IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:15-cv-2546

[redacted] Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

CLOVIS ONCOLOGY, INC. and PATRICK J. MAHAFFY,

Defendants.

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS AND JURY TRIAL DEMAND

Plaintiff [redacted] ("Plaintiff"), by his attorneys, except for his own acts, which are alleged on knowledge, alleges the following based upon the investigation of counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by Clovis Oncology, Inc. ("Clovis" or the "Company"), as well as regulatory filings and reports, securities analyst reports, press releases and other public statements issued by Clovis, and media reports about Clovis. Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a securities class action on behalf of all persons who purchased Clovis common stock between May 20, 2014 and November 13, 2015, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiff's claims are asserted against Clovis and Patrick J. Mahaffy ("Mahaffy"), President, Chief Executive Officer ("CEO"), and a director of the Company.

2. Clovis is a biopharmaceutical company focused on acquiring, developing, and commercializing cancer treatments in the United States, Europe, and other international markets. Since May 19, 2014, Clovis and certain of its current and former executive officers and directors have materially misrepresented the nature and significance of the data collected from its clinical trials for its lung cancer treatment rociletinib, or CO-1686.

3. On November 16, 2015, before the stock market opened, Clovis issued a press release regarding its regularly scheduled Mid-Cycle Communication Meeting with the U.S. Food and Drug Administration (the "FDA") held a week prior. The Company disclosed that the FDA "requested additional clinical data for use in the efficacy analysis for both the 500mg and 625 mg

BID dose patient groups for rociletinib." In the press release, the Company acknowledged that the FDA needed further information because the New Drug Application ("NDA") that Clovis submitted for rociletinib "contained immature data sets based on both unconfirmed response rates and confirmed response rates. . . . . This was also true of the Company's Breakthrough Therapy designation submission." The use of the immature data was very significant, however, because "[a]s the efficacy data have matured, the number of patients with an unconfirmed response who converted to a confirmed response was lower than expected."

4. As a result of the news, the trading price of Clovis's common stock plunged from its closing price of $99.43 on November 13, 2015 to close at $30.24 per share on November 16, 2015, the next trading day, resulting in a single-day loss of approximately 70%. Accordingly, Clovis's November 16 announcement resulted in a loss of approximately $2.17 billion in market capitalization.

JURISDICTION AND VENUE

5. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and § 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

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

7. This Court has jurisdiction over each Defendant named herein because each Defendant has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and § 27 of the Exchange Act because Clovis resides in this District—Clovis's principal executive offices are located at 2525 28th Street, Suite 100, Boulder, Colorado 80301.

PARTIES

9. Plaintiff purchased Clovis stock during the Class Period as set forth herein and in his certification filed herewith.

10. Clovis is a corporation organized and existing under the laws of Delaware. The Company maintains its principal executive offices at 2525 28th Street, Suite 100, Boulder, Colorado 80301. Clovis's common stock trades on the NasdaqGS stock exchange ("NASDAQ") under the ticker symbol "CLVS."

11. Defendant Mahaffy is a co-founder of the Company and is President, CEO, and a director of the Company.

12. Clovis and Mahaffy are collectively referred to herein as "Defendants."

CONTROL PERSON ALLEGATIONS

13. By reason of Mahaffy's positions with the Company as an executive officer and director, Mahaffy possessed the power and authority to control the contents of Clovis's annual and quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Mahaffy was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his positions with the Company, and his access to material, non-public information available to him but not to the public, Mahaffy knew that the adverse facts specified herein had

not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. Mahaffy is liable for the false statements pleaded herein.

FURTHER SUBSTANTIVE ALLEGATIONS

Background

14. Clovis is a biopharmaceutical company focused on acquiring, developing, and commercializing cancer treatments in the United States, Europe, and other international markets. The Company's development programs are targeted at specific subsets of cancer, combining personalized medicine with companion diagnostics to direct therapeutics to those patients most likely to benefit from them. Clovis has three product candidates in clinical development: rociletinib (CO-1686), which is in Phase II development for the treatment of non-small cell lunch cancer; recaparib, which is in Phase II and Phase III clinical trials for the treatment of ovarian cancer; and lucitanib, which is in Phase II clinical trials for the treatment of breast and lung cancers. Clovis has received Breakthrough Therapy designation from the FDA for rociletinib and rucaparib. The Company maintains global rights to rociletinib and rucaparib, and U.S. and Japanese rights to lucitanib.

