EFiled: Dec 17 2010 6:21PM EST
Transaction ID 34880401
Case No. 5795-VCL

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

LOUISIANA MUNICIPAL POLICE EMPLOYEES' RETIREMENT SYSTEM, Plaintiff, -against- DAVID PYOTT, HERBERT W. BOYER, LOUIS J. LAVIGNE, GAVIN S. HERBERT, STEPHEN J. RYAN, LEONARD D. SCHAEFFER, MICHAEL R. GALLAGHER, ROBERT ALEXANDER INGRAM, TREVOR M. JONES, DAWN E. HUDSON, RUSSELL T. RAY, and DEBORAH DUNSIRE, Defendants, and ALLERGAN, INC., Nominal Defendant.	:	C.A. No. 5795-VCL

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO U.F.C.W. LOCAL 1776 & PARTICIPATING EMPLOYERS PENSION FUND'S MOTION FOR INTERVENTION

Dated: December 17, 2010

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Plaintiff Louisiana Municipal Police Employees' Retirement System ("Plaintiff") submits this memorandum of law in opposition to the motion filed by U.F.C.W. Local 1776 & Participating Employer Pension Fund (the "Movant") to intervene, and to subsequently stay these proceedings and appoint its own counsel as lead counsel (the "Motion").[1] As set forth below, the Motion should be denied in its entirety.

PRELIMINARY STATEMENT

When it was clear that this action was progressing smoothly and swiftly, the Movant sought to inject itself into the process with a belated books and records demand, and now seeks to delay the case – and have one of its counsel appointed as sole lead counsel – by moving to intervene and to stay this action based on its books and records demand, the results of which are speculative at best. The Movant, however, has not shown that its interests are not being adequately represented by the Plaintiff, or that it could assert claims or causes of action that would do anything but mirror those alleged in the Complaint. Indeed, the Movant has failed to put forth any indication that it could or would assert new claims or allegations or somehow craft a more compelling complaint. Accordingly, intervention here – whether as a matter of right or in the Court's discretion - is unwarranted and indefensible under Rule 24 of the Rules of the Court of Chancery (the "Rules").

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[1] References in the form (Mot. at ¶__) are to the Motion. References in the form (¶__) are to the Verified Amended Derivative Complaint filed October 11, 2010 (the "Complaint"). Unless otherwise noted, emphasis through italics, bolding or underlining is added herein.

Additionally, granting the Motion would serve only to unduly delay the adjudication of the rights of the original parties, while providing absolutely no benefit to Allergan, Inc.

("Allergan" or the "Company"), the entity on whose behalf Plaintiff brought this action.

As is clear from the Complaint and the briefing submitted on Defendants' motions to dismiss the Complaint, the record to support Plaintiff's fiduciary duty and corporate waste claims, and the record to support demand futility in this action, is overwhelming. From at least 1997 through 2008, the Allergan Board – the Individual Defendants herein – acted affirmatively in approving Strategic Plans that had, as their number one corporate priority, the illegal marketing and promotion of Allergan's flagship product, BOTOX®, for off-label uses not sanctioned by the United States Food and Drug Administration (the "FDA"). *See, e.g.*, ¶¶38-39. While the Complaint utilizes allegations in *qui tam* complaints and many other sources of information to assert this decade-long period of Board misconduct, Count I of the criminal Information – to which the Allergan Board authorized the Company to plead guilty – expressly asserted that Allergan engaged in illegal marketing and promotion of BOTOX® from at least January 1, 2000 through December 31, 2005, as follows:

> From on or about January 01, 2000, through on or about December 31, 2005 … defendant, ***Allergan, Inc.***, the producer and manufacturer of BOTOX … ***introduced into interstate commerce*** … ***quantities of BOTOX*** … ***which was misbranded*** under 21 U.S.C. § 352(f)(1), in that this drug … lacked adequate directions for its use, ***because the defendant Allergan, Inc., marketed and promoted the drug … for uses that were outside its labeling, to wit, off-label uses*** specifically for the treatment of headache, pain, spasticity, and juvenile cerebral palsy, ***and these off-label uses had not been approved by the Food and Drug Administration***.

Information at ¶1.[2]

The Information further expressly asserted that the Board members ***knew*** that the promotion of BOTOX® for unapproved uses violated FDA rules and regulations, and could subject the Company to enforcement actions, fines and penalties. Paragraph 15 of the Information quotes from Allergan's Form 10-K for the year ended December 31, 2004, which was signed by all members of the Board at that time, as follows:

> ***Companies cannot actively promote FDA-approved pharmaceutical, biologic or medical device products for off-label uses***, but they may disseminate to physicians articles published in peer reviewed journals…. ***If, however, our promotional activities fail to comply with the FDA's … regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA or another enforcement agency***.

As alleged in the Complaint, the Board members were also made aware on a regular basis of the Company's off-label BOTOX® sales compared to its on-label sales through monthly "Customer Surveys" that were forwarded to the Board. ¶35. Thus, this is not a case where the Board failed to catch mistakes of rogue employees, and where a plaintiff would need to allege either the lack of the Company's internal control mechanisms or the Board's utter failure to follow its internal control procedures in the face of so-called "red flags" to state a viable claim. Rather, as pleaded in the Complaint, this case involves actions of the Allergan Board through which the Board members affirmatively directed and approved Strategic Plans to increase the Company's off-label BOTOX® sales through an illegal promotion and market scheme.

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[2] The Information was submitted to the Court in the Transmittal Affidavit of Shannon E. German, dated October 25, 2010, in support of the Individual Defendants' opening brief in support of their motion to dismiss the Complaint. Along with certain other source materials, it is also being submitted herewith as Exhibit 3 in the accompanying Affidavit of Meghan A. Adams ("Adams Decl.").

