigations” and “[e]nsuring processes are in place for maintaining . . . compliance with law”⁴ The Board has a standing Audit Committee, which oversees the Company’s compliance program with a focus on “[f]inancial, accounting, disclosure, corporate compliance, distributors, insurance, capital, credit, anti-bribery and anti-corruption matters and other risks reviewed in its oversight of the internal audit and corporate compliance functions.”⁵ The Board also oversees Biogen’s compliance program, which is led by a Corporate Compliance Committee of senior officers.⁶ The compliance program enumerates policies and practices that “prohibit illegal remuneration in violation of federal and state anti-kickback statutes” and that provide for “appropriate . . . making of grants and charitable contributions so that such funds are not conditioned, express or implied, on any agreement to

³ JX 16; Pl.’s Pre-Trial Br. 8.

⁴ JX 24 at 1.

⁵ JX 42 at 41.

⁶ JX 58 at 9.

prescribe, purchase, recommend, influence or provide favorable formulary status for any Biogen product.”⁷

Biogen acknowledges that sales of its products “depend, to a significant extent, on the availability of and extent of adequate coverage, pricing and reimbursement from government health administration authorities, private health insurers and other organizations.”⁸ For this reason, Biogen’s sales partly rely on certain charities that provide financial assistance to Medicare patients. These charities “operate[] funds that receive payments from pharmaceutical manufacturers and others, and that then use those payments, less administrative fees that [the charity] charges, to cover the drug co-pay obligations of patients, including Medicare patients.”⁹ Those practices, however, are subject to state and federal laws pertaining to health care fraud and abuse. Among those laws is the federal Anti-Kickback Statute, which generally prohibits a prescription drug manufacturer from directly or indirectly receiving or paying any remuneration to generate business, including the purchase or prescription of a particular drug.¹⁰ A violation of the Anti-

⁷ JX 57 at 2.

⁸ JX 13 at 49.

⁹ JX 22 at Recital B.

¹⁰ 42 U.S.C. § 1320a-7b(b)(2) (“Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

Kickback Statute constitutes a fraudulent claim for purposes of the federal False Claims Act.¹¹

B. Biogen Is Subpoenaed in Federal and State Investigations

On April 21, 2016, Biogen disclosed that it had received subpoenas from state and federal authorities that were investigating Biogen’s “sales and promotional practices.”¹² In the same disclosure, Biogen revealed that it had also received a document subpoena on March 4, 2016 as part of a federal investigation (the “Investigation”) into Biogen’s “relationship with non-profit organizations that provide assistance to patients taking drugs sold by Biogen.”¹³ Biogen’s disclosure did not identify which agencies had issued the subpoenas. On May 27, 2016, Bloomberg reported that Biogen was among three pharmaceutical companies that had recently disclosed having received federal subpoenas for documents concerning their relationships with charities that help patients to afford their products.¹⁴ The

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.”).

¹¹ *Id.* § 1320a-7b(g) (“[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31 [the False Claims Act].”).

¹² JX 2 at 31.

¹³ *Id.*

¹⁴ See JX 23 (citing Ben Elgin & Robert Langreth, *Gilead Subpoenaed as Feds Probe Drugmaker-Charity Connections*, Bloomberg (May 27, 2016, 5:00 AM EDT),

article reported that the other two companies—Gilead Sciences, Inc. (“Gilead”) and Jazz Pharmaceuticals plc (“Jazz”)—disclosed that their subpoenas were issued by the United States Attorney’s Office for the District of Massachusetts, which operates a health-care fraud unit.¹⁵

Following its initial disclosure about the subpoenas in 2016, Biogen regularly reported in filings with the U.S. Securities and Exchange Commission (the “SEC”) that it had received those subpoenas.¹⁶ In its Form 10-Q for the second quarter of 2020, Biogen disclosed:

We have learned that state and U.S. governmental authorities are investigating our sales and promotional practices and have received related subpoenas. We are cooperating with the investigation.

We have received subpoenas and other requests from the U.S. government for documents and information relating to our relationship with non-profit organizations that assist patients taking drugs sold by Biogen and the government has challenged some of our contributions to these organizations. We have reached an agreement in principle with the government to resolve *this* matter.¹⁷

<https://www.bloomberg.com/news/articles/2016-05-27/gilead-subpoenaed-as-feds-probe-drugmaker-charity-connections>). The trial record reflects a May 31, 2016 version of the article. JX 46.

¹⁵ *Id.*

¹⁶ *See, e.g.*, JX 13 at 47 (Form 10-Q dated July 23, 2019); JX 14 at 47–48 (Form 10-Q dated October 22, 2019); JX 43 at 40 (Form 10-Q dated April 23, 2020).

¹⁷ JX 56 at 44 (emphasis added).

That same Form 10-Q also disclosed that Biogen had “reached an agreement in principle with the government to resolve the matter.”¹⁸

C. The TAF Settlement

On November 20, 2019, the U.S. Attorney for the District of Massachusetts announced a \$4 million settlement with The Assistance Fund (“TAF”), a charity that provided financial assistance to Medicare patients.¹⁹ The settlement resolved government claims that TAF violated the False Claims Act by enabling certain pharmaceutical companies, including Biogen, to pay kickbacks to Medicare patients taking the companies’ drugs (the “TAF Settlement”).²⁰ In the corresponding Settlement Agreement, the federal government made the following accusations:

Biogen made payments to TAF’s MS fund on May 24 and July 17, 2012, as part of a coordinated effort—which in an email to a Biogen vice president, TAF’s co-founder termed the TYS[abri] project”—by TAF and Biogen to use Biogen’s money to cover Medicare co-pays for Tysabri patients. TAF knew that, when the fund opened after each of these two Biogen payments, [a vendor] immediately would send a “batch file” of Medicare co-pay assistance applications for Tysabri patients. As a result, when TAF’s MS fund opened after Biogen’s payments on May 24 and July 17, 2012, Tysabri patients received a disproportionate share of the grants that the fund provided. Subsequently, TAF reported to Biogen, both directly and through [the vendor], TAF’s success in directing Biogen’s funding to Tysabri patients.²¹

¹⁸ *Id.*

¹⁹ PTO ¶ 6.

²⁰ *Id.*

²¹ JX 22 at 3–4 (first alteration in original).

Reuters published a news article about the TAF Settlement on the same day.²² Reuters reported that TAF allegedly engaged in improper practices from 2011 to 2014 and that TAF did not admit wrongdoing as part of the settlement.

D. The DOJ Settlement

In supplemental post-trial briefing, Biogen informed the court that it had executed a settlement agreement with the federal government on December 17, 2020, “to resolve the DOJ’s investigation.”²³ Biogen’s supplemental brief contains a hyperlink to a settlement agreement between Biogen, the DOJ on behalf of the Inspector General of the U.S. Department of Health and Human Services, and Paul Nee, the relator in a federal *qui tam* action (the “DOJ Settlement”). The DOJ Settlement agreement arose from a federal *qui tam* action filed in the United States District Court for the District of Massachusetts.²⁴ That action alleged that Biogen’s payment of co-pays through two charitable assistance programs were kickbacks, and “as a result, Biogen caused the submission of false or fraudulent claims to Medicare for [two of its drugs] associated with these payments.”²⁵ The recitals in the DOJ

²² JX 20.

²³ Def.’s Supp. Post-Trial Br. 8 n.22.

²⁴ Settlement Agreement, available at <http://www.justice.gov/usao-ma/press-release/file/1346601/download>. The settlement agreement relates to conduct from the period January 1, 2011 through December 31, 2013. *Id.* ¶ E.

²⁵ *Id.*

Settlement agreement include some of the same government accusations reflected in the TAF Settlement agreement.²⁶

In its supplemental post-trial brief, Biogen touts that the DOJ Settlement “does not require Biogen to implement any changes to its compliance programs or internal controls.”²⁷ Biogen conveniently avoids mention of the fact that the DOJ Settlement agreement required Biogen to pay \$22 million in exchange for releases from certain civil and administrative claims, and does not release claims for, *inter alia*, criminal liability or claims arising under the Internal Revenue Code.²⁸ Among the signatories to the DOJ Settlement agreement is an Assistant United States Attorney from the District of Massachusetts.

As of the time of trial, the Company was still cooperating with the other state and federal investigations into Biogen’s “sales and promotional practices.”²⁹ Biogen’s post-trial submissions provided no further update as to those matters.

²⁶ *See id.* (“At Biogen’s direction [a vendor] then sent TAF ‘batch files’ of applications for Medicare-eligible Tysabri patients, and TAF (after receiving Biogen’s payment) subsequently approved most or all of those applications and covered those patients’ Medicare co-pays for Tysabri. Medicare subsequently paid these patients’ claims for Tysabri.”).

²⁷ Def.’s Supp. Post-Trial Br. 8 n.22.

²⁸ Settlement Agreement ¶¶ 1, 3, 6.

²⁹ JX 56 at 44.