15. Rociletinib (CO-1686) is a novel, oral, targeted covalent (irreversible) inhibitor of the cancer-causing mutant forms of epidermal growth factor receptor (EGFR) currently being studied for the treatment of non-small cell lung dominant acquired T790M resistance mutation, while sparing wild-type, or normal EGFR at anticipated therapeutic doses, with an improved toxicity profile. The TIGER program is the accelerated clinical development program for

rociletinib in patients with mutant EGFR NSCLC. The Company currently has several ongoing clinical trials in the TIGER program:

- TIGER-X is evaluating rociletinib in two groups of patients; the first in patients directly after progression on their first and only EGFR-directed TKI therapy, such as Tarceva or Iressa, who have developed the T790M mutation. The second group includes later-line T790M-positive patients after progression on their second or later TKI therapy or subsequent chemotherapy.
- TIGER-1 is a randomized Phase 2/3 registration study versus erlotinib in newly-diagnosed patients; the Phase 2 portion is currently enrolling patients.
- TIGER-2 is a global registration study underway in both T790M-positive and T790M-negative patients directly after progression on their first and only TKI therapy.
- TIGER-3 is a randomized, comparative study versus chemotherapy in both T790M-positive and T790M-negative patients with acquired TKI resistance.

16. Data from TIGER-X, combined with data from TIGER-2, were submitted by the Company as the basis of NDA and MAA submissions for rociletinib.

17. Throughout the Class Period, Clovis has misrepresented the nature of the TIGER program's results.

The Material Misrepresentations and Omissions

18. On May 19, 2014, Clovis issued a press release announcing that the FDA "granted Breakthrough Therapy designation for the Company's investigational agent CO-1686 as monotherapy for the treatment of second-line EGFR mutant NSCLC in patients with the T790M

mutation." The press release explained that "[t]he Breakthrough Therapy designation was granted based on interim efficacy and safety results from an ongoing Phase 1/2 study of CO-1686. CO-1686 is the Company's novel, oral, targeted covalent (irreversible) inhibitor of mutant forms of the epidermal growth factor receptor (EGFR) for the treatment of non-small cell lung cancer in patients with initial activating EGFR mutations as well as the dominant resistance mutation T790M."

19. The Company also touted the significance of rociletinib's Breakthrough Therapy designation: "The Breakthrough Therapy designation was enacted as part of the 2012 FDA Safety and Innovation Act and is intended to expedite development and review of drugs to treat serious or life-threatening medical conditions ***when preliminary clinical evidence demonstrates that the drug may have substantial improvement on at least one clinically significant endpoint over available therapies***. Breakthrough Therapy designation includes all the features of the Fast Track designation, as well as more intensive guidance from the FDA on a drug's clinical development program." (Emphasis added.)

20. On August 6, 2015, the Company held a conference call to discuss its second quarter 2015 results. Mahaffy began the call by stating the Company has "completed regulatory submissions on schedule for rociletinib in U.S. and Europe and [Clovis is] preparing for the potential U.S. commercial launch for rociletinib before year end." Mahaffy went on to explain that a "validation period" is required to complete the regulatory submissions and the Company "anticipate[s] receiving the validation for these filings during the third quarter." Mahaffy demonstrated his belief in the year-end launch of CO-1686 by stating, "We are now finalizing the

recruitment of our sales force and expect to have the full U.S. commercial team including that sales force in place next month."

21. Mahaffy also stated, "Overall rociletinib is well-tolerated. The most frequent adverse reaction or lab abnormalities reported were diarrhea, nausea, fatigue, QTC prolongation and hyperglycemia. Importantly, the only Grade 3 adverse reaction or lab abnormality reported in greater than 5% of patients was hyperglycemia. As a result, we believe our data demonstrate the safety and activity of rociletinib in a uniquely relevant patient population."

22. On September 29, 2015, Clovis issued a press release announcing that "[t]he U.S. Food and Drug Administration (FDA) has accepted Clovis's New Drug Application (NDA) for rociletinib and has granted it priority review status with a Prescription Drug User Fee Act (PDUFA) action date of March 30, 2016." The press release went on to state:

> Additionally, the European Medicines Agency (EMA) has accepted the Marketing Authorization Application (MAA) for rociletinib. Europe's Committee for Medicinal Products for Human Use (CHMP) granted Clovis an accelerated assessment for the drug, which reduces the time limit for CHMP to reach an opinion from 210 days to 150 days. Accelerated assessment is granted in recognition of the likelihood that a therapeutic will be of major public health interest in the EU, given the importance of therapeutic innovation in a patient population that exhibits a high unmet need.
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> Rociletinib is the company's novel, oral, targeted covalent (irreversible) mutant-selective inhibitor of EGFR in development for the treatment of NSCLC in patients with initial activating EGFR mutations, as well as the dominant resistance mutation T790M. ***Data from both the pivotal, single-arm TIGER-X and TIGER-2 clinical trials served as the basis for the U.S. and EU regulatory submissions for the treatment of advanced mutant EGFR T790M-positive lung cancer***. Rociletinib was given Breakthrough Therapy designation by the FDA in May 2014.

