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Nevada State Bar No. 0655
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Reno, Nevada 89505
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***Attorneys for Plaintiff***

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

HOWARD MCMASTER, Case No.

Plaintiff,

v.

FRANCK'S LAB, INC., doing business as FRANCK'S COMPOUNDING LAB; PAUL W. FRANCK; ANTHONY JAMES CAMPBELL; and DOES 1 through 10, inclusive,

Defendant.
_____/

**COMPLAINT AND JURY DEMAND**

COMES NOW, Plaintiff HOWARD MCMASTER, by and through his counsel of record, Thomas E. Drendel, Esq., of the law offices of Bradley, Drendel & Jeanney, Ltd., and for causes of action against the Defendants, and each of them, alleges:

**JURISDICTION & PARTIES**

1. This is an action for personal injuries arising from a defective product. This Court has diversity jurisdiction as this is a controversy between parties of diverse citizenship and an amount in controversy that exceeds $75,000 pursuant to the provisions of 42 U.S.C. §1332.

2. Plaintiff, HOWARD MCMASTER, is a citizen of Reno, Nevada.

3. Defendant, FRANCK'S LAB, INC., dba FRANCK'S COMPOUNDING LAB is a corporation incorporated under the laws of Florida with its principal place of business in the State of Florida and selling compounded or formulated products for utilization in the medical field, including Brilliant Blue-G ("BBG") dye; Triamcinolone ("TMC") and Avastin.



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4. Defendant, PAUL W. FRANCK is a citizen of the State of Florida, is a principal and shareholder of defendant FRANCK'S LAB INC. and was involved in the management and operations of FRANCK'S LAB, INC., and direction the manner in which BBG, TMC and Avastin were compounded in the laboratory.

5. Defendant, ANTHONY JAMES CAMPBELL, is a citizen of the State of Florida, was a lead chemist with FRANCK'S LAB, INC. and had responsibility for overseeing the laboratory operations and assuring compliance with the rules, laws and regulations concerning compounding pharmacies, including the federal rules and regulations concerning the manufacture, sale and distribution of drugs, including BBC, TMC and Avastin.

6. The true names and capacities of DOES 1 through 10 are unknown to Plaintiff at this time. Plaintiff is informed and believes and thereon alleges that these DOE defendants are in someway liable for the events referred to in this Complaint and caused damage to Plaintiff. Plaintiff will amend this Complaint when their identities and relationship to his injuries are discovered. Does 1 through 10 and not citizens of the State of Nevada or corporations with their principal place of business in the State of Nevada.

7. Plaintiff is informed and believes that at all time herein mentioned, the defendants, and each of them, were the agents, servants, employees, joint venturers, and partners of each other and at all times were acting within the course and scope of said relationships.

8. Venue is proper in this district and in this, the unofficial northern division thereof, because Plaintiff is a citizen in this district, the tort occurred in this district and the Defendants were doing business in this district at the time of the injury.

**FIRST CAUSE OF ACTION**
**(FOR PRODUCT LIABILITY - NEGLIGENCE)**

9. Plaintiff incorporates herein by reference paragraphs 1-8 as though fully set forth herein.

10. On November 15, 2011, Plaintiff underwent a vitrectomy procedure on his left eye performed by Dr. Steven Friedlander at the Northern Nevada Medical Center located at 2375 E. Prater Way in Sparks, Nevada. During the procedure, Dr. Friedlander injected Plaintiff's eye



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with BBG, the product the defendants formulated, manufactured, compounded, marketed and sold as an appropriate product to be utilized in such procedure. The Defendants represented that BBG was pure, sterile, and fit for the represented purpose of assisting in procedures like vitrectomies and the product could be injected into an eyeball in order to assist the doctor in achieving the desired result.

11. Plaintiff's condition worsened after the November 15, 2011, procedure, and he lost his vision and use of his left eye.

12. Plaintiff was advised that numerous other patients who were injected with BBG had suffered similar complications. Plaintiff was further advised that the sudden, unexpected and unusual number of patients who developed the same or similar complications led to an investigation by the doctor, the Federal Drug Enforcement Agency (FDA) and others which concluded that all of the patients who suffered these complications due to BBG which was negligently manufactured.