E. The Employment Verdict

On July 13, 2018, a former Biogen employee sued the Company, claiming that she had been terminated in retaliation for raising concerns about discrimination and about improper off-label marketing of a Biogen drug.³⁰ The former employee claimed that “she was pressured to ensure a multiple sclerosis drug, Zinbryta, was prescribed by a hematologist to a patient with aplastic anemia, which was not an FDA-approved use,” and that Biogen retaliated against her after she filed a related ethics complaint.³¹ A federal jury in Washington found in favor of the plaintiff on her federal Title VII sex discrimination claim, her federal Title VII retaliation claim, her federal False Claims Act retaliation claim, and various state law claims (the “Federal Jury Verdict”).³² The jury awarded the former employee almost \$6 million, which was subsequently reduced by about \$1.7 million.³³

³⁰ PTO ¶ 5. Off-label marketing is an unlawful act that is distinct from paying kickbacks or engaging in Medicare fraud. “In the United States, a physician may prescribe an approved pharmaceutical product for any use, including uses not approved by the FDA. Prescribing a pharmaceutical product for an FDA-approved use is referred to as ‘on-label’ use; prescribing the same product for an unapproved use is referred to as ‘off-label’ use. . . . It is illegal, however, for a manufacturer to market a drug for off-label use. Under [federal statutes and regulations], drug manufacturers cannot market or promote drugs for uses that the FDA has not approved.” *Louisiana Mun. Police Emps.’ Ret. Sys. v. Pyott*, 46 A.3d 313, 318 (Del. Ch. 2012) (citing 21 U.S.C. § 331(a), (d); 42 U.S.C. § 262(a)(1), (b); 21 C.F.R. § 601.12), *rev’d on other grounds*, 74 A.3d 612 (Del. 2013).

³¹ JX 16.

³² PTO ¶ 5.

³³ *Id.*

F. Plaintiff's Demands

Plaintiff is a current stockholder of Biogen and was a stockholder when he made the operative demand.³⁴ He first acquired Biogen stock in February 2011.³⁵ Sometime prior to October 2016, Plaintiff came across a news article that mentioned, as Plaintiff described at his deposition, “some Medicare something about Biogen.”³⁶ Plaintiff mentioned this article to a lawyer with whom he was acquainted, who referred Plaintiff to Pomerantz LLP, Plaintiff’s current counsel.³⁷

On October 11, 2016, Plaintiff served a demand on Biogen pursuant to Section 220 of the DGCL. The demand stated that Plaintiff desired to investigate potential wrongdoing by the Board, and it referenced the May 27, 2016 Bloomberg article and the Company’s April 21, 2016 disclosure that it had received a subpoena on March 4, 2016.³⁸ Biogen rejected Plaintiff’s demand on November 1, 2016, contending that it did not meet Section 220’s form and manner requirements and that Plaintiff had no proper purpose.³⁹ Plaintiff delivered additional demands on November 4,

³⁴ *Id.* ¶¶ 7, 15.

³⁵ JX 27. The parties dispute whether Plaintiff has owned Biogen stock continuously since February 2011. For reasons explained below, because Plaintiff was a stockholder at the time of the Demand, the issue of continuity is not necessary for this decision.

³⁶ Deposition of Melvin Gross (“Gross Dep.”) 15–16.

³⁷ *Id.* 9–10.

³⁸ JX 4. Plaintiff testified that he has a subscription to Bloomberg. Gross Dep. 56.

³⁹ JX 5.

2016 and June 21, 2018, again referencing the Bloomberg article and the subpoenas relating to Biogen’s relationships with charities, but Biogen rejected both of these demands for largely the same reasons as the first.⁴⁰

On December 3, 2019, Plaintiff served on Biogen what has become the operative demand (the “Demand”).⁴¹ The stated purposes of the Demand were ostensibly to (1) “investigate possible corporate wrongdoing and/or breaches of fiduciary duty owed to the Company and its shareholders by its officers and directors” and (2) “determine the independence of the Board members.”⁴² As before, the Demand identified the subpoenas mentioned in the Bloomberg article and the March 4, 2016 subpoena disclosed in the Company’s April 21, 2016 Form 10-Q. The Demand specifically referred to the federal investigation “of Biogen and other companies address[ing] concerns that the companies may be violating the kick-back rules by making charitable contributions,” which the Demand defined as the “Investigation.” The Demand also cited the TAF Settlement and the Federal Jury Verdict in further support of Plaintiff’s purposes. The Demand listed eight categories of documents that Plaintiff sought to inspect.⁴³

⁴⁰ JX 6, 7, 8, and 9.

⁴¹ JX 23.

⁴² *Id.* at 4-5. The Demand also sought to determine whether Biogen’s officers and directors “acted in good faith” (*id.* at 4), but Plaintiff did not pursue that as a separate purpose at trial.

⁴³ *Id.* at 3.

Biogen rejected Plaintiff's Demand.⁴⁴ Biogen contended that the Demand was defective because it failed to comply with Section 220's form and manner requirements by not attaching documentary evidence of contemporaneous and continuous ownership of Biogen stock; it failed to state a proper purpose; and it requested inspection of documents that were not necessary and essential to Plaintiff's stated purpose.⁴⁵ On January 3, 2020, Plaintiff supplemented the Demand with additional evidence purporting to show continuous ownership of Biogen stock and addressing Biogen's other objections.⁴⁶ Biogen responded on January 24, 2020, reiterating its denial of the Demand.⁴⁷

Plaintiff filed the Verified Complaint on February 14, 2020 (the "Complaint"), seeking to compel Biogen to produce the books and records set forth in the Demand. As of trial, Biogen still had not produced any documents in response to the Demand.⁴⁸

The court conducted a half-day video trial on August 12, 2020. After post-trial briefing, the parties submitted, at the court's request, supplemental submissions

⁴⁴ PTO ¶ 17.

⁴⁵ *Id.*

⁴⁶ *Id.* ¶ 18.

⁴⁷ *Id.* ¶ 19.

⁴⁸ *Id.* ¶ 22. There has been no indication that Biogen produced any documents after the trial.

addressing the Delaware Supreme Court’s intervening decision in *AmerisourceBergen Corp. v. Lebanon County Employees’ Retirement Fund*, 243 A.3d 417 (Del. 2020) (“*AmerisourceBergen II*”), *aff’g* 2020 WL 132752 (Del. Ch. Jan. 13, 2020).

III. ANALYSIS

“Section 220(c) provides that stockholders who seek to inspect a corporation’s books and records must establish that ‘(1) [s]uch stockholder is a stockholder; (2) [s]uch stockholder has complied with [Section 220] respecting the form and manner of making demand for inspection of such documents; and (3) [t]he inspection such stockholder seeks is for a proper purpose.’”⁴⁹ “After meeting these requirements, the plaintiff must demonstrate by a preponderance of the evidence that ‘each category of books and records is essential to accomplishment of the stockholder’s articulated purpose for the inspection.’”⁵⁰

Biogen has followed the recent trend in adopting what has been referred to as an “overly aggressive defense strategy” in opposing inspection.⁵¹ As explained

⁴⁹ *AmerisourceBergen II*, 243 A.3d at 425 (alterations in original) (quoting 8 *Del. C.* § 220).

⁵⁰ *Woods Tr. of Avery L. Woods Tr. v. Sahara Enters., Inc.*, 238 A.3d 879, 889 (Del. Ch. 2020) (quoting *Thomas & Betts Corp. v. Leviton Mfg. Co.*, 681 A.2d 1026, 1035 (Del. 1996)).

⁵¹ *Petry v. Gilead Sciences, Inc.*, 2020 WL 6870461, at *2 (Del. Ch. Nov. 24, 2020).

below, Biogen’s defenses do not warrant complete denial of Plaintiff’s inspection rights.

A. Verification of Complaint

As a threshold matter, Biogen asserts that this action should be dismissed because Plaintiff failed to verify his Complaint.⁵² Under Court of Chancery Rule 3(aa), “the matter set forth in any pleading must be verified by someone attesting to its correctness and truthfulness.”⁵³ If a plaintiff fails to comply with Rule 3(aa), Rule 41(b) permits the defendant to move for dismissal of the action.⁵⁴ Dismissal under Rule 41(b) is a “harsh sanction” that is proper “when a party knowingly misleads a court of equity in order to secure an unfair tactical advantage.”⁵⁵

Plaintiff signed a Verification to his Complaint, wherein he attested that he was “familiar with the allegations of the Complaint” and that he “reviewed the Complaint.”⁵⁶ The signature on the Verification was notarized. In his deposition, Plaintiff admitted that he did not read every word or even every page before signing

⁵² Def.’s Pre-Trial Br. 20–21.

⁵³ *Bessenyei v. Vermillion, Inc.*, 2012 WL 5830214, at *3 (Del. Ch. Nov. 16, 2012), *aff’d*, 67 A.3d 1022 (Del. 2013).

⁵⁴ *Id.* at *2; *see* Ct. Ch. R. 41(b).

⁵⁵ *Bessenyei*, 2012 WL 5830214, at *3 (quoting *Parfi Hldgs. AB v. Mirror Image Internet, Inc.*, 954 A.2d 911, 932–33 (Del. Ch. 2008)).

