UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ANDREW NELSON,	x	Civil Action No. 12-7317
Plaintiff,	x	**FOURTH AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL**
vs.	x	
BIOGEN INC. AND ELAN PHARMACEUTICALS, LLC.,	x	
Defendants.	x	

Plaintiff, by and through his attorneys, for his Fourth Amended Complaint and Jury Demand against Defendants alleges as follows:

BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' and/or its corporate predecessors' negligent and wrongful conduct in connection with the development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the immunosuppressant natalizumab, sold under the trade name " Tysabri®."

2. This suit is brought under the causes of actions under the statutory and common laws of the State of New Jersey to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries Plaintiff sustained as a result of the Defendants' and/or their corporate predecessors' negligent and wrongful conduct in connection with, inter alia, the development, formulation, manufacturing, testing, packaging, promoting,

marketing, distributing, labeling, recommended dosing and/or sale of the immunosuppressant natalizumab, sold under the trade name " Tysabri®."

PARTIES

3. At the initiation of this action, Plaintiff was a resident and citizen of the State of New Jersey. Plaintiff resided at 3304 Autumn Drive, Tinton Falls, NJ 07753. Plaintiff currently resides at 8 Fairhaven Drive, New City, New York 10956.

4. Defendant Biogen Inc., formerly Biogen Idec Inc., ("Biogen") is a Delaware corporation with a principal place of business at 225 Binney Street, Cambridge, MA, Middlesex County, Massachusetts 02142. Biogen's principal place of business when Plaintiff initiated this action was 133 Boston Post Road, Weston, Middlesex County, Massachusetts 02493.

5. Defendant Elan Pharmaceuticals, LLC ("Elan"), formerly Elan Pharmaceuticals, Inc., is a limited liability company organized under the laws of the State of Delaware with a principal place of business at 515 Eastern Avenue, Allegan, MI 49010. Defendant Elan is a wholly-owned subsidiary of Athena Neurosciences, LLC. Athena Neurosciences, LLC is a wholly owned subsidiary of Elan Holdings Limited. Elan Holdings Limited is a wholly owned subsidiary of Elan Corporation Limited ("Elan Corp."). Elan Corporation Limited is a wholly owned subsidiary of Perrigo Company plc.

6. At all times relevant, Defendant Elan was in engaged in a joint enterprise with Biogen and engaged in the business of developing, licensing, manufacturing, packaging, distributing, selling, marketing, and/or introducing into interstate commerce, and into the State of New Jersey, either directly or indirectly through third parties or related entities, the immunosuppressant natalizumab, sold under the trade name "Tysabri®."

7. At all times relevant to this action, Defendant Elan was the registered trademark holder and distributor for Tysabri® in the United States.

8. At all times relevant hereto, Defendants acted through their directors, officers, employees, affiliates, subsidiaries, and other agents, and their acts within the scope of their agency and employment.

9. Biogen and Elan are subject to the jurisdiction and venue of this Court.

JURISDICTION & VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) (1) because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

11. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) (1) because Defendants reside in this District. Defendants reside in this District for purposes of 28 U.S.C. § 1391 because they are subject to personal jurisdiction in this District. Defendants are subject to general personal jurisdiction in this District because they have continuous and systematic contacts with this District through marketing and distributing Tysabri® in this District. Defendants have purposefully availed themselves of doing business in New Jersey under the protection of New Jersey's laws, and the exercise of personal jurisdiction over Defendants in this District does not offend traditional notions of fair play or substantial justice.

12. Venue is proper in this division because Plaintiff received Tysabri® infusions and treatment in Bergen County. Plaintiff commenced Tysabri® infusions with his physician Dr. Kenneth Citak at Neurology Group of Bergen County, 1200 East Ridgewood Avenue, Ridgewood, NJ 07450. Plaintiff received the infusions at Valley Health Medical Group, 15 Essex Rd #24, Paramus, NJ 07652.

FACTUAL BACKGROUND

13. In August 2000, Defendants Biogen and Elan announced that they had entered into a joint collaboration agreement to bring Tysabri® to market. The agreement required Defendants Biogen and Elan to share equally in the revenues and costs and set up a number of joint teams. Both companies participated in the development of Tysabri®, including clinical trials, as well as the marketing of Tysabri®, generically known as natalizumab. The agreement also required that any information discovered by one company, including adverse events, be reported to the other company in a timely manner.