13. The investigation by numerous state, county and federal health agencies concluded that the Defendants' BBG product was negligently manufactured and that the Defendants had violated numerous federal rules and regulations. On July 9, 2012, the United States Food and Drug Administration ("FDA") issued a Warning Letter FLA-12-38, which advised PAUL W. FRANCK and FRANCK'S LAB, INC., that:

a. The subject BBG was adulterated within the meaning of Section 501(a)(1) of the Act [21 U.S.C.§ 351 (a)(1)] and that it was contaminated with filthy, putrid or decomposed substances;

b. The BBG was adulterated within the meaning of Section 501(c) of the Act [21 U.S.C.§ 351 (c)] in that its strength different from, or its purity or quality fell below, that which is purported to possess;

c. The BBG and all sterile drugs compounded by the defendants were adulterated under Section 501(a)(2)(A) of the Act [21 U.S.C.§ 351 (a)(2)(A)] in that they were prepared, packed and stored under unsanitary conditions whereby they may have been contaminated by filth;



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d. The BBG was misbranded within the meaning of Section 502(a) of the Act [21 U.S.C.§ 352 (a)] because their labeling was false and misleading;

e. The FDA investigators observed numerous instances of unsanitary and inappropriate practices by compounding technicians who left and re-entered clean rooms without changing lab coats, who were touching non-sterile items while wearing their sterile gloves and then returned to compounding activities, etc.; and

f. The BBG drug products were misbranded insofar as they were labeled as being sterile, and they contained filthy, putrid, or decomposed substances.

14. The Defendants knew that failing to follow safe and appropriate compounding practices could result in complications, including fatal ones. In 2009, the Defendants compounded cocktails that were given to prized polo horses from the Venezuelan-owned Lechuza Caracas team in preparation for championship matches near West Palm Beach, Florida. Twenty-one of these prized polo horses died from errors committed by the Defendants in compounding these cocktails.

15. The FDA investigation following the incident with the polo horses led the agency to conclude that the defendants were mixing brews outside of federal guidelines and were utilizing drugs that had not been approved for use in the United States.

16. Tragic complications of the patients who ended up receiving injections of the contaminated BBG are just one example of the problems in the largely unregulated area of compounding pharmacies. Recently, hundreds of patients who underwent steroid injections were stricken with meningitis due to the contamination of the steroid fluid.

17. The Defendants owed a duty of reasonable care to Plaintiff to design, compound, manufacture, market, sell and distribute the BBG in a condition that was safe for its intended purpose and consistent with the representations that it was a sterile product. The Defendants' duty included a duty to insure that the product did not cause patients who were injected with BBG in their eye to suffer from unreasonable risks of injury from the product, especially in light of the fact that it is known that infections in the eye are extremely difficult to treat.



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18. Defendants breached their duty to Plaintiff in the testing, design, compounding, manufacturing, packaging, storing, warnings, marketing, advertising, promotion and distribution of BBG and otherwise failed to exercise ordinary care to avoid the risk of infection and harm.

19. The Defendants knew prior to the date of Plaintiff's surgery of November 15, 2011, that their dye was contaminated, non-sterile and unfit to be used in eye surgery procedures; posed an unreasonably dangerous risk of infection and they failed to do anything to recall the product from the market or warn the medical community and the public of the substantial risk of serious complications.

20. The Defendants recklessly and wantonly conducted their laboratory compounding practices in clear violation of applicable federal law and allowed such filthy and inappropriate conditions to exist to the point that it was all but certain that the drugs they were compounding were going to be contaminated.

21. The Defendants knew that the patients who were going to be injected with their BBG were at risk for developing serious injuries and complications but they nevertheless continued with their practices in conscious disregard of the health and safety of the ultimate consumes of BBG.

22. As a direct, proximate and legal result of the negligence, carelessness, recklessness and other wrongdoing actions of the Defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER sustained general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.

23. The Defendant's conduct was so reckless, malicious, oppressive, fraudulent and despicable and carried on with a willful and conscious disregard for the safety of the patients who were likely to be injected with BBG. Therefore, punitive damages should be imposed upon the defendants, and each of them, by way of an example and to punish such conduct in an amount to be determined by the trier of fact.