⁵⁶ Dkt. 2.

the Verification.⁵⁷ He did, however, state that he glanced through the Complaint, read the headings, and had a general idea of the Complaint's contents.⁵⁸

Under similar circumstances, this court has declined to find that a potential Rule 3(aa) violation justified shifting fees, much less dismissing the action. For example, in *Dias v. Purches*, 2012 WL 4503174 (Del. Ch. Oct. 1, 2012), although there was a question about whether the plaintiff reviewed the company's Form S-4 before filing a complaint based thereon, the court concluded that the plaintiff's decision to consult with his counsel to help him review the Form S-4 and evaluate the merits of the case "was a prudent way to proceed." *Id.* at *3–4. Similarly, in *Wayman Fire Protection, Inc. v. Premium Fire & Security, LLC*, 2014 WL 897223 (Del. Ch. Mar. 5, 2014), the plaintiff's representative was "careless in his efforts to verify the allegations in [the] complaint [and] only barely met its obligations under the Rule," but the court still found that the plaintiff did not "act[] in bad faith . . . or fail[] to provide the requisite verification." *Id.* at *32.

The "harsh sanction" of dismissal is not appropriate here. Plaintiff, who has no legal experience, credibly testified that he had a general idea about his Complaint's contents and that he relied on his attorneys to supply the technical

⁵⁷ Gross Dep. 59–62.

⁵⁸ *Id.*

details. Plaintiff was entitled to rely on his counsel's expertise.⁵⁹ Although Plaintiff could have done more to obtain better familiarity with all of the allegations in his Complaint, no evidence suggests that Plaintiff acted in bad faith or knowingly misled this court in search of an unfair advantage. Accordingly, I am not persuaded that Plaintiff's Verification was ineffective.

B. Proper Purpose

Plaintiff's Demand states two purposes. First, Plaintiff seeks to investigate "the possibility of breaches of fiduciary duty by Biogen's Board related to the investigation by the United States Attorney offices (the 'Investigation') relating to Biogen's alleged kickback violations."⁶⁰ Second, Plaintiff seeks to investigate "the independence and disinterest of the Board relating to the Company's alleged kickback violations."⁶¹ Biogen argues that Plaintiff has no proper purpose because (1) Plaintiff lacks a purpose of his own, (2) Plaintiff failed to demonstrate a credible basis to suspect wrongdoing, and (3) Plaintiff failed to establish that any wrongdoing under investigation would be actionable.

⁵⁹ See *infra* Section III.B.1.

⁶⁰ Pl.'s Pre-Trial Br. 13.

⁶¹ *Id.*

1. Plaintiff's Own Purpose

Biogen argues that Plaintiff is not entitled to inspect books and records because Plaintiff has no purpose at all. Specifically, Biogen argues that the purposes articulated in the Demand belong entirely to Plaintiff's counsel rather than Plaintiff himself. In doing so, Biogen analogizes this case to *Wilkinson v. A. Schulman, Inc.*, 2017 WL 5289553 (Del. Ch. Nov. 13, 2017).

In *Wilkinson*, the stockholder's deposition testimony revealed that his reasons for wanting to investigate the company differed substantially from the reasons listed in the demand. The stockholder testified that he was unaware of any facts related to the wrongdoing that the demand sought to investigate. After signing the demand, the stockholder was entirely uninvolved in his lawyers' follow-up efforts. He relied solely on counsel when he signed the subsequent complaint without verifying the allegations, and he did not review the company's answer or participate in responding to the company's interrogatories. The court found that the stockholder had "simply lent his name to a lawyer-driven effort by entrepreneurial plaintiffs' counsel." *Id.* at *2. Under those circumstances, the court concluded that the stockholder's purported purposes were not his actual purposes, and it held that the stockholder was not entitled to inspect any books and records.

“As multiple subsequent decisions of this court have made clear, *Wilkinson* involved extreme facts.”⁶² In *Inter-Local Pension Fund GCC/IBT v. Calgon Carbon Corp.*, 2019 WL 479082 (Del. Ch. Jan. 25, 2019), *aff’d*, 237 A.3d 818 (Del. 2020), Vice Chancellor Zurn observed that a “key factor” leading to the denial of inspection in *Wilkinson* was the misalignment of goals between the stockholder and his counsel. *Id.* at *9. In rejecting a *Wilkinson* defense, Vice Chancellor Zurn found that the alignment of goals between the stockholder and counsel in *Calgon Carbon* was sufficient to establish an actual purpose, even though the stockholder “did not originally conceive of the purposes for the Demand and could not independently articulate the legal nuances of the Demand and its Requests at deposition.” *Id.* at *10. Notably, the plaintiff’s testimony regarding its purposes “align[ed] with those professed in the Demand and [did] not mirror the situation in [*Wilkinson*] where counsel usurped the process for a different purpose.” *Id.*

Even more recently, in *Gilead*, Vice Chancellor McCormick reiterated that *Wilkinson* resulted from “extreme facts . . . where the attorneys disregarded their

⁶² *Gilead*, 2020 WL 6870461, at *1. To date, every written decision from this court that has discussed *Wilkinson* has distinguished *Wilkinson* on its extreme facts. *See id.*; *Inter-Local Pension Fund GCC/IBT v. Calgon Carbon Corp.*, 2019 WL 479082, at *9–10 (Del. Ch. Jan. 25, 2019), *aff’d*, 237 A.3d 818 (Del. 2020); *Kosinski v. GGP Inc.*, 214 A.3d 944, 950–52 (Del. Ch. 2019); *Donnelly v. Keryx Biopharmaceuticals, Inc.*, 2019 WL 5446015, at *3–4 (Del. Ch. Oct. 24, 2019); *Schnatter v. Papa John’s Int’l, Inc.*, 2019 WL 194634, at *13–14 (Del. Ch. Jan. 15, 2019), *abrogated on other grounds by Tiger v. Boast Apparel, Inc.*, 214 A.3d 933 (Del. 2019).

client’s objectives entirely and pursued their own.” *Gilead*, 2020 WL 6870461, at *17. Recognizing the heavy role of lawyer involvement in the process, the court rejected Gilead’s *Wilkinson* argument even as to a plaintiff whose “knowledge of the basis for her demand was exceptionally weak,” because that fact alone did not compare to “the confluence of unusual facts present in *Wilkinson*.” *Id.* at *15 n.163.

Biogen points to similarities between the role of counsel here and that of counsel in *Wilkinson*. Plaintiff’s counsel, Pomerantz LLP, prepared the Demand, which articulated the purposes and identified the categories of books and records sought. Plaintiff did not review Biogen’s response or any subsequent exchanges between the parties, and Plaintiff was not involved in responding to Biogen’s interrogatories. Plaintiff, instead, relied on his counsel’s expertise.

That Plaintiff heavily relied on his lawyers’ efforts does not undermine his legitimate concern regarding the Company and his right to use counsel to investigate that concern. Like the defendant in *Gilead*, Biogen “proved that lawyers were heavily involved in the process, but that is to be expected considering the significant role lawyers play in representative litigation generally.”⁶³ Counsel may play a “dominant role” in Section 220 actions, just as they may in the follow-on derivative litigation.⁶⁴ Even in *Wilkinson*, the court explained that “[a] stockholder obviously

⁶³ *Gilead*, 2020 WL 6870461, at *16.

⁶⁴ *Id.* at *16–17 (“It would also be inconsistent with this policy [of encouraging stockholders to pursue Section 220 actions in advance of derivative suits] to prohibit

can use counsel to seek books and records. Section 220 expressly contemplates that a stockholder can make a demand ‘in person or by attorney or other agent.’ Indeed, given the complexity of Delaware’s sprawling Section 220 jurisprudence, a stockholder is well-advised to secure counsel’s assistance.”⁶⁵ The use of counsel becomes a problem when “an entrepreneurial law firm initiate[s] the process, draft[s] a demand to investigate different issues than what motivated the stockholder to respond to the law firm’s solicitation, and then pursue[s] the inspection and litigate[s] with only minor and non-substantive involvement from the ostensible stockholder principal.”⁶⁶

The crucial difference between this case and *Wilkinson*, however, is that Plaintiff initiated this case on his own accord. Plaintiff became concerned after reading a news article suggesting that Biogen was involved in wrongdoing relating to Medicare. The article prompted him to discuss his concern with a lawyer he knew, who then referred Plaintiff to his current counsel. Since then, every iteration of

lawyers from playing a ‘dominant role’ in Section 220 actions while permitting them to do so in derivative litigation.”) (citing *In re Fuqua Indus., Inc. S’holder Litig.*, 752 A.2d 126 (Del. Ch. 1999)).

⁶⁵ *Wilkinson*, 2017 WL 5289553, at *3; see also *Calgon Carbon*, 2019 WL 479082, at *10 (“Individual stockholders and smaller institutions cannot be expected to have an independent, in-house team to cultivate purely homegrown legal analyses of their investments. Stockholders are entitled . . . to rely on that counsel to raise concerns, to advise them on how to remedy those concerns, and to pursue appropriate remedies.”).

⁶⁶ *Wilkinson*, 2017 WL 5289553, at *3.