14. In May 2004, Biogen and Elan Corp. submitted a Biologics License Application ("BLA") to the FDA for approval of Tysabri® for the treatment of MS.

15. Tysabri® (natalizumab), formerly known as Antegren, is a potent immunosuppressant drug. In November 2004, the United States Food and Drug Administration ("FDA") approved Tysabri® for the treatment of remitting and relapsing multiple sclerosis ("MS"). On or about November 24, 2004, Defendants began to market and distribute Tysabri® in the United States.

16. MS is a degenerative neurological disease characterized by recurrent episodes of inflammation in the white matter of the central nervous system ("CNS"). Surrounding and protecting the nerve fibers of the central nervous system is a fatty tissue called myelin, which helps nerve fibers conduct electrical impulses. The inflammation destroys the myelin sheath, a covering of the nerve cells leaving multiple areas of scar tissue and adversely affecting CNS function.

17. Tysabri® is a monoclonal antibody that binds to a specific site on lymphocytes, interrupting cellular communication in the immune system. Tysabri® prevents lymphocytes

from migrating from the bloodstream into the brain where they can cause inflammation and damage cells that insulate nerve fibers in MS patients. However, it is also believed that Tysabri® prevents white blood cells both from migrating to places in the body where they are needed, leaving a patient vulnerable to "opportunistic infections," which occur when ordinarily benign organisms infect individuals with impaired immune systems.

18. Since approximately 1992, Tysabri® has been linked to one such opportunistic infection, Progressive Multifocal Leukoencephalopathy ("PML"). PML is a typically fatal brain disease caused by the immunosuppressive effects of Tysabri®. Specifically, PML is caused by JC virus, a strain of papovavirus ordinarily latent in the human kidney, replicating in the brains of individuals with impaired immune systems. It is estimated that approximately fifty to sixty percent of the population has contracted the JC virus. PML manifests itself with symptoms such as impaired cognition, difficulty thinking, cortical blindness and weakness on one side of the body. PML usually results in death within one to four months of the onset of the disease, but some patients live years.

19. On or about October 23, 1996, Athena Neurosciences, Inc ("Athena") filed an investigational new drug ("IND") application number BB-IND 6895 for Tysabri® (natalizumab) with the FDA. On or about July 1, 1996, Elan acquired Athena and all rights to the IND application number BB-IND 6895. On or about January 19, 1999, Athena notified the FDA that the IND application number BB-IND 6895 had been transferred to Elan.

20. In August of 2000, Biogen and Elan entered into a "Development and Marketing Collaboration Agreement" between Biogen, Inc. and Elan (the "Agreement") under which Biogen and Elan exchanged "worldwide royalty-free" co-exclusive licenses to develop, manufacture, distribute, and sell Tysabri®. The Agreement required the establishment of a Joint

Steering Committee ("JSC"), comprised of three senior members of Biogen and Elan Pharma Intl, respectively, to oversee and manage a newly created Joint Project Team and Joint Commercialization Team ("Joint Project Team"). The JSC was required, among other things, "to ensure a regular flow of information between the parties."

21. Article 13.3 of the Agreement, was captioned ADVERSE DRUG EVENTS, and provided, in pertinent part, as follows:

The Parties agree that the groups responsible for the safety surveillance and pharmacovigilance of the Licensed Product [including Tysabri®] at each company shall meet within sixty (60) days following the Effective Date to develop detailed procedures regarding the format, timing and content of the safety information to be exchanged between the parties, and shall meet periodically thereafter to update the procedures.

22. Under the agreement both Defendant Biogen and Defendant Elan bear responsibility for labeling changes. Section 4.5(a) of the agreement states that "Each Party shall be given the opportunity to have one or more of its representatives participate in all substantive discussions and meetings with Regulatory Authorities, which relate to Licensed Products, including, but not limited to, with respect to any Drug Approval Applications."

23. Section 5.4 of the agreement further states that neither party may add, delete or modify claims of efficacy or safety in its promotion of any licensed product unless it is approved by the JCT. The agreement contemplates that both Biogen and Elan act in concert regarding the labeling and warnings for Tysabri®.