The Complaint describes a wide range of actions and programs the Company implemented pursuant to the Board's Strategic Plans. These ranged from (a) paying illegal kickbacks to healthcare professionals for prescribing BOTOX® for off-label uses (¶¶66-71); (b) instituting an initiative through which Allergan exploited one of its four on-label indications to grow off-label pain and headache sales (¶¶40-43); (c) promoting the use of off-label seminars and presentations, at which physicians were instructed on various off-label uses for BOTOX® and how to bill Medicare for such off-label procedures (¶¶44-46); (d) developing corporate programs to further its Strategic Plans, including the BOTOX® Advantage Program, the Temporary Price Allowance Program, and the Physician Partnership Program (¶50); (e) approving the use of an extensive lobbying campaign to lobby government healthcare programs to expand coverage for off-label uses of BOTOX® (¶58); (f) approving the dissemination of false statements regarding the efficacy of BOTOX® for off-label uses to the public, physicians Allergan targeted, Allergan employees, Medicare contractors and others (¶¶59-65); and (g) approving, signing and issuing false statements in the Company's annual proxy statements filed with the SEC (¶¶72-77).

The foregoing allegations – which are pled in detail in the Complaint – were derived from a variety of legitimate sources.[3] These include: the Information filed on September 1, 2010, in *U.S. v. Allergan*, Criminal Action No. 1:10-CR-375-ODE (N.D. Ga.) (Ex. 3); the U.S. Department of Justice press release of September 1, 2010 (Ex. 4);

[3] Plaintiff's initial Complaint is attached to the Adams Decl. as Exhibit 1, and the Amended Complaint is attached as Ex. 2. The following source materials are attached to the Adams Decl. as Exhibits 3-12.

the complaint filed in *United States ex rel. Amy M. Lang & Charles Rushin v. Allergan, Inc.*, Civ. No. 1:07-1288-WSD (N.D. Ga.) (Ex. 5); the complaint filed in *United States ex rel. Cher Beilfuss & Kathleen O'Connor-Masse v. Allergan, Inc.*, Civ. No. 1:08-1883-WSD (N.D. Ga.) (Ex. 6); the complaint filed in *United States ex rel. Albert E. Hallivis v. Allergan, Inc.*, Civ. No. 1:09-3434-WSD (N.D. Ga.) (Ex. 7); documents obtained from personal injury and/or wrongful death case trials (examples at Ex. 8(a)-(m)); annual reports including letters to investors in such reports (examples and excerpts from the annual reports are at Ex. 9(a)-(c)); three Warning Letters sent to Allergan (Ex. 10(a)-(c)); the Charters of the Corporate Governance Committee and the Audit and Finance Committee of the Allergan Board (Ex. 11(a)-(b)); and the Company's Code of Business Conduct and Ethics (Ex. 12).[4]

Movant argues in the Motion to intervene that Plaintiff and its counsel are inadequate to represent the interests of the Company because Plaintiff filed a complaint without first making a books and records demand. As more fully described below, however, while a books and records review is certainly one avenue for discovering a factual basis for asserting a viable derivative complaint, another avenue is the use of public and other investigative materials, which was entirely appropriate in this case given the type of claims alleged in the Complaint and the wealth of information that Plaintiff

[4] As noted in Plaintiffs' opposition to the dismissal motions filed by Defendants, confirmation and further information concerning the allegations in Plaintiffs' Complaint were identified in the Government Memorandum in Support of Binding Plea and Sentencing Memorandum, filed October 4, 2010 (the "Sentencing Memorandum"), and the Plea and Plea Agreement of Allergan, Inc., dated October 5, 2010 (the "Allergan Plea"). These documents are attached to the Adams Decl., respectively, as Exhibits 13 and 14.

was able to access without resorting to the time-consuming process of a books and records search.

As a direct result of the Individual Defendants' misconduct, the Company pleaded guilty to a violation of the Federal Food, Drug, and Cosmetic Act (the "FDCA") and was forced to pay ***$600 million*** in criminal and civil fines, penalties and settlement payments.

For reasons stated in more detail below, the Complaint should be upheld notwithstanding the pending books and records proceeding, and the Motion to intervene should be denied. Given the admissions made by the Company in its guilty plea, the misconduct alleged in the Information by the Government and by former Allergan employees and affiliates in the *qui tam* complaints, the well-pleaded allegation that a widespread off-label promotion marketing scheme was undertaken pursuant to the Board's Strategic Plans over a ten year period, the Board's admitted knowledge of FDA rules and regulations, and the facts learned by the Plaintiff through its own investigation, including information from records of wrongful death and personal injury cases, there is no question that this Court should uphold the Complaint, reject the Defendants' arguments in seeking a dismissal of this case,[5] and deny the Motion to intervene.

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[5] As the Court is well-aware, on a motion to dismiss fact allegations in the Complaint must be taken as true, with all logical inferences made in the plaintiff's favor. *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896-97 (Del. 2002). Here, in addition to other permissible inferences that can and should be drawn in Plaintiffs' favor, the Allergan Plea and the Sentencing Memorandum provide many examples of the type of logical inferences that can and should be made from the facts pleaded in the Complaint. In the Allergan Plea, for example, the Company admitted that it was "pleading guilty ***because it is in fact guilty of the crime charged in Count One of the Criminal Information***." Allergan Plea at 1 & ¶19. As noted above, the operative paragraph in Count One specifically referenced the Company's wrongful promotion of off-label uses of BOTOX®. The Sentencing Memorandum further confirms the Plaintiff's primary allegation that the

PROCEDURAL HISTORY

After having filed its initial complaint on September 3, 2010, Plaintiff filed the operative Complaint in this action on October 11, 2010, on behalf of nominal defendant Allergan and against the Company's Board of Directors (the "Board" or "Individual Defendants"). The Complaint asserts a claim for breach of the Board members' fiduciary duty of loyalty and for the commission of waste. The Complaint alleges that, in breach of their duties to Allergan, the Board members directed the Company's management to aggressively and illegally promote its flagship drug, BOTOX®, for uses not approved by the FDA, which scheme included, *inter alia*, paying kickbacks to doctors in violation of the federal anti-kickback laws, making false and misleading statements in Allergan's