Plaintiff's demand has embodied Plaintiff's original concern and has sought to investigate Biogen's relationships with non-profits that provide financial assistance to Medicare patients.⁶⁷

Perhaps unconvinced, Biogen's counsel repeatedly pressed the Plaintiff at his deposition about the origin of the Demand and what prompted him to engage counsel—an apparent attempt to test his memory with the hope of unearthing nuggets of inconsistency to undermine the *bona fides* of his purpose. Plaintiff was forthright and unwavering. When asked what prompted him years earlier to discuss Biogen with his lawyer friend, Plaintiff responded: “I read Bloomberg. I read Wall Street Journal. I read various financial papers. And there was some mention over there about some Medicare something with Biogen. And I don't remember.” Gross Dep. 16; *see also id.* 19–20 (“There was something about some sort of Medicare something or other. I don't recall. Again, I did not delve too deeply into it. That happened to stick in my mind.”); *id.* 20 (“The truth is, I'm glad to remember what I said two weeks ago. I don't remember what I said two years ago. When you'll be almost 92 years old, if your memory will be as good as mine, you won't complain, but it's not that good. But it was a while ago.”); *id.* 24 (“I would like to know exactly

⁶⁷ Biogen argues that the Demand exceeded the scope of Plaintiff's concern, which involved a Medicare probe, when it cited the Federal Jury Verdict, which involved Biogen's off-label marketing practices. As discussed in footnote 76 below, I agree. However, the reference to the Federal Jury Verdict did not change the Demand's stated purpose, which did not depart from Plaintiff's original concern relating to Medicare.

what they did over here with this Medicare thing. Again, I only know exactly what I had read, and the questions evolved. And I gave the—mentioned it to the attorneys to see what happens.”); *id.* 32 (“Q: What reason do you have to suspect that there was mismanagement by Biogen’s board of directors? A: Again, off of this article I read at some point. Again, I can’t give a specific date or magazine or paper that I read about it, but just the question came up after I read that article. Q: What question came up? A: Just about some mismanagement or some Medicare. Just sort of an up-in-the-air-type thing. I know there was Medicare something involved. I don’t recall exactly what. Again, I did not understand exactly what it’s all about, but from reading that article it was something that I thought that it was worth mentioning.”).

Plaintiff testified that he relied on his counsel to pursue his purpose: “I think I used attorneys just a few times in my life, and I’ve always relied on their ability. That’s why I pay an attorney.” Gross Dep. 21. Plaintiff testified that he signed the Verification to the Complaint, and he understood that by doing so his counsel “more or less . . . would . . . be allowed to look at books of the company. Again, I don’t know exactly what it said. I glanced through it. My attorneys tells [sic] me to sign it; I sign it. Again, he’s representing me. I don’t read every word. But I have a general idea, and that’s about it.” *Id.* 61. Plaintiff testified that he saw the operative demand letter before signing the special power of attorney and verification attached to it. *Id.* 27; *see* JX 23.

Section 220 does not require a stockholder to have the sophistication of a corporate lawyer, investment banker, or law professor. The statute does not require a stockholder-plaintiff to pass a memory test administered by a savvy litigator, and it is not an invitation to harass. Section 220 requires that the plaintiff be a stockholder with a proper purpose. To comply with the statute and exercise their rights, stockholders are allowed to engage and rely on the guidance of counsel. “The fact that Plaintiff sought and accepted the advice of counsel is to his credit, not his detriment.”⁶⁸ Plaintiff satisfies the statutory requirements established by our law as a stockholder seeking to inspect books and records of a corporation in which he owns shares.

To reiterate, this case is not *Wilkinson*. There is no misalignment of purpose between client and counsel, nor are there the extreme circumstances that led to the harsh result in *Wilkinson*. Plaintiff’s stated purpose is his own, actual purpose.⁶⁹

⁶⁸ *Kosinski*, 214 A.3d at 951–52.

⁶⁹ As a variation on the *Wilkinson* theme, Biogen argues that Plaintiff has no purpose because he let his counsel determine the intended use(s) of the demanded books and records. Def.’s Supp. Post-Trial Br. 9–11. Biogen points to statements from Plaintiff’s deposition in which Plaintiff testified that he had “no idea” what he would do after inspecting the books and records, but that he had hired counsel to make that decision for him. *Id.* Biogen’s attempt to characterize Plaintiff as purposeless is unavailing. In *AmerisourceBergen II*, the Delaware Supreme Court affirmed that “a stockholder is not required to state the objectives of his investigation.” 243 A.3d at 427. Thus, Plaintiff was not required to personally identify whether the books and records would be used for a derivative suit, for serving a demand on the Board, or for any other end use. As Biogen correctly points out, however, the Supreme Court acknowledged that such objectives may be relevant to evaluating whether “the stockholder’s stated purpose is not its actual

2. Credible Basis to Suspect Wrongdoing

Biogen argues that Plaintiff is not entitled to inspection because he has not made the required showing to investigate mismanagement and wrongdoing.⁷⁰ As the Delaware Supreme Court recently reiterated in *AmerisourceBergen II*:

[A] stockholder seeking to investigate wrongdoing must show, by a preponderance of the evidence, a credible basis from which the court can infer there is possible mismanagement as would warrant further investigation. Although not an insubstantial threshold, the credible basis standard is the lowest possible burden of proof. A stockholder need not show that corporate wrongdoing or mismanagement has occurred in fact, but rather the threshold may be satisfied by a credible showing, through documents, logic, testimony or otherwise, that there are legitimate issues of wrongdoing.⁷¹

The stockholder must make more than “a bare allegation of possible waste, mismanagement, or breach of fiduciary duty.”⁷²

purpose.” *Id.* But Biogen has not sufficiently shown that Plaintiff had any other purpose. “[I]n order to succeed [on a defense that the stockholder’s stated purpose is not its actual purpose], the defendant must prove that the plaintiff pursued its claim under false pretenses, and its primary purpose is indeed improper. Such a showing is fact intensive and difficult to establish.” *Pershing Square, L.P. v. Ceridian Corp.*, 923 A.2d 810, 817 (Del. Ch. 2007) (footnotes omitted). Biogen asserts that Plaintiff’s actual, improper purpose was either to satisfy his curiosity or to conduct a fishing expedition. Def.’s Supp. Post-Trial Br. 11. Biogen’s only support for this assertion is that Plaintiff relied heavily on counsel to carry out Plaintiff’s desire to investigate the Medicare-related allegations he had read about. As discussed, Plaintiff was entitled and encouraged to rely on counsel. Plaintiff has an actual purpose, and Biogen has not proven otherwise.

⁷⁰ See Def. Supp. Post-Trial Br. 5–8.

⁷¹ 243 A.3d at 426 (footnotes and quotation marks omitted).

⁷² *Id.*

In applying the standard to a plaintiff’s demand, “the court may consider on-going lawsuits, investigations, circumstantial evidence, and even hearsay statements evincing possible wrongdoing.”⁷³ Most apt for this case, “[o]ngoing investigations and lawsuits can provide the necessary evidentiary basis to suspect wrongdoing or mismanagement warranting further investigation. This type of evidence is stronger when governmental agencies or arms of law enforcement have conducted the investigations or pursued the lawsuits.”⁷⁴

Again, *Gilead* is instructive. As noted earlier, Gilead, along with Biogen and Jazz, had announced in early 2016 that it had received federal subpoenas seeking documents concerning its relationships with non-profits. Gilead was also facing a federal *qui tam* action reflecting detailed allegations that the company had violated federal anti-kickback laws. Gilead’s stockholders sought to investigate, among other things, “[k]ickback schemes resulting in DOJ investigations into False Claims Act violations.” *Id.* at *12. In its opinion granting the stockholders’ demand for inspection, the court found that “[t]he combination of multiple government investigations relating to possible False Claims Act violations plus the ongoing *qui*

⁷³ *Gilead*, 2020 WL 6870461, at *11.

⁷⁴ *Lebanon Cty. Emps.’ Ret. Fund v. AmerisourceBergen Corp.* (“*AmerisourceBergen I*”), 2020 WL 132752, at *9 (Del. Ch. Jan. 13, 2020), *aff’d*, 243 A.3d 417 (Del. 2020).

tam litigation alleging the exact same conduct . . . establishes a credible basis to suspect possible wrongdoing as to False Claims Act violations.” *Id.* at *14.

Plaintiff here offers three sources of evidence to support a finding of a credible basis to infer mismanagement: the Investigation and related subpoenas, the TAF Settlement, and the Federal Jury Verdict. That evidence reveals that the federal authorities, and perhaps state authorities as well, are (or were) investigating Biogen’s relationships with non-profits that provide financial assistance to patients taking Biogen’s drugs. As this court’s prior decisions have found, ongoing governmental investigations can be strong evidence of a credible basis to suspect wrongdoing.⁷⁵ The subpoenas’ evidentiary weight is bolstered by the TAF Settlement, which further implicates Biogen for the exact same reasons as the subpoenas and provides detailed allegations about Biogen’s participation in the illegal kickback scheme. Just as the government investigation plus the *qui tam* litigation established a credible basis in *Gilead*, the government investigation plus the TAF Settlement demonstrate

⁷⁵ See, e.g., *AmerisourceBergen I*, 2020 WL 132752, at *9 (finding credible basis sufficiently demonstrated by government investigations, reports, and lawsuits); *In re Plains All Am. Pipeline, L.P.*, 2017 WL 6016570, at *4 (Del. Ch. Aug. 8, 2017) (newspaper articles and a grand jury indictment); *Cohen v. El Paso Corp.*, 2004 WL 2340046, at *2 (Del. Ch. Oct. 18, 2004) (a formal SEC investigation and write-down of financials); *Freund v. Lucent Techs., Inc.*, 2003 WL 139766, at *3 (Del. Ch. Jan. 9, 2003) (a formal SEC investigation, revision of financial statements, and related lawsuits); *Saito v. McKesson HBOC, Inc.*, 2001 WL 818173, at *4 (Del. Ch. July 10, 2001) (restatement of financials due to accounting irregularities, admission of irregularities, termination of high-ranking executives, and institution of criminal proceedings by federal authorities), *aff’d in part, rev’d in part*, 806 A.2d 113 (Del. 2002).

a credible basis to suspect possible mismanagement here.⁷⁶ The additional revelations detailed in the December 2020 DOJ Settlement agreement, though not necessary to establish Plaintiff’s burden, are powerful evidence supporting the right to inspection. “[T]he low credible basis threshold is met where wrongdoing is merely *possible*—it need not be proven.”⁷⁷ Plaintiff has met his minimal burden and has established a proper purpose to investigate wrongdoing.