24. As far back as 1992, based on animal studies and other in vitro experiments, scientists who developed Tysabri® concluded that it was far too dangerous for use in humans. As mentioned above, individuals who take Tysabri® become susceptible to PML because

Tysabri® suppresses the immune system. By suppressing the immune system, Tysabri® allows the JC virus, ordinarily latent in a patient's kidney, to travel to the brain via the bloodstream, where it begins uncontrolled replication.

25. Despite the above evidence, in May 2004 Biogen and Elan Corp. submitted a Biologics License Application ("BLA") to the FDA for approval of Tysabri® for the treatment of MS. The submission included one-year data from ongoing trials which Defendants refused to disclose to the public. Although Biogen is the BLA holder, Elan participated in the decisions and developed leading up to the BLA and after. Elan remained a co-marketer and co-developer of Tysabri® after approval.

26. In February 2005, as a result of three reports of patients being diagnosed with PML and two cases proving fatal, the FDA withdrew Tysabri® only three months after its approval, and all clinical trials were put on hold. A year later, in February 2006, Defendants conducted a clinical trial in which they reported no additional cases of PML. Consequently on June 5, 2006, the FDA permitted Tysabri® to come back on the market.

27. The FDA's approval for the reintroduction of Tysabri® into the market restricted the drug's use to monotherapy for remitting and relapsing MS. To gain FDA approval for reintroducing Tysabri® on the market, Defendants developed the Tysabri® Outreach: Unified Commitment to Health ("TOUCH") prescribing program. TOUCH requires every Tysabri® prescriber, infusion site, and MS patient receiving Tysabri® in the United States to enroll in the risk management program run by Defendant Biogen that monitors patients for any signs of PML.

28. On March 1, 2005, the New York Times published an article in which Dr. Lawrence Steinman, a professor of neurology and head of immunology at the Stanford University School of Medicine and a leading expert on Tysabri® who participated in its original

development, stated that no one should have been surprised that patients being treated with Tysabri® would contract PML. According to Dr. Steinman, the risk of serious infections like PML was "unfortunately logical" given that Tysabri® works by interfering with the immune system. Dr. Steinman said, "I'm shocked that it happened so soon, but I knew it was going to happen sooner or later." Dr. Steinman also said that Biogen executives asked him to tone down his criticisms of Tysabri® after he had expressed his apprehensions about the drug in speeches and in an article in the journal *Science* in July 2004.

29. In 2006, Dr. Steinman published an article entitled "Progressive Multifocal Leukoencephalopathy and Multiple Sclerosis: Lessons from Natalizumab." Dr. Steinman stated that "Biogen and Elan were quick to present efficacy data in the entire study populations through their various marketing methods….however, no data from the two phase III trials have been published." Dr. Steinman concluded that drugs, such as Tysabri®, with unknown safety profiles would not be tested on patients with a favorable prognosis and certainly not on those with a questionable diagnosis.

30. In an interview with the Associated Press on or around July 24, 2008, Shane Cooke, Chief Financial Officer of Defendant Elan Corp., stated that "neurologists and their MS patients in North America and Europe were increasingly confident that Tysabri® . . . was safe when used on its own." Cooke also said "the further we go (without any new PML cases), the more comfortable that people become and the more that patients demand to be put on Tysabri®."

31. Upon information and belief, at this time, Defendant Biogen developed a marketing strategy that involved a strategic publication plan in which the primary goal was to reinforce Tysabri®'s efficacy and to ghostwrite articles regarding the perceived efficacy of Tysabri®. Biogen used key opinion leaders and paid consultants to push the efficacy of Tysabri® in an

effort to compete with the other MS drugs on the market.

32. On July 30 and 31, 2008, two more cases of PML were reported in patients who had taken Tysabri®. Although Defendant Biogen claimed that the first case of PML was reported to the company on July 30, 2008, upon information and belief, Plaintiff allege that Defendants withheld material information about those two PML cases from the public for at least two months prior to their announcement. The first case of PML occurred in a patient who had received Tysabri® monthly monotherapy for seventeen months. The second case of PML occurred in a patient who had received Tysabri® monthly monotherapy for fourteen months.