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Board acted affirmatively in approving Strategic Plans that had, as their number one corporate priority, the promotion of off-label uses of BOTOX®. As the Sentencing Memorandum states: "In its 1997 Strategic Plan, long before getting FDA approval for the off-label indications, Allergan made it a top corporate priority to maximize Botox sales for the treatment of off-label uses, including spasticity, migraine, and pain, and highlighted migraine and pain as two of Allergan's top three future growth opportunities. Even though BOTOX's on-label uses were very limited at the time, the 1997 Strategic Plan identified the brand as Allergan's fastest growing business, with the greatest peak year sales, and highest margins. In fact, several of Allergan's Strategic Plans forecast that Botox's on-label sales would shrink and that all growth from Botox Therapeutic would come from off-label sales. ***In order to meet the ambitious Botox sales goals demanded by its Strategic Plans, Allergan had to expand sales beyond the four narrow FDA-approved indications***." Sentencing Memorandum at 11. The Sentencing Memorandum also confirms Plaintiff's allegation that the illegal promotion scheme extended significantly beyond December 31, 2005, as follows: "Allergan dramatically expanded its therapeutic Botox field sales force ***far beyond levels justified by the drug's approved indications***. ***Between February 2003 and February 2008***, Allergan almost tripled its payroll of sales personnel, while obtaining only one very narrow label extension…. ***The clearest connection between the number of sales representatives and off-label sales growth was made in Allergan's 2007-2011 Strategic Plan***, which stated that in '2006 [Allergan] Added 45 New NMCs [sales representatives] & Spasticity grew 25% [and in] 2007 [it] Added 19 New NMCs & Spasticity Est[timated] 18%.'" Sentencing Memorandum at 27-28. Spasticity was not an FDA-approved use at the time of the 2007-2011 Strategic Plan. ¶39.

annual proxy statements, and committing other violations of the Civil False Claims Act, 31 U.S.C. § 3729, *et seq*., resulting in significant harm to the Company. ¶1.

On October 26, 2010, Allergan and the Individual Defendants (together, "Defendants") moved to dismiss the Complaint. Plaintiff filed a consolidated opposition to the dismissal motions on November 24, 2010, and Defendants filed reply briefs on December 8, 2010. Unbeknownst to Plaintiff, the Movant served its books and records demand on November 3, 2010. Movant filed the present Motion to intervene and to stay the action on November 30, 2010.

STATEMENT OF FACTS

BOTOX® has been one of Allergan's top-selling drugs and has constituted a major source of revenue for the Company. ¶¶31-34. Its rapidly increasing sales from 2000 to 2009 – during which time Allergan's total net sales of BOTOX® rose well over 500% – was fueled in large part by the Defendants' illegal off-label marketing scheme for the BOTOX® therapeutic product line. *Id*. Indeed, according to "Customer Surveys" that Allergan's Board and management used to track the Company's off-label sales of BOTOX®, the majority of Allergan's sales of BOTOX® therapeutic have been for off-label uses, and over 80% of the Government or insurance company reimbursements for BOTOX® have generally been for off-label prescriptions. ¶¶34-35.

According to Sally Yates, the U.S. Attorney for the Northern District of Georgia, with respect to BOTOX®, Defendants "made it a ***top corporate priority to maximize sales of far more lucrative off-label uses that were not approved by FDA***." ¶38. Indeed, in response to the criminal Information filed by the Government on September 1,

2010, the Board of Directors of Allergan authorized the Company to plead guilty to Count I of the Information, which alleged, *inter alia*, that from on or about January 1, 2000, through on or about December 31, 2005, Allergan "caused to be introduced into interstate commerce, quantities of BOTOX, a drug and biologic within the meaning of 21 U.S.C. § 321(g)(1) and 42 U.S.C. § 262(i), ***which was misbranded*** under 21 U.S.C. § 352(f)(1), in that this drug and biologic lacked adequate directors for its use, ***because the defendant ALLERGAN, INC., marketed and promoted the drug and biologic for uses that were outside its labeling, to wit, off-label uses*** specifically for the treatment of headache, pain, spasticity, and juvenile cerebral palsy, ***and these off-label uses had not been approved by the Food and Drug Administration.***" ¶98 (citing Information at ¶1); *see also* Information at ¶16 (stating that the four conditions BOTOX® had been approved to treat "were relatively rare in comparison to the off-label conditions ***that ALLERGAN actively promoted it to treat***"); ¶17 ("Since as early as its 1997-2001 Strategic Plan, ALLERGAN made it a top corporate priority to maximize sales of BOTOX for spasticity, migraine headache and pain, none of which were approved by the FDA. Many of ALLERGAN's yearly Strategic Plans forecast that BOTOX's on-label sales would shrink and that all incremental growth would come from off-label sales."); ¶21 ("Undeterred by the poor clinical trial results and FDA's unwillingness to expand the BOTOX label to include headache associated with CD without further evidence of efficacy. ALLERGAN continued ***to market and promote BOTOX for headache and pain by claiming that CD was misdiagnosed or underdiagnosed***."); ¶25 ("ALLERGAN used a variety of tactics ***to carry out its illegal off-label marketing strategy*** …"). Thus, not only did the guilty plea

admit the Company had engaged in the "misbranding" of BOTOX®, it also admitted that the Company had "marketed and promoted [BOTOX®] for uses that were outside its labeling."

As alleged in the Complaint, the Individual Defendants made off-label marketing of BOTOX® the centerpiece of the Company's 1997-2001 Strategic Plan, and its Strategic Plans thereafter. ¶39. As alleged in detail in the Complaint, pursuant to this corporate objective to effectuate the Strategic Plans and extensively promote off-label uses of BOTOX®, among other things, Defendants:

- Developed the "CD/HA Initiative," whereby they "exploited [Allergan's] on-label [CD] indication to grow off-label pain and headache" sales by claiming that CD was under-diagnosed and, even when doctors did not "see" any CD, those doctors could diagnose CD based on headache and pain symptoms (¶¶40-43);

- Had Allergan personnel convince doctors to mischaracterize patients' actual diagnoses and record inaccurate and fraudulent diagnoses that would allow these doctors to obtain reimbursement from the Government for BOTOX® used to treat myofascial pain, even though myofascial pain was an off-label use that is not covered by Medicare (*id.*);

- Held off-label seminars and presentations where, among other things, physicians (who were paid by Allergan for their attendance) were instructed (often by other physician/speakers paid by Allergan) on the various off-label uses of BOTOX®, including overactive bladder and neurogenic bladder, and how to bill Medicare for such off-label procedures (¶¶44-46);

- Hired injectors to attend off-label seminars and conducted and funded other off-label injection training sessions and workshops to train other doctors, thereby using its sales force as a network to facilitate such "injector training" for physicians (*id.*); and

- Provided Company sales representatives and field personnel with free vials of BOTOX® every quarter so that they could distribute them to physicians at no cost. ¶47.