Biogen contends that Plaintiff’s evidence is insufficient because it does not show that Biogen’s directors or officers were complicit in or had knowledge of the alleged misconduct.⁷⁸ Biogen’s argument fails for two reasons. First, that exact argument has been considered and rejected by this court. In *Gilead*, “[t]he parties also dispute[d] whether Plaintiffs [] presented evidence demonstrating that Gilead’s board of directors and senior officers were aware of the categories of alleged

⁷⁶ Plaintiff presents the Federal Jury Verdict as additional evidence of possible wrongdoing, but the Federal Jury Verdict does not support the purposes of Plaintiff’s Demand. The Federal Jury Verdict found that Biogen had illegally retaliated against the plaintiff after she alleged that Biogen had violated restrictions on off-label marketing. That allegation does not relate to violations of the prohibition on kickbacks or Biogen’s relationship with non-profits, which are the bases of the TAF Settlement and the Investigation. Plaintiff concedes that his Demand is confined to the “Investigation” (which Plaintiff defines as “the investigation by U.S. Attorney offices . . . relating to Biogen’s alleged kickback violations”) and associated issues of director disinterestedness. Pl.’s Pre-Trial Br. 15–16. The Federal Jury Verdict falls outside these confines. Nevertheless, even without considering the Federal Jury Verdict, Plaintiff has established a credible basis to suspect possible wrongdoing.

⁷⁷ *Jacob v. Bloom Energy Corp.*, 2021 WL 733438, at *7 (Del. Ch. Feb. 25, 2021) (emphasis in original).

⁷⁸ Def.’s Pre-Trial Br. 34–38.

wrongdoing. Such a showing is not required to support a credible basis where [] Plaintiffs have not limited their purposes to pursuing derivative claims.”⁷⁹ As explained later in this Opinion, Plaintiff has not limited his purpose to pursuing derivative litigation. To establish a right to inspection, plaintiff “need not attempt to connect [Biogen’s] possible wrongdoing directly to individual members of the Board or Company officers.”⁸⁰

Second, even if Plaintiff must demonstrate a credible basis to infer possible mismanagement at the level of the board or senior officers, Plaintiff has done so here. In its public disclosures, Biogen’s management acknowledged that sales of Biogen’s products depend “to a significant extent” on coverage, pricing, and reimbursement from government health administration authorities, as well as private insurers and other organizations.⁸¹ The Board established a Corporate Compliance Committee consisting of senior officers.⁸² These senior officers oversee a compliance program, which outlines policies that “prohibit illegal remuneration in violation of federal and state anti-kickback statutes.”⁸³ Additionally, the TAF

⁷⁹ *Gilead*, 2020 WL 6870461, at *15; *see AmerisourceBergen I*, 2020 WL 132752, at *15, *19.

⁸⁰ *Bloom Energy*, 2021 WL 733438, at *8.

⁸¹ JX 13 at 49.

⁸² JX 58 at 9.

⁸³ JX 57 at 2.

Settlement provides evidence that a Biogen vice president actively participated in the alleged kickback scheme, which shows knowledge at the management level.⁸⁴ Collectively, the importance of government reimbursements to Biogen’s revenue, the existence of an officer-level committee to ensure compliance with the laws governing receipt of those reimbursements, and the alleged involvement of a vice president in an alleged violation of those laws are sufficient to establish a credible basis to suspect that Biogen’s directors or officers knew or should have known about the possible wrongdoing.⁸⁵

3. Actionable Claim Objections

The Company argues that Plaintiff has failed to state a proper purpose because he has not established an ability to bring a lawsuit based on the wrongdoing he seeks to investigate. In *AmerisourceBergen II*, the Delaware Supreme Court “dispel[led] the notion that a stockholder who demonstrates a credible basis from which the court can infer wrongdoing or mismanagement must demonstrate that the wrongdoing or

⁸⁴ JX 22 at 4 (“Biogen made payments . . . as part of a coordinated effort — which, in an e-mail to a Biogen vice president, TAF’s co-founder termed the TYS[abri] project — by TAF and Biogen.”). Biogen contends that the vice president implicated in the TAF Settlement was not a senior officer. Def.’s Opening Post-Trial Br. 11 n.37. Regardless of the vice president’s exact status, the accusation suggests that knowledge of the scheme was not limited to line employees far below the officers’ and directors’ ranks.

⁸⁵ See *Gilead*, 2020 WL 6870461, at *15 (“There is thus a credible basis to suspect that the board and senior management knew about the possible wrongdoing. If they did not, there is a credible basis to suspect that they failed to monitor a business segment that was ‘mission critical,’ as well as vitally important to the lives of millions of people.”).

mismanagement is actionable.”⁸⁶ In reconciling its holding with past decisions from this court, the Supreme Court left open the slight possibility that the actionability requirement may apply when “[1] the stockholder’s sole reason for investigating mismanagement or wrongdoing is to pursue litigation and [2] a purely procedural obstacle, such as standing or the statute of limitations, stands in the stockholder’s way such that the court can determine, without adjudicating merits-based defenses, that the anticipated litigation will be dead on arrival.”⁸⁷ The Supreme Court acknowledged that this exception will only apply “[i]n the rare case.”⁸⁸

The Supreme Court based this rare exception on three cases where the plaintiff’s sole purpose of investigation was to facilitate litigation. In *Polygon Global Opportunities Master Fund v. West Corp.*, 2006 WL 2947486 (Del. Ch. Oct. 12, 2006), the plaintiff purchased the company’s stock just after the company announced a take-private recapitalization, via a transaction that the plaintiff could do nothing to stop. Still, the plaintiff sought books and records to investigate wrongdoing in the approval of the transaction. Because the plaintiff could not vote down the transaction and would shortly cease to be a stockholder, there was no

⁸⁶ *AmerisourceBergen II*, 243 A.3d at 431; *see also id.* at 437 (“The stockholder need not demonstrate that the alleged mismanagement or wrongdoing is actionable.”).

⁸⁷ *Id.* at 437. The court may find the procedural obstacle to be sufficient when it is “the product of a determinate procedural history and based on undisputed facts.” *Id.* at 423.

⁸⁸ *Id.*

possibility for the plaintiff to seek an audience with the board, prepare a shareholder resolution, or mount a proxy fight.⁸⁹ Thus, the court concluded that the “sole purpose” for investigating wrongdoing was to bring a claim for breach of fiduciary duties. *Id.* at *5. In *Graulich v. Dell Inc.*, 2011 WL 1843813 (Del. Ch. May 16, 2011), the plaintiff sought to investigate whether the company’s directors took appropriate actions to monitor and prevent improper activities. The plaintiff’s demand, which devoted only two short, unclear paragraphs to explaining his purpose, stated that, “[i]f it is found that the directors and their agents failed in their duties, then an appropriate suit will be commenced.” *Id.* at *5 n.49. The court emphasized that this was “the only stated purpose” in the demand. *Id.* at *1. Finally, in *West Coast Management & Capital, LLC v. Carrier Access Corp.*, 914 A.2d 636 (Del. Ch. 2006), the plaintiff demanded inspection of books and records after its previous lawsuit for breach of fiduciary duty was dismissed for failure to plead demand futility. In that context, the court concluded that “[i]t is clear that West Coast’s sole purpose for investigating claims of wrongdoing is to obtain additional information to replead demand futility in order to pursue a second derivative suit.” *Id.* at 645–46. In each of these three cases, the court went on to find that a procedural

⁸⁹ See *Saito v. McKesson HBOC, Inc.*, 806 A.2d 113, 117 (Del. 2002) (“[S]tockholders may use information about corporate mismanagement in other ways, as well [as derivative litigation]. They may seek an audience with the board to discuss proposed reforms or, failing in that, they may prepare a stockholder resolution for the next annual meeting, or mount a proxy fight to elect new directors.”).

obstacle to litigation effectively thwarted the plaintiff's sole purpose. The Supreme Court found each decision to be "within the discretion that rests in the Court of Chancery's hands when it assesses the *bona fides* of a stockholder's stated purpose under Section 220."⁹⁰

Plaintiff has not limited the purpose of his Demand solely to litigation. The Demand states that it was made "for purposes including, but not limited [to], pursuing a potential stockholder derivative action and/or serving a demand on the Company's Board."⁹¹ It also states that the requested books and records would "serve to inform the stockholder's future actions, including the viability of litigation."⁹² To be sure, the Demand can be fairly read to suggest that evaluating whether to institute litigation is a likely use of the demanded books and records. But by using the phrase "including, but not limited to," Plaintiff has expressly not limited himself to instituting litigation.⁹³ Furthermore, the Demand recognizes the

⁹⁰ *AmerisourceBergen II*, 243 A.3d at 432.