33. Plaintiff is informed and believes that Defendants withheld material information about twelve suspected PML cases linked to Tysabri®. Prior to July 24, 2008, those twelve cases were privately reported in the FDA's Adverse Event Reporting System ("AERS"), a computerized information database to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. At least two of those twelve cases were reported by doctors as early as May 2008, when Tysabri® was used as monotherapy.

34. On August 1, 2008, Defendants held a joint conference call to discuss the two confirmed cases they had announced publicly. Officials for Defendant Biogen refused to disclose or discuss the number of Tysabri® patients suspected to be afflicted with PML. Defendant Biogen spokeswoman Naomi Aoki declined to provide any more specifics about the suspected PML cases, stating that "we don't want to get into the whole business of discussing suspected cases." When pressed by media outlets, Biogen refused to discuss the prognosis of the patient and whether the patient might die.

35. Upon information and belief, Defendant Biogen and Elan sent a Dear Healthcare Professional Letter advising of two PML adverse event cases, but failed to state that the longer

treatment duration increased the risk of PML despite the fact that one patient had received infusions for 14 months and the other received infusions for 17 months. Instead, Defendants stated that clinical vigilance is the most important factor in these cases. Even worse, Biogen continued to allege that there was no clear relationship between duration treatment and developing PML.

36. Between October 29, 2008 and July 24, 2009, nine additional cases of PML were publicly reported after treatment with Tysabri® monthly monotherapy for longer treatment duration.

37. After the July 24, 2009 announcement, Defendants stopped sharing information about new cases with the public on their websites. Specifically, Defendant Biogen stated that any new cases would be reported by word of mouth to medical professional and patient groups. Additionally Biogen stated that it would not be providing updates on the status of past PML patients other than at presentations at medical meetings. Biogen further indicated that physicians who wanted more information could call medical Affairs regarding the PML cases.

38. In September 2009, two more cases of PML were reported in patients taking Tysabri®. One case was reported in the New England Journal of Medicine, and the other was reported by Ralf Gold of the Ruhr University Bochum in Germany, who presented the data at the European Committee for Treatment and Research in Multiple Sclerosis. Defendant Biogen refused to comment on or confirm the existence of those PML cases.

39. In a letter dated March 26, 2009, the FDA notified Defendant Biogen's Senior Vice President of Regulatory Affairs that Defendant Biogen' s promotion of Tysabri® was misleading because they "fail to communicate **any** risk information associated with the use of this product."

40. In November 2009, Defendants announced that they were updating the U.S. label for Tysabri® to reflect the increased risk of PML when the drug is taken over a longer period of time. Defendants knew and should have known for years prior to 2009 that the risk of developing PML increases significantly the longer Tysabri® is taken by a patient. Yet, Defendants failed to timely and adequately warn consumers and healthcare providers about that increased risk.

41. Upon information and belief, during communications between the FDA, Biogen and Elan, the FDA indicated that it was important to look at PML outcomes and disability and sharing these outcomes with patients and prescribers. It is believed that this information was never made publically available.

42. It was not until July 2010 that Defendants actually revised the U.S. label for Tysabri® to reflect the increased risk of developing PML with longer treatment duration. The revised U.S. label for Tysabri® states: "In patients treated with Tysabri®, the risk of developing PML increases with longer treatment duration . . . . There are no known interventions that can reliably prevent PML or adequately treat PML if it occurs. It is not known whether early detection of PML and discontinuation of TYSABRI® will mitigate the disease." However, this warning is located in the warning and precautions part of the label, not in a black box warning.

43. By mid-January 2010, the number of confirmed cases of patients who developed PML after treatment with Tysabri® had risen to thirty-one, and by January 21, 2010 eight had died.

44. On February 5, 2010 the FDA released its own safety announcement warning patients and medical professionals that the risk of PML increases with each Tysabri® infusion received.

45. In a letter dated March 25, 2010, the FDA notified Defendant Biogen's Senior Vice President of Regulatory Affairs that Defendant Biogen's promotion of Tysabri® contained "false or misleading" information. The letter explained that Defendant Biogen's promotional information regarding Tysabri® "minimized important risks associated with the use of Tysabri® and omits the drug's approved indication." The promotional material in question was a webcast to potential TOUCH prescribers and physicians.