As further alleged in the Complaint, Defendants ensured that the illegal marketing scheme to maximize revenue growth from off-label sales of BOTOX® was fully integrated into and permeated nearly every aspect of Allergan's corporate culture by, among other things:

- Dramatically expanding its therapeutic BOTOX® field sales force ***far beyond levels justified by the drug's approved indications*** **(**¶¶3, 32, 47-48);

- Developing and implementing a formalized Foundation Training course for Allergan personnel who were responsible for making sales calls on physicians (including those who would not typically treat patients who had any of the four FDA-approved conditions), which training included "specific and repeated discussions of *off-label* uses of BOTOX®, including the use to treat headache and pain," and training designed to teach Company personnel to specifically promote such off-label uses (¶51);

- Hiring Regional Scientific Specialists and "medical liaisons" (typically PhD's, pharmacists, or physicians) to work closely with the sales force to target physicians for off-label uses; Payor Reimbursement Account Managers to work with the sales force to identify physician advocates, who would assist Allergan in advancing its policy goals of expanding approved uses for BOTOX® and eliminating dose restrictions/maximums; and Provider Reimbursement Account Managers to provide in-kind consultation services (including reviewing physician claims payments, preparing excel spreadsheets on how to maximize reimbursement, conducting detailed audits of doctors' billing records to demonstrate how they could make more money by injecting BOTOX® for off-label uses, and operating the BOTOX® Reimbursement Hotline) to physicians the Company targeted to maximize reimbursements associated with prescribing BOTOX® for off-label uses. (¶¶41, 47, 48); and

- Establishing Customer Team Units whereby Allergan employees would track physician attendance at Allergan-sponsored off-label CME programs, target specific physicians for invitations to off-label CME programs, and identify physicians who utilized high volumes of BOTOX® for invitations to become "preceptors" or "key opinion leaders" who would be paid to train and lecture other physicians. ¶52.

Defendants also developed and instituted various corporate programs to further the Strategic Plans' goals of maximizing sales of BOTOX® for off-label uses, including the:

- BOTOX® Advantage Program™, whereby ***Allergan funded a third-party hotline*** with $10 million to $15 million annually pursuant to which physicians could call and obtain off-label billing assistance, including pre-drafted letters to insurance companies or government healthcare programs to obtain reimbursement for BOTOX® when prescribed for off-label uses (¶50);

- Temporary Price Allowance Program, which guaranteed physicians, targeted by the Company, an off-invoice discount equal to the annual price increase for that year, which Allergan devised to create a spread between each physician's acquisition cost of BOTOX® and the Medicare reimbursement amount (*id.*); and

- Physician Partnership Program, which allowed Allergan to use and pay physicians to be "travelling mentors" to promote off-label uses and doses for BOTOX®. *Id.*

In furtherance of its Strategic Plans, Defendants also made a number of false statements regarding the efficacy of BOTOX® for off-label uses, oftentimes citing to supposedly supportive scientific and clinical evidence, even when there was little actual clinical evidence that such uses were effective:

- During Allergan's CME programs and off-label injection training sessions;

- On websites that were funded and controlled by the Company;[6]

[6] Allergan aggressively used Company-controlled organizations and websites to market BOTOX® for off-label uses. ¶¶54-58. Alliance for Patient Access ("AFPA"), ***an organization that is fully-funded by Allergan***, assists with lowering coverage barriers by payors for-off label uses. ¶54. WE MOVE is an educational organization ***funded by Allergan and founded by Mitchell Bren, who is the chief scientific officer for BOTOX® at Allergan***. WE MOVE creates off-label dosing guidelines for spasticity, which Allergan then distributes to physicians as "medical literature." ¶55. ***Allergan also funds The Neurotoxin Institute*** ("NTI"), an organization whose purpose is to promote off-label

- In articles and abstracts published in journals and magazines ***that were ghost-written by Allergan employees, but submitted to professional journals under the names of practicing physicians***;[7] and

- To Medicare contractors in an attempt to convince them to enact coverage determinations reimbursing physicians for the use of BOTOX® to treat migraine headaches. ¶¶59-65.

Pursuant to the Board's Strategic Plans, the Company also offered and paid illegal kickbacks – in the form of cash, travel, lodging, and meals – to health care providers to induce them to order BOTOX® or BOTOX® injection services, where payment would be made under a federal health care program. ¶¶66-71. These payments, which were determined in a manner that accounted for the volume or value of business generated by the particular physician's prescriptions of BOTOX® for off-label uses, were made in

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uses of BOTOX® and provide doctors with off-label information regarding those uses. ¶56. The Government's Sentencing Memorandum expressly confirms these allegations in the Complaint, as follows: "In 2003, Allergan had a website designed by a large health care marketing corporation ***to appear as the education arm of an independent public interest entity.*** Allergan had an on-line neurotoxin institute created and ***directed its operation with the intent to seed the medical and scientific community with off-label promotional material about its unapproved uses of Botox.*** The Mission Statement for the on-line neurotoxin education organization was to 'validate and disseminate consistent information regarding the expanding uses of Botox.' However, ***an Allergan executive admitted its control over the organization, stating that 'they act under our direction in creating the content and setting direction.'"*** Sentencing Memorandum at 26.