(Emphasis added.)

The Truth Emerges

23. The truth finally emerged when on November 16, 2015, before the market opened, Clovis issued a press release that disclosed the FDA's request for more data due to the insufficiency of Clovis's previously submitted clinical trial results. The press release stated, in pertinent part:

> [D]uring its regularly scheduled Mid-Cycle Communication Meeting held last week with the U.S Food and Drug Administration (FDA), the agency requested additional clinical data for use in the efficacy analysis for both the 500mg and 625mg BID dose patient groups for rociletinib. The Company will provide this information in a Major Amendment to the FDA by close of business today.
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> 'We remain confident in rociletinib and its potential to treat patients with mutant EGFR T790M-positive lung cancer,' said Patrick J. Mahaffy, President and CEO of Clovis Oncology. 'We will continue to work diligently with the FDA and our NDA submission.'
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> In the Mid-Cycle Communication meeting, the FDA emphasized that its efficacy analysis would focus solely on confirmed responses. ***The New Drug Application (NDA) submitted by Clovis to the FDA contained immature data sets based on both unconfirmed response rates and confirmed response rates***. These data sets were updated in the 90 day efficacy update the Company submitted at the end of October.
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> As the rociletinib clinical trials were rapidly enrolling, ***Clovis presented interim data publicly and at medical meetings and these data therefore included a data set based primarily on unconfirmed responses. This was also true of the Company's Breakthrough Therapy designation submission***. In the Company's NDA submission, both immature confirmed and unconfirmed response analyses were submitted. As the efficacy data have matured, the number of patients with an unconfirmed response who converted to a confirmed response was lower than expected.
>
> ***In the intent to treat analysis of the 79 patients in the 500mg dose group, the current confirmed response rate is 28 percent and 34 percent in the 170 patients in the 625mg dose group***, with an encouraging duration of response in both doses. The most frequent reasons that patients' responses were not confirmed in a subsequent scan wre due to progression, often due to brain metastasis, and due to subsequent scans not demonstrating tumor shrinkage greater than 30 percent.

> The Company anticipates that the review of this additional information will results in a delay of a potential approval. This additional review could lead to an extension of the Company's March 30, 2016 Prescription Drug User Fee Act (PDUFA) date.

(Emphasis added.)

24. As a result of the news, the trading price of Clovis's common stock plunged from its closing price of $99.43 on November 13, 2015, to close at $30.24 per share on November 16, 2015, a single-day loss of approximately 70%. Accordingly, Clovis's November 16 announcement resulted in a loss of approximately $2.17 billion dollars in market capitalization.

LOSS CAUSATION

25. During the Class Period, as detailed herein, Defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Clovis's common stock and operated as a fraud or deceit on Class Period purchasers of Clovis common stock by materially misleading the investing public. Later, when Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the trading price of Clovis's common stock fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of Clovis's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

FRAUD-ON-THE-MARKET DOCTRINE

26. At all relevant times, the market for Clovis's common stock was an efficient market for the following reasons, among others:

a) Clovis common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b) Clovis filed periodic public reports with the SEC and the NASDAQ; and

c) Clovis regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

27. As a result of the foregoing, the market for Clovis's common stock promptly digested current information regarding Clovis from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of Clovis common stock during the Class Period suffered similar injury through their purchase of Clovis common stock at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

28. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading,

and/or the forward-looking statement was authorized or approved by an executive officer of Clovis who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

29. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Clovis common stock during the Class Period (the "Class"). Excluded from the Class are Defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

30. The members of the Class are so numerous that joinder of all members is impracticable, since Clovis has millions of shares of stock outstanding and because the Company's shares were actively traded on the NASDAQ. As of October 30, 2015, Clovis had more than 38 million shares issued and outstanding. While the exact number of Class members in unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class and that they are geographically dispersed.

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

(a) whether the Exchange Act was violated by Defendants;

(b) whether Defendants omitted and/or misrepresented material facts in their publicly disseminated reports, press releases, and statements during the Class Period;

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

(d) whether Defendants participated and pursued the fraudulent scheme or course of business complained of herein;

(e) whether Defendants acted willfully, with knowledge, or recklessly in omitting and/or misrepresenting material facts;

(f) whether the price of Clovis common stock was artificially inflated during the Class Period as a result of the material nondisclosures and/or misrepresentations complained of herein; and

(g) whether the members of the Class have sustained damages as a result of the decline in value of Clovis's common stock when the truth was revealed, and if so, what is the appropriate measure of damages.

32. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct in a substantially identical manner.

33. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

34. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

COUNT I
Violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5 (Against All Defendants)

35. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

36. This Count is asserted by Plaintiff on behalf of himself and the Class against all Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

37. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Clovis's common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Clovis's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Defendants, and each of them, took the actions set forth herein.