⁹¹ JX 23 at 5.

⁹² *Id.* at 2.

⁹³ *See Khan v. Delaware State Univ.*, 2017 WL 815257, at *4 (Del. Super. Ct. Feb. 28, 2017) ("The use of 'including but not limited to' language is a tool commonly employed by contract drafters to avoid the application of the *expressio unius est exclusio alterius* rule [*i.e.*, the expression of one thing is the exclusion of another]."). I am also disinclined to read the "including" language as inherently limiting these documents' use to litigation in light of the Supreme Court's holding that a stockholder need not articulate an objective of the investigation. *AmerisourceBergen II*, 243 A.3d at 427 ("[W]e agree with the Court of Chancery's observation that a stockholder is not required to state the objectives of his investigation.").

Plaintiff's ability to use the results of his investigation for other purposes, such as to "compel the Company's Board to take action to treat and correct the underlying wrong."⁹⁴ At his deposition, Plaintiff, admitting his reliance on counsel, stated: "You go on a trail, you don't know where it leads to."⁹⁵ Unlike the unique circumstances found in the cases cited by *AmerisourceBergen II*, Plaintiff has not already pursued litigation, and Plaintiff has not made his Demand under circumstances that would preclude his ability to address wrongdoing through other means. In light of the Demand's language and context, I do not find that the Demand was made for the sole purpose of litigation. Thus, this case does not invoke the rare exception to the Supreme Court's holding in *AmerisourceBergen II* that a plaintiff need not demonstrate actionable wrongdoing.

As here, when the stockholder's reason for investigating wrongdoing is not solely to pursue litigation, the court should "defer the consideration of defenses that do not directly bear on the stockholder's inspection rights, but only on the likelihood that the stockholder might prevail in another action."⁹⁶ Thus, this action is not the proper proceeding to consider Biogen's defenses that any underlying wrongdoing

⁹⁴ JX 23 at 2.

⁹⁵ Gross Dep. 25. In *Gilead*, the court concluded that the plaintiffs did not have the sole purpose of instituting litigation, and it pointed to a plaintiff's testimony that "[t]his is simply an investigation. If it turns out there's no [wrongdoing], then it will be the end of it." *Gilead*, 2020 WL 6870461, at *20 (alteration in original).

⁹⁶ *AmerisourceBergen II*, 243 A.3d at 437.

would be exculpated or time-barred,⁹⁷ or that Plaintiff needed to demonstrate at the time of the Demand that he owned stock that would afford him standing to bring a derivative suit.⁹⁸ These issues do not bear on Plaintiff's right to inspect the Company's books and records.

4. Director Independence and Disinterestedness

As its second purpose, the Demand seeks to investigate the independence and disinterest of the Board. "Another purpose for using Section 220 is to investigate questions of director disinterestedness and independence."⁹⁹ Biogen does not

⁹⁷ Def.'s Pre-Trial Br. 38–40; Def.'s Supp. Post-Trial Br. 3–5.

⁹⁸ Biogen argues that Plaintiff must establish that he has owned Biogen stock continuously since the time of the alleged wrongdoing, and that this continuous-ownership requirement is a form and manner requirement that Plaintiff must have proved when he made the Demand. Def.'s Pre-Trial Br. 21–26; Def.'s Opening Post-Trial Br. 2–6. Biogen's argument fails for at least two reasons. First, Section 220 only requires a plaintiff to demonstrate ownership of the company's stock at the time of the inspection demand. 8 *Del. C.* § 220(b); *see also Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 776 (Del. Ch. 2016) (Section 220 requires "documentation sufficiently proximate in time to the date of the demand as to be consistent with and corroborate the averment of stock ownership made in the demand itself."). Biogen concedes that Plaintiff established stock ownership concurrently with the Demand. PTO ¶ 15. Second, because derivative litigation is not the sole purpose of Plaintiff's complaint, it is not necessary for Plaintiff to establish that he would have standing to bring any subsequent derivative litigation. *See AmerisourceBergen I*, 2020 WL 132752, at *14 ("AmerisourceBergen's argument [that the suspected wrongdoing must be actionable] fails for a threshold reason. The plaintiffs are not seeking books and records for the sole purpose of investigating a potential *Caremark* claim."); *Gilead*, 2020 WL 6870461, at *19–20 ("[A] defense to a future derivative claim affects a stockholder's ability to invoke Section 220 only where the stockholder identifies pursuing a derivative claim as its *sole* purpose." (emphasis in original)). Therefore, I need not consider whether Plaintiff established such continuous ownership at the time he made his Demand.

⁹⁹ *Yahoo!*, 132 A.3d at 784.

contend that this purpose is improper in itself. Instead, Biogen merely argues that inspection to investigate board independence should be denied because Plaintiff has not established a proper purpose to investigate possible mismanagement or wrongdoing.¹⁰⁰ Because the Plaintiff has established a proper purpose to investigate wrongdoing, Biogen’s argument fails. “It is well settled that the desire to investigate director independence is a proper purpose, particularly in instances where the stockholder seeks to investigate whether demand upon the board to pursue claims on behalf of the company would be futile.”¹⁰¹ Thus, Plaintiff has also stated a proper purpose to investigate the independence and disinterestedness of the Board.

C. Scope of Inspection

Having established a proper purpose for inspection, Plaintiff must also show, by a preponderance of the evidence, that the books and records he has demanded are essential to his purpose.¹⁰² Section 220 is not a license to obtain the equivalent of comprehensive discovery under Court of Chancery Rule 34.¹⁰³ Instead, “the court

¹⁰⁰ Def.’s Pre-Trial Br. 40–41 (citing *Se. Pennsylvania Transp. Auth. v. Facebook, Inc.*, 2019 WL 5579488, at *10 (Del. Ch. Oct. 29, 2019)).

¹⁰¹ *In re Facebook, Inc. Section 220 Litig.*, 2019 WL 2320842, at *16 (Del. Ch. May 30, 2019).

¹⁰² *Sahara Enters.*, 238 A.3d at 889.

¹⁰³ *See Kaufman v. CA, Inc.*, 905 A.2d 749, 754 (Del. Ch. 2006) (“Section 220 is not meant as a replacement for discovery under Rule 34”); *Sec. First Corp. v. U.S. Die Casting & Dev. Co.*, 687 A.2d 563, 570 (Del. 1997) (“A Section 220 proceeding should result in an order circumscribed with rifled precision. Rule 34 production orders may often be broader in keeping with the scope of discovery under Court of Chancery Rule 26(b).”); *Palantir*,

must give the [stockholder] everything that is ‘essential,’ but stop at what is ‘sufficient.’”¹⁰⁴ “Where a § 220 claim is based on alleged corporate wrongdoing, . . . the stockholder should be given enough information to effectively address the problem, either through derivative litigation or through direct contact with the corporation’s directors and/or stockholders.”¹⁰⁵

“The starting point (and often the ending point) for an adequate inspection will be board-level documents that formally evidence the directors’ deliberations and decisions and comprise the materials that the directors formally received and considered (the ‘Formal Board Materials’).”¹⁰⁶ “If the plaintiff makes a proper showing, an inspection may extend to informal materials that evidence the directors’

203 A.3d at 755 (“The point of a summary § 220 action is to give the stockholder access to a discrete set of books and records that are necessary for its purpose—a set that is much less extensive than would likely be produced in discovery under the standards of Rule 26 in a plenary suit.”); *Saito*, 806 A.2d at 114 (“[Section 220] does not open the door to the wide ranging discovery that would be available in support of litigation.”).

¹⁰⁴ *Palantir*, 203 A.3d 738, 751–52 (Del. 2019) (quoting *Thomas & Betts*, 681 A.2d at 1035, and citing *Yahoo!*, 132 A.3d at 775).

¹⁰⁵ *Saito*, 806 A.2d at 115.

¹⁰⁶ *AmerisourceBergen I*, 2020 WL 132752, at *24; see also *Palantir*, 203 A.3d at 752–53 (“[T]he Court of Chancery should not order emails to be produced when other materials (e.g., traditional board-level materials, such as minutes) would accomplish the petitioner’s proper purpose.”).

deliberations, the information that they received, and the decisions they reached ('Informal Board Materials')."¹⁰⁷

Plaintiff seeks to inspect eight categories of Biogen's books and records.¹⁰⁸

1. Categories 1–2

Category 1 seeks "[a]ll documents produced and/or being produced in response to the Investigation." Category 2 seeks "[a]ll communications between the Company and any state, federal, or international government agency or entity regarding the Investigation."