[7] Confirming this key element of Allergan's Strategic Plans as pleaded in the Complaint, the Sentencing Memorandum states: "Allergan viewed physician advocates as the ultimate 'critical success factor' for gaining policy expansions for pain and headache and referred to the advocates as the company's 'Trojan horses.'" Sentencing Memorandum at 23. It further confirms that Allergan went to great lengths to conceal that it was the driver behind the physician advocates, failing to disclose its actions in documentation submitted to Medicare, ensuring that materials it "ghostwrote" did not look alike, and scheduling meetings with a Medicare Part B Carrier Medical Director to surreptitiously find out whether he suspected Allergan's involvement with the advocates. *Id*. at 23-24.

violation of the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b). ¶¶66-71. Health care providers were illegally compensated in the following ways:

- Through a series of invitation-only BOTOX® marketing programs organized by the Allergan Institute of Distinction, pursuant to which physicians recommended by Allergan sales and marketing personnel would be paid approximately $1,500 and provided with a free-of-charge stay in a full-service resort in Newport Beach, California (¶68); and

- Payment to healthcare providers for their participation in "preceptorships," pursuant to which Allergan sales representatives, reimbursement business managers, and regional healthcare policy managers would "shadow" a physician in order to promote BOTOX® for off-label uses. ¶69.

As more fully described in Plaintiffs' opposition to the dismissal motions, Allergan also spent approximately $4.85 million since 2005 to lobby government healthcare programs to expand coverage for off-label uses of BOTOX® and eliminate any payer-imposed limitation on the amount of BOTOX® injected into patients. ¶58. Allergan executed this part of the scheme by recruiting and using physician "advocates" to lobby Medicare and Medicaid to expand coverage. *Id*.

Finally, Defendants made numerous misstatements and omissions in Allergan's annual proxy statements regarding the Board's performance (or non-performance) of its duties with respect to the Company's off-label marketing of BOTOX®, including:

- Failing to disclose the extent to which the Company's financial performance depended on off-label marketing and promotion of BOTOX®;

- The circumstances surrounding the Board's waiver of the Company's Code of Business Conduct and Ethics (*see* Adams Decl., Ex. 12);

- The nature of the Board's performance of their duties under the Charters of the Board's various committees (*see id.*, Ex. 11(a)-(b)); and

- The numerous instances in which the Board was informed of legal compliance violations and/or criminal violations concerning the Company's unlawful marketing of BOTOX®. ¶¶72-77.

The Defendants' conduct detailed above was the subject of a multi-year investigation by the Government, which began in 2007 and culminated this year with Allergan agreeing to plead guilty to Count I of the Information and pay $600 million to resolve civil and criminal charges brought against it. ¶¶95-96.[8] Significantly, these figures do not include ongoing administrative legal fees and other costs, or any payments the Company has made, and may make in the future, as a result of wrongful death and other personal injury cases brought by persons who claim to have been injured by medical procedures using Botox® for off-label indications.[9]

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[8] As Plaintiff noted in its opposition to the dismissal motions, the $600 million payment is a massive amount for this Company. The Company reported $621.3 million in total net income in 2009, $563.1 million in 2008, and $499.3 million in 2007. *See* http://www.marketwatch.com/investing/stock/agn/financials. In the first and second quarters in 2010, the Company had total net income of $167.9 million and $240.1 million. *See* http://www.marketwatch.com/investing/stock/agn/financials/income/quarter. In contrast, in the third quarter 2010, Allergan reported a total net loss of $670.5 million, reflecting the tremendous damages the Individual Defendants' actions had on the Company. Notably, the $600 million payment is ***96%*** of the Company's reported net income in 2009, and more than 100% of its reported net income in both 2007 and 2008.

[9] Allergan has faced a plethora of products liability and wrongful death lawsuits related to off-label use of BOTOX®. ¶¶102-104. These suits allege that the Company illegally promoted BOTOX® for non-approved uses and failed to adequately warn about the risk of the severe and potentially life-threatening BOTOX® injuries they or their family members suffered. *Id*. Various of the suits have resulted in jury awards or settlements requiring Allergan to pay millions of dollars to the victims. *Id*.

Finally, in addition to the $600 million payment to resolve civil *qui tam* claims and pay a criminal fine, including the forfeiture of $25 million in assets (¶98), as part of the resolution, Allergan entered into a corporate integrity agreement ("CIA") with the HHS-OIG that requires the Company to (a) submit compliance reports, and to post on its website any payments to doctors, such as honoraria, travel or lodging; (b) maintain its current compliance

The resolution of the Government's investigation includes a civil settlement of $225 million to resolve claims that, from 2001 through at least 2008, Allergan "promoted BOTOX® for off-label indications that were not medically accepted and therefore not covered by federal health care programs, made unsubstantiated and misleading statements about the safety and efficacy of BOTOX® for off-label indications, instructed doctors to miscode Botox® claims for uncovered indications using inappropriate diagnosis codes to ensure payment by government health care programs, and provided inducements to doctors to inject more BOTOX®." ¶97. Moreover, while Allergan pleaded guilty to a criminal misdemeanor "misbranding" charge covering only the period 2000 through 2005, the Complaint expressly alleges that the Board misconduct continued through at least 2008 (*id.*), based in part on allegations in the three *qui tam* cases filed against the Company, and the Sentencing Memorandum states that the Company's 2007-2011 Strategic Plan continued to promote off-label uses of BOTOX®, further confirming this key allegation in the Complaint.

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program and undertake a series of compliance-related obligations, including additional monitoring, maintenance of specific written standards, auditing, training, education, reporting, and disclosure for five years; and (c) submit to a review, assessment and report of the Company's compliance program by an independent third-party review organization. *Id*. ¶101.

ARGUMENT

I. The Motion Should Be Denied Because the Movant Has Failed to Comply with Rule 24(c)

Rule 24(c) specifically requires the filing of a "pleading setting forth the claim or defense for which intervention is sought." The Movant, however, has failed to file a proposed pleading along with its Motion for intervention, and the Motion should be denied on this basis alone. *See Caras v. American Original*, 1987 WL 25366, at *1 (Del. Ch. Nov. 23, 1987) (motion to intervene denied, *inter alia*, for failure to file a pleading setting forth a good claim or defense) (citing *Wright & Miller, Federal Practice and Procedure*: Civil 2d § 1914 (1986)).