38. Defendants, by the use of means and instrumentalities of interstate commerce: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers and acquirers of the Company's common stock in an effort to maintain artificially high market prices for Clovis's common stock in violation of Section 10(b) of the Exchange Act and Rule 10-5.

39. As a result of their making and/or their substantial participation in the creation of affirmative statements and reports to the investing public, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, as embodied in SEC Regulation S-K (17 C.F.R. § 229.10, et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and performance so that the market prices of the Company's publicly traded securities would be based on truthful, complete, and accurate information. Defendants' material misrepresentations and omissions as set forth herein violated that duty.

40. Defendants engaged in the fraudulent activity described above knowingly and intentionally or in such a reckless manner as to constitute willful deceit and fraud upon Plaintiff and the Class. Defendants knowingly or recklessly caused their reports and statements to contain misstatements and omissions of material fact as alleged herein.

41. As a result of Defendants' fraudulent activity, the market price of Clovis common stock was artificially inflated during the Class Period.

42. In ignorance of the true financial condition of Clovis, Plaintiff and other members of the Class, relying on the integrity of the market and/or on the statements and reports of Clovis containing the misleading information, purchased or otherwise acquired Clovis's common stock at artificially inflated prices during the Class Period.

43. Plaintiff and the Class's losses were proximately caused by Defendants' active and primary participation in Clovis's scheme to defraud the investing public by, among other things, failing to fully and accurately disclose to investors adverse material information regarding the Company. Plaintiff and other members of the Class purchased Clovis's common stock in reliance

on the integrity of the market price of those shares, and Defendants manipulated the trading price of Clovis's common stock through their misconduct as described herein. Plaintiff's and the Class's losses were a direct and foreseeable consequence of Defendants' concealment of the true financial condition of Clovis.

44. Throughout the Class Period, Defendants were aware of material non-public information concerning Clovis's fraudulent conduct (including the false and misleading statements described herein). Throughout the Class Period, Defendants willfully and knowingly concealed this adverse information, and Plaintiff's and the Class's losses were the foreseeable consequence of Defendants' concealment of this information.

45. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases and sales of Clovis common stock during the Class Period.

COUNT II
Violation of Section 20(a) of the Exchange Act
(Against Mahaffy)

46. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

47. During the Class Period, Mahaffy was privy to non-public information concerning the Company and its business and operations via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to him in connection therewith. Because of his possession of such information, Mahaffy knew or recklessly disregarded the fact that adverse facts specified herein

had not been disclosed to, and were being concealed from, the investing public. Plaintiff and other members of the Class had no access to such information, which was, and remains solely under the control of the Defendants.

48. Mahaffy was involved in drafting, producing, reviewing and/or disseminating the materially false and misleading statements complained of herein. Mahaffy was aware (or recklessly disregarded) that materially false and misleading statements were being issued by the Company and nevertheless approved, ratified, and/or failed to correct those statements, in violation of federal securities laws. Throughout the Class Period, Mahaffy was able to, and did, control the contents of the Company's SEC filings, reports, press releases, and other public statements. Mahaffy was provided with copies of, reviewed and approved, and/or signed such filings, reports, releases and other statements prior to or shortly after their issuance and had the ability or opportunity to prevent their issuance or to cause them to be corrected.

49. Mahaffy also was able to, and did, directly or indirectly, control the conduct of Clovis's business, the information contained in its filings with the SEC, and its public statements. Moreover, Mahaffy made or directed the making of affirmative statements to securities analysts and the investing public at large, and participated in meetings and discussions concerning such statements. Because of his position and access to material non-public information available to him but not the public, Mahaffy knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were false and misleading. As a result, Mahaffy is responsible for the accuracy of Clovis's corporate releases detailed herein and is therefore responsible and liable for the misrepresentations contained herein.

50. Mahaffy acted as a controlling person of Clovis within the meaning of Section 20(a) of the Exchange Act. By reason of his position with the Company, Mahaffy had the power and authority to cause Clovis to engage in the wrongful conduct complained of herein. Mahaffy controlled Clovis and all of its employees. As alleged above, Clovis is a primary violator of Section 10(b) of the Exchange Act and SEC Rule 10b-5. By reason of his conduct, Mahaffy is liable pursuant to section 20(a) of the Exchange Act.

51. As a direct and proximate result of the wrongful conduct of Clovis and Mahaffy, Plaintiff and members of the Class suffered damages in connection with their respective purchases and sales of the Company's common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

(A) Declaring this action to be a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiff as a representative of the Class and its counsel as Class counsel;

(B) Awarding Plaintiff and the members of the Class damages, including interest;

(C) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including and attorneys' fees; and

(D) Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

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DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury.

Dated: November 19, 2015