Biogen objects to these categories as overbroad. Plaintiff's stated purpose is not to conduct a criminal inquiry into whether any Biogen employees violated anti-kickback statutes; instead, Plaintiff's purpose is to investigate, as a stockholder,¹⁰⁹ whether Board members violated their fiduciary duties relating to the alleged violations that are the subject of the Investigation. A more limited purpose entails a more limited scope of inspection.¹¹⁰

¹⁰⁷ *AmerisourceBergen I*, 2020 WL 132752, at *25; *see also id.* ("In an appropriate case, an inspection may extend further to encompass communications and materials that were only shared among or reviewed by officers and employees ('Officer-Level Materials').").

¹⁰⁸ *See* JX 23.

¹⁰⁹ *See* 8 *Del. C.* § 220(b) ("A proper purpose shall mean a purpose reasonably related to such person's interest as a stockholder.").

¹¹⁰ *Cf. AmerisourceBergen I*, 2020 WL 132752, at *24 ("When 'a plaintiff has shown evidence of wide-ranging mismanagement or waste, a more wide-ranging inspection may be justified.'" (quoting *Lucent*, 2003 WL 139766, at *5)).

Plaintiff relies on two decisions in support of his demand to inspect all documents provided to government investigators. In my view, neither decision supports the broad inspection sought here. In *In re Facebook, Inc. Section 220 Litigation*, 2019 WL 2320842 (Del. Ch. May 30, 2019), the plaintiff at one point demanded all documents produced to the government in connection with certain investigations. The demand was repeatedly refined and narrowed, until eventually the court granted inspection of “[h]ard-copy documents provided to, or generated by, the Board relating to [the] investigations.” *Id.* at *18. The court also granted inspection of “electronic communications, if coming from, directed to or copied to a member of the Board, concerning . . . government investigations,” after the court was satisfied that the board had conducted relevant business outside the boardroom and that the redacted board minutes would not be sufficient to accomplish the plaintiff’s purpose. *Id.* at *18, n.185. Thus, the court in *Facebook* did not require production of all documents produced in response to an investigation, but it instead narrowed the production to certain board-level documents and communications relating to the investigation. This court has taken a similar approach in other cases, limiting an investigation-related production to board-level conduct.¹¹¹

¹¹¹ See, e.g., *Bloom Energy*, 2021 WL 733438, at *10 (granting inspection of “formal Board documents . . . and documents submitted to or reviewed by the Board or senior management summarizing what the investigation entailed, any conclusions or investigations, and internal reports and follow-up reports relating to the investigation(s)”); *Carapico v. Philadelphia Stock Exch., Inc.*, 791 A.2d 787, 793 (Del. Ch. 2000) (granting inspection of

The limited scope of production in *Facebook* is consistent with this court’s holding in *Louisiana Municipal Police Employees’ Retirement System v. Countrywide Financial Corp.*, 2007 WL 2896540 (Del. Ch. Oct. 2, 2007). In *Countrywide*, the plaintiff sought to investigate possible backdating or springloading of stock options granted to corporate executives. *Id.* at *1. The plaintiff demanded “[a]ny documents made available or produced by Countrywide or its board of directors to any governmental, investigative or regulatory body . . . in connection with any formal or informal investigation into Countrywide’s stock option grants.” *Id.* at *13. The defendant did not challenge the scope of that category of documents, and the court granted the inspection. *Id.* at *13–14. It is not clear from the opinion that any other government investigation into the company’s granting of stock options existed at that time. In any event, it was “Countrywide’s Board of Directors [which] had wide discretion to issue stock options to corporate executives,” so any investigation was necessarily focused on the board’s exercise of that discretion. *Id.* at *1. Thus, the production in *Countrywide* was inherently narrowed to largely board-level documents.

With regard to investigation-related communications, “[t]his court regularly orders companies to produce communications related to government investigations

“reports presented to or minutes of meetings of the Exchange Board of Governors . . . relating to [] the SEC inquiry”).

and litigation in Section 220 cases where those investigations supply or support a credible basis for [suspecting] wrongdoing.”¹¹² As with investigation-related documents, however, investigation-related communications are also usually limited to board-level materials.¹¹³

Consistent with the recent precedents of this court, the Plaintiff’s right to inspect investigation-related books and records will be confined to board-level materials.¹¹⁴ These documents and communications will enable Plaintiff to assess the extent to which Board members were made aware of the alleged wrongdoing and to evaluate how the Board members responded to the Investigation. “[T]hese documents [and communications] are necessary and essential to reveal the degree of

¹¹² *Gilead*, 2020 WL 6870461, at *26; *accord Bloom Energy*, 2021 WL 733438, at *10.

¹¹³ *See, e.g., Gilead*, 2020 WL 6870461, at *26 (granting inspection of “high-level communications between Gilead and government investigators”). This court has granted inspection of “Orders and other communications with the SEC concerning its investigation.” *Lucent*, 2003 WL 139766, at *5. The court in *Lucent* did not purport to grant inspection of *all* communications. The fact that the plaintiff in *Lucent* sought communications in connection with orders suggests a level of formality and authoritativeness that may be present in board-level communications but not in all communications. *See id.* (“Documents relating to the SEC *formal order of investigation* are reasonably required to satisfy Freund’s stated purpose.” (emphasis added)). In any event, Plaintiff has not persuaded me that *all* communications between Biogen and the government are necessary for Plaintiff’s purpose.

¹¹⁴ Plaintiff impliedly conceded that his Demand is overbroad when, in post-trial briefing, he argued that Biogen’s production of the Investigation documents should be “limited only to the extent the Court limited such production in *Facebook*.” Pl.’s Opening Post-Trial Br. 13.

[the company's] compliance with positive law and government regulations.”¹¹⁵ Biogen must produce these board-level documents. Plaintiff has not persuaded the court that any other documents or communications that were provided to the government are necessary to investigate potential wrongdoing by members of the Biogen Board.

2. Categories 3–4

Category 3 seeks “[a]ll minutes, agendas, presentations, and participant notes provided to or reviewed by the Board (the ‘Meeting Minutes’) regarding the Investigation.” Category 4 seeks “[a]ll Meeting Minutes concerning Biogen’s policies and procedures relating to the Investigation.”

The Demand’s request to inspect board materials includes “notes” of the Board members.¹¹⁶ In addition, the Demand seems to seek inspection of electronic documents, specifically emails and text messages between Board members, “to the extent the Board maintains its records in electronic form.”¹¹⁷ Biogen resists inspection of Categories 3–4 to the extent that they exceed the scope of what is commonly considered to be formal board materials.

¹¹⁵ *Gilead*, 2020 WL 6870461, at *27; see also *Bloom Energy*, 2021 WL 733438, at *10.

¹¹⁶ JX 23 at 3.

¹¹⁷ *Id.*

With regard to electronic communications, “the Court of Chancery should not order emails to be produced when other materials (*e.g.*, traditional board-level materials, such as minutes) would accomplish the petitioner’s proper purpose.”¹¹⁸ “If a corporation has traditional, non-electronic documents sufficient to satisfy the petitioner’s needs, the corporation should not have to produce electronic documents.”¹¹⁹ “[B]ut if non-email books and records are insufficient, then the court should order emails to be produced.”¹²⁰ Similarly, the Board members’ notes are informal board materials and may be unnecessary if the formal board materials prove to be sufficient for Plaintiff’s purpose.¹²¹

As the Supreme Court explained in *Palantir*, a stockholder seeking inspection of informal materials must prove that the materials are necessary and essential.

A petitioner meets her burden to prove necessity by identifying the categories of books and records she needs and presenting some evidence that those documents are indeed necessary. . . . When [the petitioner] reasonably identifies the documents it needs and provides a basis for the court to infer that those documents likely exist in the form of electronic mail, the respondent corporation cannot insist on a

¹¹⁸ *Palantir*, 203 A.3d at 752–53.

¹¹⁹ *Id.* at 756.

¹²⁰ *Id.* at 752–53.

¹²¹ *Yahoo! Inc.*, 132 A.3d at 791 (including “memos and notes” in the category of “Additional Board Documents” rather than the more formal “Board-Level Materials”); *In re UnitedHealth Grp., Inc. Section 220 Litig.*, 2018 WL 1110849, at *8 (Del. Ch. Feb. 28, 2018) (granting inspection of “meeting preparation materials,” such as memos, outlines, notes, and talking points, separately and additionally to “written materials,” such as minutes, agendas, reports, and presentations, because plaintiffs had shown that meeting preparation materials were necessary for their purpose), *aff’d*, 196 A.3d 885 (Del. 2018).

production order that excludes emails even if they are in fact the only responsive corporate documents that exist and are therefore by definition necessary.¹²²

Plaintiff has not met his burden to establish a right to inspect electronic communications and directors' notes. Plaintiff presented no evidence or argument that the requested informal board materials are necessary or, conversely, that the formal board materials would be insufficient for him to investigate the alleged wrongdoing. Although Plaintiff included informal board materials in his Demand, he has not addressed that specific request in his pre-trial brief, at trial, or in his post-trial briefs. Accordingly, Plaintiff has effectively abandoned his request for informal board materials.¹²³ For this reason, Biogen will not be compelled to produce emails, text messages, or participant notes in Category 3.