46. The primary concern with the webcast was the statement that the "majority of Natalizumab-treated patients who developed PML have survived and exhibit varying levels of disability." At the same time that Defendant Biogen was disseminating this information, it was known that PML was very often fatal with approximately twenty percent (20%) of MS patients dying and approximately forty percent (40%) of patients rendered severely disabled. Despite this fact, Biogen downplayed the disability and mortality rates of PML.

47. On February 18, 2011, Defendant Biogen reported ninety-five confirmed cases of PML, and twenty deaths. However, in a safety announcement the FDA reported one hundred and two cases Tysabri® related cases of PML world wide as of February 28, 2011.

48. On April 22, 2011, the FDA issued a drug safety communication stating that patients who took an immune system suppressing medication prior to taking Tysabri® have been shown to be at an increased risk for developing PML. Defendants knew or should have known that taking an immunosuppressant prior to Tysabri® could increase the risk of PML given the literature stemming back from the 1990s and early 2000s relating to the JC Virus and PML. Additionally, Defendants knew that most patients would have been on immunosuppressant drugs prior to commencing Tysabri® given that it was a third or fourth line treatment. It is anticipated that approximately forty-two percent of patients with PML had been treated with an

immunosuppressant prior to receiving Tysabri®.

49. At no point, did Biogen or Elan warn Plaintiff that taking an immunosuppressant medication prior to a Tysabri® infusion could cause an increased risk for PML.

50. In august 2011, an article entitled "Natalizumab treatment for multiple sclerosis: updated recommendations for patient selection and monitoring" in Lancet Neurology found that previous use of multiple sclerosis treatment increases the risk of PML three or four times.

51. On January 20, 2012, the FDA issued a drug safety communication stating that testing positive for anti-JC Virus antibodies has been identified as a risk factor for PML. The FDA further stated that the patients who are found to be anti-JCV antibody positive and have one or more of the other known risk factors for PML should carefully determine the benefits and risks of treatment. The FDA warned that the estimated risk of PML with all three known risk factors increases dramatically to 11/1,000 users.

52. Prior to taking Tysabri®, Plaintiff and Plaintiff's prescriber were never warned that longer treatment duration, use of prior immunosuppressant or an anti-JCV antibody positive test could increase the risk of developing PML.

53. By January 2012, 201 cases of PML in Tysabri® patients had been reported. Currently, there is no treatment, prevention, or cure for this condition.

54. Plaintiff Andrew Nelson was diagnosed with MS in October 2002. Plaintiff's MS was characterized by vision impairment, numbness and pain down his legs and arms and dizziness.

55. In January 2007, Plaintiff commenced Tysabri® infusions with his physician Dr. Kenneth Citak at Neurology Group of Bergen County. Plaintiff received the infusions at Valley Health Medical Group in Paramus, NJ.

56. For the next three years Plaintiff received monthly infusions, without any warning that the risk of PML increases with longer treatment duration.

57. Dr. Citak would not have prescribed Tysabri® to Mr. Nelson if Defendants had adequately warned about the risk of developing PML increases with longer treatment duration.

58. Dr. Citak would also not have prescribe Tysabri® to Mr. Nelson if Defendants had adequately warned that the drug should only be prescribed to patients who had not had success with other MS drugs or treatments.

59. Dr. Citak would not have prescribed Tysabri® to Mr. Nelson if Defendants had adequately warned that the use of an immunosuppressant prior to treatment with Tysabri® could increase the risk of PML.

60. Dr. Citak would not have prescribed Tysabri® to Mr. Nelson if Defendants had adequately warned that those who are found to be anti-JCV antibody positive have an increase in the development of PML.

61. Throughout the time that Mr. Nelson was receiving Tysabri®, the drug's labeling was inadequate and contained no warning that the risk of developing PML increases with longer treatment duration.

62. Throughout the time that Mr. Nelson was receiving Tysabri®, the drug's labeling also contained no warning that only patients who had not had success with other MS drugs or treatments should be treated with Tysabri®.

63. Throughout the time that Mr. Nelson was receiving Tysabri®, the drug's labeling contained no warning that use of immunosuppressant prior to Tysabri® increases the risk of PML.

64. Throughout the time that Mr. Nelson was receiving Tysabri®, the drug's labeling

contained no warning that an anti-JCV antibody positive test increases the risk of PML.