The Movant makes a half-hearted attempt to justify this failure by asking that this action be stayed pending Movant's receipt of Company documents in response to its books and records demand. Movant cannot have it both ways. On the one hand, Movant is asserting that it cannot file a proposed "complaint in intervention at this time because it has not yet received the documents in response to its books and records demand." Mot. at n.1. On the other hand, it is arguing that "Allergan is in the process of procuring certain requested books and records" and Movant "is in the process of obtaining" such books and records, which contain "new, relevant information … not available to [Plaintiff] and not presented in [Plaintiff's] complaint" that would allow Movant to "vigorously litigate the case" and "adequately represent the shareholders' interests." Mot. at ¶¶ 20, 25. Movant fails, however, to set forth what those documents are, and provides no indication that the documents it expects to obtain through its books and

records demand would be of any value in crafting new claims, facts, or allegations in any complaint that the Movant could file in the future.

Accordingly, Movant's failure to file a proposed complaint and to identify what type of documents it has already received and/or plans to receive in response to its books and records demand provides a threshold issue upon which the Motion should be denied.

II. Intervention as a Matter of Right Under Rule 24(a) is Not Permissible Here

Rule 24(a)(2) permits a person to intervene in an action "when the applicant claims an interest relating to the property or transaction which is the subject of the action *and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties*." Ct. Ch. R. 24(a) (emphasis added). In assessing a motion to intervene under Rule 24(a)(2), "a court must first determine if the applicant has an interest at risk in the litigation." *See Marie Raymond Revocable Trust v. MAT Five LLC*, 980 A.2d 388, 398 (Del. Ch. 2008).

Here, the Movant does not have an "interest at risk" in this action, nor will it – or the Company for that matter – be adversely affected if the Motion to intervene is denied. On the one hand, if the Complaint is upheld, as it should be, there will certainly be no harm to the Movant since the Plaintiff will then be entitled to conduct full discovery of the Company and the Individual Defendants. Indeed, the Motion will simply delay these proceedings, and delay the time when the Plaintiff will be able to obtain unfettered discovery from Allergan and the Individual Defendants, rather than the limited production that might be available under a books and records demand. *See* Mot. at ¶23,

citing *Norfolk Cnty. Ret. Sys. v. Jos. A. Bank Clothiers, Inc*., 2009 Del. Ch. LEXIS 20, at *18 (Feb. 12, 2009).

On the other hand, if the Complaint is dismissed, there would be no impediment to the Movant in moving forward with its books and records demand. Indeed, even if this Court were to dismiss the case on demand futility grounds – which, Plaintiff respectfully submits, it cannot given the facts pleaded in the Complaint – if the Movant "makes substantially different allegations of demand futility based on additional information, issue preclusion, from both a logic and fairness standpoint, would not apply." *W. Coast Mgmt. & Capital, LLC v. Carrier Access Corp.*, 914 A.2d 636, 643 n.22 (Del. Ch. 2006). Thus, if its books and records demand were to somehow produce significant new facts that the Movant could use to craft a new complaint with substantially different allegations, denial of the Motion to intervene would cause it no harm.

The cases cited by the Movant in this regard do not change this result, as they are inapposite to the situation presented here. Each of the cited cases involved second plaintiffs that alleged substantially similar allegations and claims as those alleged in an existing complaint filed by an initial plaintiff. This is precisely what the Movant claims it would *not* do once it obtains documents pursuant to its books and records demand. *See In re Career Educ. Corp. Deriv. Litig.*, Consol. C.A., 2007 WL 2875203, at *14 (Del. Ch. Sept. 28, 2007) (dismissal warranted because issue preclusion barred shareholders from relitigating demand futility since prior derivative action against defendants had been dismissed and the two actions involved the same claims, facts, and allegations pertaining to demand futility); *Henik v. LaBranche*, 433 F. Supp. 2d 372, 381-82 (S.D.N.Y. 2006)

(issue preclusion barred second derivative suit that raised identical issues regarding demand futility as the prior derivative suit); *In re Sonus Networks Inc. S'holder Deriv. Litig.*, 422 F. Supp. 2d 281, 294 (D. Mass. 2006) (demand futility question was virtually identical in both cases and any "new" factual allegations in second complaint were "not the result of a different factual situation or changed circumstances sufficient to transform the demand futility question").

Further, as explained in greater detail in Section III below, there is absolutely no indication that Plaintiff is not capable of prosecuting this derivative action on behalf of the Company or its shareholders. To the contrary, Plaintiff has been a forthright advocate for and representative of the Company and its shareholders. It, and its counsel, made a detailed investigation of public and, even, difficult to access sources of information in drafting the Complaint, have vigorously prosecuted this action from the outset, and are more than capable of representing the interests of the Movant and other injured parties.

Accordingly, intervention as a matter of right pursuant to Rule 24(a) does not apply here.

III. Permissive Intervention Pursuant to Rule 24(b) is Not Warranted Here

It is well established that a motion for discretionary intervention under Rule 24(b) should be denied if it "restates claims pled by the original plaintiff or if the original plaintiff adequately can represent the intervenor's interest." *S. St. Corp. Recovery Fund I v. Salovaara*, 1999 WL 504778, at *2 (Del. Ch. July 9, 1999); *see also Wier v. Howard Hughes Med. Inst*., 404 A.2d 140, 145 (Del. Ch. 1979) ("where the petition for leave to

intervene adds nothing to the claim asserted in the original complaint, leave to intervene may appropriately be denied").

As set forth below, the Movant has utterly failed to show that any complaint it might file would contain new facts or allegations or set forth new legal arguments, or that Plaintiff and its counsel cannot adequately represent the Movant's interests in this action.[10] Moreover, granting the pending Motion to intervene would only serve to unduly delay these proceedings and prejudice the original parties to this action. *See Marie Raymond Revocable Trust*, 980 A.2d at 399 (permissive intervention denied where such intervention would unduly delay the action and prejudice the existing parties); *see also* Rule 24(b) ("In exercising its discretion the Court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties"). Under the relevant law and the facts of this case, the Court should not use its discretion to permit the Movant to interfere in these proceedings with no apparent benefit to the injured party – the Company.