Biogen must permit inspection of the formal board materials relating to the Investigation or to any implicated policies and procedures. "Formal board materials" refers to minutes, agendas, reports, and presentations provided to, created by, or

¹²² *Palantir*, 203 A.3d at 755–56.

¹²³ *Emerald P'rs v. Berlin*, 726 A.2d 1215, 1224 (Del. 1999) ("Issues not briefed are deemed waived."); *In re Asbestos Litig.*, 2007 WL 2410879, at *4 (Del. Super. Ct. Aug. 27, 2007) ("It is well-settled in Delaware that the failure to raise a legal issue in the text of the opening brief generally constitutes a waiver of that claim Moving parties must provide adequate factual and legal support for their positions in their moving papers in order to put the opposing parties and the court on notice of the issues to be decided.").

reviewed by the Board or by any committee thereof.¹²⁴ The “Investigation,” as defined in the Demand, refers to the investigation by the U.S. Attorney’s offices relating to Biogen’s alleged violations of the federal Anti-Kickback Statute.¹²⁵

As explained above, Plaintiff has not established a right to inspect books and records relating to the allegations raised in the Federal Jury Verdict, which are not within the definition of the “Investigation” in the Demand. Therefore, they are not sufficiently related to Plaintiff’s proper purpose. Although Biogen is not required to search for or permit inspection of books and records relating to the Federal Jury Verdict, to the extent that the Federal Jury Verdict is discussed in the same formal board materials being produced in connection with the Investigation, those discussions should not be redacted.

3. Categories 5-6

Category 5 seeks “Documents sufficient to demonstrate the Company’s policies, controls, and procedures for ensuring Biogen’s compliance with applicable statutes and regulations, including without limitation those designed to ensure compliance.” Category 6 seeks “[a]ll documents evidencing what committee and/or

¹²⁴ Of course, if text messages, emails, or notes were included with these formal board materials, then they must be produced for inspection.

¹²⁵ JX 23 at 1.

subcommittee of the Board is responsible for the active oversight and monitoring of the Investigation.”

Biogen argues that these categories improperly exceed the scope of formal board materials, are unrelated to the transactions alleged in the Demand, and are “hopelessly overbroad.”¹²⁶ Biogen acknowledges, however, that its compliance department “maintains policies designed to ensure compliance with statutes and regulations” and that the policies “are reviewed on a regular basis and updated as needed.”¹²⁷ Similarly, Biogen possesses documents that evidence which committee or subcommittee of the Board is responsible for the active oversight and monitoring of the Investigation.¹²⁸ “These requests seek discrete categories of information, which are easy to produce, and where inspection is routinely granted.”¹²⁹

Given that responsive documents exist and are readily available, Biogen shall permit inspection of its compliance policies that pertain to the Anti-Kickback Statute and the making of grants and contributions to nonprofit organizations that assist patients taking drugs sold by Biogen. Biogen is to make available for inspection all of the foregoing compliance policies, including updates, that are or were in existence

¹²⁶ Def.’s Pre-Trial Br. 55.

¹²⁷ JX 59 at 3.

¹²⁸ *Id.*

¹²⁹ *Gilead*, 2020 WL 6870461, at *25.

during the relevant time period specified in the Demand.¹³⁰ Similarly, Biogen is to produce or make available for inspection documents sufficient to identify the Board committees or subcommittees responsible for oversight and monitoring of the Investigation as defined in the Demand.

4. Category 7

Category 7 seeks “[a]ll documents evidencing other stockholders’ demands for the inspection of Books and Records sent to Biogen relating to the subject matter of this Demand.” Plaintiff has not demonstrated that some other stockholder’s books and records demand relating to the subject matter of Plaintiff’s Demand is necessary and essential to satisfying his stated purposes. He did not argue this point in his pre-trial or post-trial briefs. In any event, Biogen maintains that it has not received any other demands for inspection of books and records.¹³¹

5. Category 8

Category 8 seeks “[a]ll director questionnaires for members of the current Board either submitted to NASDAQ or prepared internally for any purpose, relating to director independence.” Biogen has confirmed that “[d]irector and officer

¹³⁰ Biogen has not contested the relevant time period.

¹³¹ JX 59 at 3.

questionnaires exist for the relevant time period and are maintained electronically by Biogen’s legal department.”¹³²

“This court regularly orders companies to produce director questionnaires where a plaintiff has demonstrated a credible basis to suspect possible wrongdoing.”¹³³ Biogen does not disagree. Instead, Biogen argues that Plaintiff should be limited to inspecting only “the most recent director disclosures and questionnaires.”¹³⁴

In *Facebook*, the court limited the company’s production to the most recent director questionnaires. *Facebook*, 2019 WL 2320842 (Del. Ch. May 30, 2019). *Facebook*, however, is distinguishable both factually and legally from this case. First, the court had already concluded that the temporal scope of the production needed to be limited because it was overbroad. The stockholder demanded documents from as early as 2011, even though the events giving rise to the stockholders’ investigation occurred in 2014 and 2015. *Id.* at *19. In the present case, the relevant time period of the documents that Plaintiff seeks to inspect is January 1, 2016 to the present.¹³⁵ Biogen first disclosed the Investigation in April 2016. Thus, Plaintiff’s Demand as to director questionnaires is not temporally

¹³² JX 59 at 4.

¹³³ *Gilead*, 2020 WL 6870461, at *27 (collecting cases).

¹³⁴ Def.’s Pre-Trial Br. 57 (citing *Facebook*, 2019 WL 2320842, at *19).

¹³⁵ JX 23.

overbroad, particularly because it is expressly limited to questionnaires “for members of the current Board.”¹³⁶

Second, *Facebook* was decided before *AmerisourceBergen II*, and the *Facebook* decision tailored the scope of inspection partly based on a notion that the stockholders’ objective was to bring a derivative claim and that such a claim would not be actionable. *Facebook*, 2019 WL 2320842, at *19 (“Claims relating to conduct in 2011, or conduct giving rise to the [2011] Consent Decree, likely would be time-barred.”). The court specifically tied the production of director questionnaires to the objective of derivative litigation when it justified its temporal limitation on the fact that “the Board’s independence for demand futility purposes will be measured as of the time the complaint alleging demand futility is filed.” *Id.* Because, under *AmerisourceBergen II*, Plaintiff was not required to limit himself to derivative litigation, and because I find that Plaintiff has not done so here, there is no basis to limit production of director questionnaires to only the most recent questionnaires.

“Because [] the Demand[] investigate[s] alleged violations of positive law and government regulations, understanding the directors’ motives and potential conflicts is paramount.”¹³⁷ Additionally, the burden on Biogen in producing these past

¹³⁶ *Id.*

¹³⁷ *Gilead*, 2020 WL 6870461, at *27.

questionnaires of current directors should be minimal.¹³⁸ Biogen shall permit inspection of director questionnaires maintained internally for the entire relevant time period.

D. Conditions to Inspection

In the Pretrial Order, Biogen sought to condition inspection as follows:

(A) requiring the Company to produce only such documents as are identified with reasonable particularity in the Demand and are necessary, essential, and sufficient to Plaintiff’s proper purpose and (B) conditioning the production of any books and records upon the prior entry of Plaintiff and Biogen into a reasonable confidentiality agreement that permits Biogen to redact privileged and non-responsive material in any produced books and records, (i) incorporates all of the produced books and records into any subsequent complaint that relies on any of the produced books and records, in accordance with Delaware law, and (ii) includes a forum selection provision requiring any subsequent derivative lawsuit based on any of the produced books and records to be filed in the Delaware Court of Chancery.¹³⁹

The Demand expressly reflects Plaintiff’s willingness to enter into a confidentiality agreement as to documents that “legitimately warrant confidential treatment.”¹⁴⁰ Although conditioning inspection on entry into a confidentiality agreement is not required in all instances,¹⁴¹ Plaintiff agreed at the outset to condition

¹³⁸ JX 59 at 4.

¹³⁹ PTO ¶ 27.

¹⁴⁰ JX 23 at 5.

¹⁴¹ See *Tiger v. Boast Apparel, Inc.*, 214 A.3d 933, 939 (Del. 2019) (holding that there is no presumption of confidentiality in Section 220 productions, and that the Court of Chancery has the power to impose reasonable confidentiality restrictions only after assessing and comparing the benefits and harms of confidentiality).

inspection on a confidentiality agreement and did not take a contrary position at trial or in any of his briefing. Accordingly, inspection will be subject to entry into a mutually agreeable confidentiality stipulation that is typical in Section 220 cases.

The other conditions that Biogen seeks are denied. Biogen did not argue in its briefs or at trial in favor of an incorporation-by-reference provision or a forum-selection provision for any derivative litigation to be brought in this court. Accordingly, these arguments are waived.¹⁴²

IV. CONCLUSION

For the foregoing reasons, judgment is entered in favor of the Plaintiff. The parties shall confer on the final order of inspection. Biogen shall produce or make available for inspection the books and records specified herein within ten business days of entry of the final order. The documents shall be produced on an attorneys' eyes only basis until such time as the parties have finalized a confidentiality stipulation governing inspection.

IT IS SO ORDERED.

¹⁴² *Emerald P'rs*, 726 A.2d at 1224 (“Issues not briefed are deemed waived.”).