65. In November 2010, Mr. Nelson was admitted to the hospital because of worsening symptoms. He suffered from gait, ataxia, dysarthria, and quadriparesis. A brain biopsy was performed in December 2010 and the results confirmed a diagnosis of PML.

66. Mr. Nelson was severely debilitated as a result of the PML and underwent steroid treatment and extensive physical therapy. Mr. Nelson continues to struggle with the debilitating effects of Tysabri®.

COUNT I

PRODUCTS LIABILITY ACT - FAILURE TO WARN

(N.J. Products Liability Act-N.J.S.A. 2A:58C-2)

78. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

79. Defendant Biogen is the registered BLA holder for Tysabri®. However, both Defendants Biogen and Elan participate in labeling decisions and changes. As stated in the joint collaboration agreement between the parties Section 4.5(a) "each party shall be given the opportunity to have one of more of its representative participate in all substantive discussions and meetings with Regulatory Authorities, which relate to Licensed Products including, but not limited to, with respect to any Drug Approval Applications."

80. Biogen's Regulatory Affairs Director, Tammy Phinney, has stated that she interacts with Elan regarding regulatory communications and that Elan participates in the Tysabri® labeling team. Upon information and belief, the Tysabri® labeling team is a cross-function team involving representatives from the regulatory departments of both companies that make decisions regarding changes or modifications to the Tysabri® label. As dictated in the

agreement between the parties, both Defendants are responsible for changes to the Tysabri® label.

81. Additionally, press releases issued by Biogen and Elan state that they are "co-marketers" for Tysabri®. Both defendants are responsible for the marketing materials provided to prescribers and patients regarding Tysabri®. Upon information and belief, the marketing departments for both companies participate in a cross-functional team that develops promotional material to be disseminated to potential Tysabri® prescribers and patients.

82. Upon information and belief, Dear Healthcare Professionals informing prescribers of PML cases and important safety developments were signed by the Senior Vice Presidents of Medical Research for both Defendants. Furthermore, upon information and belief, representatives for both Defendants participated in conference calls with FDA regarding regulatory issues, including novel risk factors and label changes for Tysabri®.

83. Given that both Defendants participated in regulatory decisions regarding Tysabri® including label changes and warnings provided to patients and healthcare providers, Plaintiff intends to pursue a failure to warn claim against both Biogen and Elan.

84. Tysabri® was defective and unreasonably dangerous when it left the possession of Defendants, in that it contained warnings insufficient to alert consumers and their physicians, including the Plaintiff and his physician, to the dangerous risks and reactions associated with the drug, namely, PML.

85. Specifically, as co-developed and co-marketers of Tysabri® Defendants owed a duty to warn healthcare providers and patients adequately that, in patients being treated with Tysabri®, the risk of developing PML increases with longer treatment duration. Defendants also owed a duty to warn prescribers and patients including Andrew Nelson that prior use of

immunosuppressant could increase the risk of PML. At the time that Andrew Nelson was receiving Tysabri® infusions, Defendants knew or should have known that approximately forty-two percent (42%) of patients who had developed PML were taking an immunosuppressant prior to Tysabri®. Furthermore, Defendants owed a duty to warn providers and patients that a positive anti-JC Virus antibody could increase the risk of developing PML. At the time that Andrew Nelson was receiving Tysabri® infusions Defendants knew or should have known that fifty to sixty percent of the population has contracted the JC Virus strain, making them more susceptible to PML.

86. Despite knowledge that these risk factors could drastically increase the development of PML, Defendants failed to warn patients, healthcare providers or the public. This lack of warning made Tysabri® an unreasonably dangerous product at the time it left Defendant's control. Furthermore, Defendants failed to use reasonable care to provide an adequate warning of this danger to healthcare providers and patients. Defendants' failure in this regard is potentially egregious as patients taking Tysabri® are reluctant to stop using the drug because, when discontinued, the drug causes MS symptoms to become worse than prior to ingestion of the drug. Additionally, Defendants knew that patients intended to use Tysabri® as longer treatment duration for MS given that it is incurable.

87. Plaintiff's development of PML and his resulting damages were proximately caused by Defendants' failure to warn him and his Tysabri® prescriber that, in patients being treated with Tysabri®, the risk of developing PML increases with (1) longer treatment duration, (2) prior use of immunosuppressant and (3) positive anti-JC Virus antibodies. Had Plaintiff and his prescriber been adequately warned that these three risk factors increase the development of PML, Plaintiff's prescriber would not have prescribed Tysabri® and Plaintiff would not have

taken Tysabri®.