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**SECOND CAUSE OF ACTION**
**(FOR STRICT LIABILITY)**

24. Plaintiff incorporates herein by reference paragraphs 1-23 as though fully set forth herein.

25. The subject BBG was defective in its compounding and manufacture since it was different from the manufacturer's intended result as set forth on the packaging and related material that accompanied the product, specifically that the product was sterile and free of any contamination. Plaintiff is informed and believes that the batch of the product that included the BBG that was injected into his eye was defective in compounding and manufacture in that it differed from other batches of BBG from these defendants.

26. The defect in the compounding and manufacture of the product, specifically the contamination and non-sterile nature of the product, existed in the product when it left the possession of the defendants.

27. The defect in the compounding and manufacture of the BBG resulted in complications to the Plaintiff's procedure and blindness in his left eye.

28. The use of this contaminated BBG, by the Plaintiff or by his physician during his procedure, was completely foreseeable by the Defendants and each of them since the Plaintiff's doctor was utilizing the product as intended by the Defendants and the medical community.

29. The BBG injected into the Plaintiff's eye failed to perform as safely and reasonably as a consumer would expect when used as intended.

30. As a direct, proximate and legal result of the strict liability and other wrongdoing actions of the Defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER suffered general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.

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31. The Defendant's conduct was so reckless, malicious, oppressive, fraudulent and despicable and carried on with a willful and conscious disregard for the safety of the patients who were likely to be injected with BBG. Therefore, punitive damages should be imposed upon the defendants, and each of them, by way of an example and to punish such conduct in an amount to be determined by the trier of fact.

**THIRD CAUSE OF ACTION**
**(FOR STRICT LIABILITY - FAILURE TO WARN)**

32. Plaintiff incorporates herein by reference paragraphs 1-31 as though fully set forth herein.

33. The BBG which was injected into Plaintiff's eye on November 15, 2011, was defective in that there was no warning on the product that it was, or could be, contaminated with filth or foreign matter.

34. The Defendants, and each of them, knew that doctors would utilize their BBG relying on the representations of the Defendants that the product was sterile and that they would have no reason to believe that the product was not sterile and, in fact the Defendants knew, or reasonably should have known based upon their background and experience, that a contaminated dye to be injected into the eye could cause serious and debilitating injuries, including blindness of the injected eye.

35. As a direct, proximate and legal result of the failure to warn and other wrongdoing actions of the defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER suffered general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.

36. Plaintiff understands that the defendants were aware of the problems with their BBG prior to November 15, 2011, yet failed to recall the product, issue warnings to the medical community or otherwise do anything to avert this contaminated product being injected into the eye of patients like the Plaintiff.

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37. The conduct of the Defendants, and each of them, was reckless, malicious, fraudulent and depressive and so despicable and contemptible that punitive damages should be awarded by the trier of fact.

**FOURTH CAUSE OF ACTION**
**(FOR BREACH OF WARRANTY)**

38. Plaintiff incorporates herein by reference paragraphs 1-37 as though fully set forth herein.

39. The Defendants represented and warranted to Plaintiff through the medical community that their BBG dye was safe and effective to be utilized in conjunction with eye surgery.

40. The subject BBG dye product that was utilized in the Plaintiff's eye procedure was, in fact, not inconsistent with the warranties and representations of the defendants but, instead, was non-sterile and contaminated that caused plaintiff serious and permanent injuries as further set further herein.

41. As a direct, proximate and legal result of the breach of warranty and other wrongdoing actions of the defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER suffered general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.

WHEREFORE, Plaintiff prays for judgment as follows:

1. For general damages in a sum to be determined at the time of trial;
2. For special damages for past and future medical expenses according to proof;
3. For other damages incurred as a result of the conduct of the defendants, according to proof;
4. For punitive damages in an amount sufficient to deter this kind of conduct which is becoming more common in the field of compounding pharmacies;
5. For pre-judgment interest;

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6. For cost of suit incurred herein; and

7. For any such other relief as the Court may deem appropriate.

DATED this 4 day of March 2013.

BRADLEY, DRENDEL & JEANNEY

Thomas Drendel, Esq.
***Attorneys for Plaintiff***

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Our File No. 202006

**UNITED STATES DISTRICT COURT**

**DISTRICT OF NEVADA**

HOWARD MCMASTER, Case No. 3:13-cv-00100

Plaintiff,

v.