A. The Movant Inappropriately Seeks to Restate Claims Pled by the Plaintiff

Although the Movant has failed to file a proposed complaint - which is a violation of Rule 24 that requires the Motion to be denied on this basis alone - it appears that any

[10] Plaintiff acknowledges that it did not reference the Sentencing Memorandum in the Amended Complaint filed October 11, 2010. However, as noted above and in Plaintiff's opposition to the dismissal motions, the allegations in the Complaint are clearly sufficient to demonstrate both demand futility and the viability of the claims asserted in the Complaint. Further, to the extent the Sentencing Memorandum adds to the mix, it essentially iterates logical and reasonable inferences that are otherwise permissible to draw in Plaintiff's favor from the facts alleged in the Complaint and, as a result, this oversight does not impair Plaintiff's ability to vigorously prosecute this case.

such complaint would (a) merely re-plead what is contained in Plaintiff's Complaint and/or plead logical inferences that the Court should already draw in Plaintiff's favor from the Complaint's allegations, and (b) assert claims and legal arguments that are identical to the claims and arguments already made by the Plaintiff. Under these circumstances, the Motion to intervene should be denied. *See S. St. Corp.*, 1999 WL 504778, at **2-3 (denying intervention where proposed complaint stated identical claims to original complaint and raised legal arguments that could be made under the certain counts of the original complaint). As the Court stated in *South Street Corp*., in the absence of new claims or legal arguments, whether an original complaint or an intervenor's proposed complaint is the operative complaint, "[e]ither way, the Court will have to resolve the same set of issues." *Id.* That is precisely the case here.

In fact, when one compares the Movant's books and records demand letter of November 3, 2010 with the allegations in the Complaint filed by Plaintiff on October 11, 2010, it is apparent that the acts that might be reflected in the documents sought in the books and records demand are already alleged, with specificity, to be within the knowledge of the Allergan Board and/or approved by it. For example, while the Movant has demanded books and records concerning "the Company's sales, marketing, or branding of BOTOX," *see* Mot. at ¶15, the Complaint is replete with allegations concerning these issues, including that the Individual Defendants were provided with monthly Customer Surveys that tracked specifically sales of BOTOX® for off-label uses compared to FDA-authorized uses. *See, e.g.*, ¶¶ 27-58, 59, 61, 63, 64, 67, 68, 69, 73, 78-94. While the Movant demanded books and records concerning "specific studies or

documents" regarding BOTOX®, *see* Mot. at ¶15, the Complaint already contains numerous allegations regarding such BOTOX® studies. *See*, *e.g.*, ¶¶55, 57, 61, 63, 64, 85, 90, 92; *see also* Adams Decl., Exs. 5-7. As a further example, the Movant demanded books and records reflecting "procedures, protocols, or controls created, designed, or intended to ensure compliance with" the FDAC or other federal health care programs, *see* Mot. at ¶15. However, the Complaint already contains detailed allegations regarding, among other things, the Company's Code of Business Conduct and Ethics, which relates to compliance with applicable laws and regulations and worldwide clinical and regulatory standards, including any waiver thereof, and the Charters of the Board's various committees, which concern compliance-related duties affecting Allergan and require general compliance oversight of the Company, among other duties. *See*, *e.g.*, ¶¶74-75, 115-17; *see also* Adams Decl., Exs. 11(a), 11(b) & 12.[11] Thus, there is virtually nothing in the books and records demand that hasn't already been alleged with specificity in the Complaint, and the Movant has completely failed to present any evidence that it has received or will receive any new, material information.

Moreover, as shown above and in Plaintiff's opposition to the dismissal motions, the Complaint filed by the Plaintiff is comprehensive and should withstand defendants' motions to dismiss, both with respect to the merits of the action and defendants' demand futility and 12(b)(6) arguments, without the delay inherent in a books and records

[11] Other demands pertain to the Company's settlements of the *qui tam* actions, its Settlement Agreement with the Government, and the CIA. However, Plaintiff already utilized the complaints filed by the Government and by the *qui tam* plaintiffs in drafting Plaintiff's Complaint, thereby negating any likely value of any responsive documents that Allergan would produce (which, in any event, will likely be objected to as privileged).

demand. On a motion to dismiss, a court must accept all well-pleaded allegations of fact as true and make all reasonable inferences in favor of the plaintiff. *Savor*, 812 A.2d at 96-97. Given the specificity of the facts alleged in the Complaint, there was simply no reason that the Plaintiff was required to, or should have, sought documents from Allergan under a books and records demand. Indeed, the facts alleged in the Complaint make clear that this Board: (a) acted affirmatively, with knowledge, in approving illegal Strategic Plans; (b) committed *ultra vires* acts not protected by the business judgment presumption; and (c) acted in a way that would made it impossible for the Board – all of whom approved the illegal strategic plans – to consider a demand in a disinterested manner.

In *Rales v. Blasband*, 634 A.2d 927, 934 n.10 (Del. 1993), the Supreme Court of Delaware noted that shareholders have "many avenues available to obtain information bearing on the subject of their claims." While it noted that one such avenue, sometimes underused, is a books and records demand, the Court also expressly stated that a plaintiff may draft a viable complaint with the use of "public sources from which the details of a corporate act may be discovered, including the media and governmental agencies such as the Securities and Exchange Commission." *Id*. Here, Plaintiff took advantage of the many public sources of information available – the criminal Information, the Government's press release, the *qui tam* complaints, exhibits and testimony from certain public trials against Allergan based on its off-label uses of BOTOX®, prior Warning Letters, corporate Charters and the Ethics Code, and, among other sources, Allergan's public statements and financial results – all of which confirmed the key fact pleaded in the Complaint, that is, that Allergan's Board, for a period of more than ten years,

approved Strategic Plans that called for the Company to illegally market and promote off-label uses of BOTOX®.[12] These sources of information further detailed the many ways in which the Company's management and employees implemented the illegal promotion scheme approved by the Board, which are alleged with particularity in the Complaint.

Thus, it is highly likely that any claims the Movant may assert in a complaint it might file, based on whatever information that it may receive in response to its books and records demand, would be redundant of the facts and claims already pleaded by Plaintiff.