88. As a direct and proximate result of the subject products' defects, Plaintiff suffered severe and permanent physical injuries. Plaintiff endured substantial pain and suffering. He incurred significant expenses for medical care and treatment. Plaintiff suffered a loss of earning capacity, economic loss, and was otherwise physically, emotionally and economically injured. Plaintiff seeks actual damages from the Defendants as alleged herein.

COUNT II

NEGLIGENT UNDERTAKING

89. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

90. When Defendants reintroduced Tysabri to the marketplace in 2006, Defendants knew the JC virus caused PML. Defendants also knew testing for antibodies to the JC virus in the blood would indicate exposure to the JC virus. Therefore, Defendants undoubtedly knew patients whose blood tested positive for JC virus antibodies would be at a higher risk of developing PML.

91. Believing that a JC virus antibody assay would help stratify the risk of developing PML, Defendants voluntarily assumed the duty to develop and commercialize a JC virus antibody assay for use with Tysabri. Defendants took steps to develop a JC virus antibody assay by consulting with doctors and organizations, including the National Institutes of Health ("NIH"), to identify patients at a higher risk.

92. Then in October 2006, Biogen acquired a JC virus antibody assay from NIH through a material licensing agreement for the purpose of developing this assay for commercial use. Despite acquiring the NIH JC virus antibody assay in October 2006, Defendants failed to

commercially release a JC virus antibody assay until January 2012, more than five years later.

93. After voluntarily assuming the duty to develop a JC virus antibody assay, Defendants failed to act reasonably in developing the NIH assay for commercial use because they failed to dedicate adequate time and resources to the Assay's development and caused unreasonable delay in its commercialization. Defendants did not invest resources of any significance until approximately 2009 when an increasing number of PML cases caused fear and discontinuations among Tysabri users.

94. Defendants were also negligent and caused unreasonable delay by deciding to develop their own version of the JC virus antibody assay, the Stratify Assay, instead of utilizing existing technology and assays available to Defendants. Defendants developed their own version of the assay so they could benefit financially by licensing it to a third party.

95. If Defendants had acted reasonably in their efforts to develop and commercialize a JC virus antibody assay, Mr. Nelson would have had a JC virus antibody assay available to him. Mr. Nelson's physicians would have tested Mr. Nelson for the JC virus antibodies, and he would have tested positive.

96. With a positive test result, Mr. Nelson and his physician would have known Mr. Nelson was at a higher risk of developing PML and would have conducted a more meaningful risk-benefit discussion regarding Tysabri as a treatment option. This discussion would have resulted in Mr. Nelson discontinuing Tysabri and not developing PML.

97. The positive JC virus antibody test result, alone, would have caused Mr. Nelson to discontinue Tysabri, but this is especially the case considering his duration of use was longer than two years and he had a prior history of immunosuppressant use.

98. Defendants were negligent in performing their voluntarily undertaken duty to develop a JC virus antibody assay because they failed to dedicate reasonable and adequate resources to the assay's development, and they allowed an unreasonable amount of time to pass before releasing their Stratify Assay. During this unnecessary delay, Tysabri continued to cause PML in MS patients, including Mr. Nelson.

99. Mr. Nelson developed PML and suffered severe physical and mental injuries as a result of his Tysabri use, and these injuries were directly and proximately caused by Defendants negligently executing the duty they voluntarily undertook to develop and commercialize a JC virus antibody assay.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment as follows:

(a) Awarding actual damages to Plaintiff incidental to Plaintiff' purchase and ingestion of Tysabri® in an amount to be determined at trial;

(b) Awarding pre-judgment and post-judgment interest to Plaintiff;

(c) Awarding the costs and expenses of this litigation to Plaintiff;

(d) Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

(e) Granting such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

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Attorneys for Plaintiff

Dated: June 13, 2016

CERTIFICATE OF SERVICE

I, Michael L. Rosenberg, hereby certify that I served PLAINTIFF'S FOURTH AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL on this 13th day of June 2016 to the following counsel of record for Biogen Idec Inc. and Elan Pharmaceuticals, LLC via the Court's ECF system:

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