FRANCK'S LAB, INC., doing business as FRANCK'S COMPOUNDING LAB; PAUL W. FRANCK; ANTHONY JAMES CAMPBELL; and DOES 1 through 10, inclusive,

Defendants.
_____/

**SUMMONS**

**TO THE DEFENDANT: YOU HAVE BEEN SUED. THE COURT MAY DECIDE AGAINST YOU WITHOUT BEING HEARD UNLESS YOU RESPOND WITHIN 20 DAYS. READ THE INFORMATION BELOW VERY CAREFULLY.**

A civil complaint has been filed by the plaintiff against you for the relief as set forth in that document (see complaint). When service is by publication, add a brief statement of the object of the action. See Rules of Civil Procedure, Rule 4 (b).

1. If you intend to defend this lawsuit, you must do the following within 20 days after service of this summons, exclusive of the day of service:

   a. File with the Clerk of Court, whose address is shown below, a formal written answer to the complaint, along with the appropriate filling fees, in accordance with the rules of the Court; and

   b. Serve a copy of your answer upon the attorney or plaintiff whose name and address is shown below.

2. Unless you respond, a default will be entered upon application of the plaintiff and this Court may enter a judgment against you for the relief demanded in the complaint.

Dated this _____ day of _____, 20__.

Issued on behalf of plaintiff's attorney

Name: Thomas Drendel, Esq.
Address: P.O. Box 1987
Reno, NV 89505
Phone Number: (775) 335-9999

CLERK OF THE COURT

_____
Deputy Clerk

United States District Court
Bruce R. Thompson US Courthouse
400 South Virginia Street
Reno, NV 89501

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& JEANNEY
P.O. BOX 1987
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Our File No. 202006

**AFFIDAVIT OF SERVICE**

(For General Use)

STATE OF _____)
)
COUNTY OF_____)

_____, being first duly sworn, deposes and says: That affiant is a citizen of the United States, over 18 years of age, and that affiant received the Summons on the _____ day of _____ _____ ,20___, and personally served _____ _____ the within named defendant, on the _____ day of _____ _____ ,20___, in _____, County of _____, State of _____, by delivering a copy of the Summons attached to a copy of the Complaint.

_____
Signature of Person Making Service

Subscribed and sworn to before me this
_____ day of _____, 20___.

_____
Notary Public

**AFFIDAVIT OF MAILING**

(For use when service is by publication and mailing)

STATE OF NEVADA )
COUNTY OF WASHOE )

_____, being first duly sworn, deposes and says: That on the _____ day of _____ ____ ,20___, affiant deposited in the United States mail at Reno, Nevada, a copy of the Summons and Complaint addressed to _____ _____

_____
Signature of Person Making Service

Subscribed and sworn to before me this
_____ day of _____, 20___.

_____
Notary Public

Note: If service is made in any manner by NRCP Rule 4, other than personally upon the defendant, or is made outside the United States, a special affidavit or return must be made.

Our File No. 202006

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# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

**I. (a) PLAINTIFFS**
HOWARD MCMASTER

(b) County of Residence of First Listed Plaintiff Washoe
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Thomas E. Drendel, Esq., Bradley, Drendel & Jeanney, Ltd., P.O. Box 1987, Reno, Nevada, (775) 335-9999

**DEFENDANTS**
FRANCK'S LAB, INC., doing business as FRANCK'S COMPOUNDING LAB; PAUL W. FRANCK; ANTHONY

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☒ 1 | ☐ 1 | Incorporated *or* Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☒ 2 | Incorporated *and* Principal Place of Business In Another State | ☐ 5 | ☒ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

**CONTRACT**
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

**REAL PROPERTY**
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

**TORTS**

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

**CIVIL RIGHTS**
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

**PRISONER PETITIONS**
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

**FORFEITURE/PENALTY**
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

**LABOR**
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

**IMMIGRATION**
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

**BANKRUPTCY**
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

**PROPERTY RIGHTS**
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

**SOCIAL SECURITY**
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

**FEDERAL TAX SUITS**
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

**OTHER STATUTES**
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

**V. ORIGIN** (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

**VI. CAUSE OF ACTION**
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**): 42 USC § 1332
Brief description of cause: PRODUCT LIABILITY

**VII. REQUESTED IN COMPLAINT:**
☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23
DEMAND $ EXCESS OF $75,000
CHECK YES only if demanded in complaint:
**JURY DEMAND:** ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY** (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 3/4/2013
SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____