B. The Plaintiff Can Adequately Represent the Movant's Interests

Permissive intervention should also be denied because the Movant has failed to make any showing that its interests are not adequately protected by Plaintiff or that Plaintiff is not capable of prosecuting this derivative action. Plaintiff currently holds 3600 shares of Allergan stock and has been an Allergan shareholder continuously since before January 1, 2000. Its standing to bring the claims alleged in the Complaint is not disputed, nor does the Movant identify any other procedural or other deficiency with respect to the Plaintiff or its counsel that could somehow provide a valid basis granting

[12] For example, the Ethics Code provides that waivers of the Code may be made on a "case-by-case basis," that waivers for directors or executive officers may be made only by the Board of Directors or the appropriate committee of the Board, and that such waivers must be promptly disclosed to the public. *See* ¶74; *see also* Adams Decl., Ex. 12 at 12. But no such disclosures were made. The Corporate Governance Committee Charter provides that the Committee will seek directors who are recognized as leaders in the fields of medicine or the biological sciences, and that each director should have relevant expertise and experience. *See* ¶75; *see also* Adams Decl., Ex. 11(a) at 2-3. This provides a further factual basis for Plaintiff's claim that the Individual Defendants were aware of the illegality of the Strategic Plans they approved. Thus, both of these documents – and the many others cites herein – provided a good faith basis for allegations in the Complaint.

discretionary intervention here.

Indeed, the Plaintiff and its counsel have vigorously pursued this case from the outset. When it was announced on September 1, 2010, that Allergan had reached an agreement with the U.S. Department of Justice to resolve criminal and civil allegations that it actively promoted its top-selling product, BOTOX®, for unapproved uses and had agreed to pay $600 million in criminal and civil penalties for its illegal conduct, Plaintiff and its counsel undertook an investigation into the Company's sales and marketing practices and the circumstances surrounding the wrongdoing alleged in this case. Plaintiff's counsel analyzed the *qui tam* complaints that were filed against Allergan and the allegations made therein. They reviewed the three Warning Letters cited in the Complaint, all of which related to prior instances where the FDA cited Allergan for misbranding or false promotion violations (the first one involving BOTOX® cosmetic, which referred to an earlier "Untitled Letter" alleging the same misconduct, and the latter two that were sent directly to CEO and Chairman Pyott). And they reviewed the materials released by the Government in connection with its multi-year investigation into the Company's sales and marketing practices, as well as other documents released to the public, including the corporate integrity agreement ("CIA") that Allergan entered into with the Department of Health and Human Services, Office of Inspector General in connection with the resolution of the governmental investigation.

Through its counsel, Plaintiff also analyzed the Company's financial statements and proxy statements, which provided the Plaintiff with a basis to allege numerous false statements and material omissions regarding, among other things, critical aspects of the

Board's performance (or non-performance) relating to the Company's off-label marketing of BOTOX® and important demand futility allegations. Plaintiff and its counsel investigated the circumstances surrounding several wrongful death lawsuits and other personal injury cases that had been filed against the Company by persons who claimed to have been injured by medical procedures using BOTOX®. This investigation allowed Plaintiff to uncover various internal Company documents, as well as testimony, that provided substantial allegations regarding the wrongdoing alleged in this case, and in particular, the Individual Defendants' knowledge of the extent of the off-label sales made by the Company through its marketing and misbranding practices, and the multiple actions that Allergan took to further the Strategic Plans approved by each of the members of the Board.

Plaintiff set forth the results of its investigation in an initial complaint filed on September 3, 2010, and more fully in the Amended Complaint filed on October 11, 2010. Plaintiff and its counsel were thus able to craft a cohesive and persuasive Complaint, on behalf of the Company, without the need for a books and records demand.

Furthermore, in addition to the information that was publicly available and the additional information that their investigation uncovered, Plaintiff's counsel is well-versed in litigation involving violations of the FDAC. Plaintiff's counsel filed one of the complaints against Pfizer that was consolidated and upheld in Judge Rakoff's July 2010 decision, *see In re Pfizer Inc. S'holder Derivative Litig.*, Master File No. 09 Civ. 7822 (JSR), 2010 U.S. Dist. LEXIS 69593 (S.D.N.Y. July 13, 2010), was deeply involved in the discovery in that case, and has now supported the proposed settlement of that action,

which has been granted preliminary approval by Judge Rakoff. As demonstrated in Plaintiff's brief in response to the motions to dismiss filed by Defendants in the present action, the facts pleaded in the Complaint are more compelling than the facts found by Judge Rakoff to be sufficient to uphold the complaint in *Pfizer*, in the face of the same kind of demand futility and 12(b)(6) arguments made there. Plaintiff's counsel also served as sole lead counsel in the securities fraud class action against Schering-Plough that resulted in a $165 million recovery for the class, which provided counsel with an even deeper base of knowledge concerning the FDAC.

Allowing Movant to intervene would merely delay the progress of the case with no apparent benefit to the injured parties.[13] Given the foregoing, Plaintiff respectfully submits that the conclusion reached by Chancellor Chandler in *South Street Corp*. is applicable here:

> This Court will deny a motion to intervene under Court of Chancery Rule 24 where the movant's claims are identical to the claims already raised and where the movant's interests are adequately protected by the original plaintiff(s). Here, I find that both conditions are met. The intervenors' claims are identical to the original claims and their general partner is pursuing them adequately and fairly.

1999 WL 504778, at *4.

Discretionary intervention under Rule 24(b) should therefore be denied.

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[13] The Movant refers to the related cases pending in California. *See* Mot. at ¶13. Plaintiff notes that although those cases were filed after the initial complaint filed by Plaintiff here, if the Court were to delay these proceedings in order to allow the books and records process to move forward, it is likely that the California court would take hold of the case. This would not be a good result for the Company or its shareholders, since the complaint in California pleads what is essentially a *Caremark* claim, which is far less likely to result in a recovery for the Company than the Complaint filed by Plaintiff here.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully submits that the pending motion to intervene should be denied in its entirety.

Dated: December 17, 2010

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