

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA**

Ruth Amanda Hardin, Michael Clay,)	Case No
Eric Biggs, Mary Jo Meyer, Individually and)	
as Representative of the Estate of James Meyer,)	
and Virginia Roberts)	
Plaintiffs,)	
)	Section:
v.)	
)	Judge:
SANOFI-AVENTIS U.S. LLC and AVENTIS)	
PHARMACEUTICALS INC.,)	Mag. Judge:
Defendants.)	

PLAINTIFFS' ORIGINAL COMPLAINT

Plaintiffs RUTH AMANDA HARDIN, MICHAEL CLAY, ERIC BIGGS, MARY JO MEYER, individually and as Representative of the Estate of James Meyer, and VIRGINIA ROBERTS collectively referred to as Plaintiffs, by and through their counsel allege against SANOFI-AVENTIS U.S. LLC and AVENTIS PHARMACEUTICALS INC.

JURISDICTION AND VENUE

1. Original subject matter jurisdiction in this Court is appropriate pursuant to 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds \$75,000.

2. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of North Carolina. At all relevant times the Defendants transacted, solicited, and conducted business in North Carolina through their employees, agents, and/or sales

representatives and consultants, and derived substantial revenue from such business in North Carolina.

3. Venue is appropriate in this Court pursuant to 28 U.S.C. §1391 because Defendants transact business in this District, or alternatively, this District is where a substantial part of the events or omissions giving rise to the claims have occurred. Venue is also proper pursuant to 28 U.S.C. §1391 because Defendants are all corporations that have substantial, and systematic and continuous contacts in the Middle District of North Carolina and they are all subject to personal jurisdiction in this District.

THE PARTIES

4. Plaintiff RUTH AMANDA HARDIN is, and all times herein mentioned was, a resident of Climax, Guilford County, North Carolina.

5. Plaintiff, MICHAEL CLAY is, and all times herein mentioned was, a resident of Roxboro, Person County, North Carolina.

6. Plaintiff, ERIC BIGGS, at all times relative herein, a resident of Franklin County, Pennsylvania.

7. Plaintiff, MARY JO MEYERS, individually and as representative of the Estate of JAMES MEYER, Deceased is and all times herein mentioned was a resident of Switzerland County, Indiana.

8. Plaintiff, VIRGINIA ROBERTS is, and all times herein mentioned was a resident of Edmond, Oklahoma County, Oklahoma.

9. Defendant SANOFI-AVENTIS U.S. LLC is, and at all times herein

mentioned was, a corporation organized and existing under the laws of the Delaware, with its principal place of business located at 55 Corporate Drive, Bridgewater, NJ 08807. Defendant SANOFI-AVENTIS U.S. LLC is engaged in business in the State of North Carolina and maintains a registered office at Corporation Service Company, 327 Hillsborough Street, Raleigh, NC 27603-1725.

10. Defendant AVENTIS PHARMACEUTICALS INC. is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business located at 55 Corporate Drive, Bridgewater, NJ 08807. Defendant AVENTIS PHARMACEUTICALS INC. is engaged in business in the State of North Carolina and maintains a registered office at Corporation Service Company, 327 Hillsborough Street, Raleigh, NC 27603-1725

11. Herein mentioned Defendants and each of them, were, in the business of designing, manufacturing, marketing, researching, inspecting, testing, distributing and selling various types of medical drugs, including Multaq® (dronedarone), an antiarrhythmic medication used to treat atrial fibrillation and atrial flutter.

GENERAL ALLEGATIONS

12. This is a products liability case arising out of severe liver injuries and serious cardiovascular injuries as a result of ingesting Multaq® (dronedarone), a prescription medicine manufactured, promoted, marketed, and distributed by Defendants.

13. Multaq® is an anti-arrhythmic medication with the active ingredients Dronedarone Hydrochloride, used to treat abnormal heart rhythm in patients who have had an abnormal heart rhythm (atrial fibrillation or atrial flutter) during the past 6 months.

14. Multaq® was approved by the U.S. Food and Drug Administration (FDA) in July 2009.

15. Multaq® was approved with a Risk Evaluation and Mitigation Strategy (REMS) with a goal of preventing its use in patients with severe heart failure or who have recently been in the hospital for heart failure because a study showed that patients given Multaq® had a greater than two-fold increase in risk of death.

16. Multaq® was marketed to patients and physicians as a new antiarrhythmic drug initially claimed to possess an improved hepatic safety profile compared to amiodarone.

17. Shortly after Multaq® went on the market in July 2009, several case reports of Multaq®-induced liver injury occurred, including two cases of acute liver failure leading to liver transplant in patients treated with the heart medication Multaq®.

18. On about January 14, 2011, FDA alerted healthcare professionals and patients about cases of rare, but severe liver injury and hepatic failure in patients treated with Multaq®.

19. On January 28, 2011, the FDA sent a warning letter to Sanofi-Aventis US LLC for failing to comply with Postmarketing Adverse Drug Experience (PADE) reporting requirements under 21 U.S.C. § 355(k) for, *inter alia*, Multaq.

20. In February 2011, the Multaq® label was updated to reflect the FDA's concern. The Defendants added "Section 5.2 – Liver Injury" under the "warnings and precautions" section of its label, which stated, in pertinent part, "[h]epatocellular liver injury, including acute liver failure requiring transplant, has been reported in patients

treated with MULTAQ in the postmarketing setting.” The label, in “Section 6.2 – Post-marketing Experience,” then downplays the risk of liver injury by adding that adverse reactions in the post-market setting may not be causally related to the drug exposure.

21. On or about July 21, 2011, the FDA reviewed data from a clinical trial evaluating the effects of Multaq® in patients with permanent atrial fibrillation. The study was stopped early after the data monitoring committee found a two-fold increase in death, as well as a two-fold increase in stroke and hospitalization for heart failure in patients receiving Multaq® compared to patients taking a placebo.

22. On or about December 19, 2011, the FDA completed a safety review of Multaq®, which showed that Multaq® increased the risk of serious cardiovascular events, including death, when used by patients in permanent atrial fibrillation (AF). The review was based on data from two clinical trials, the PALLAS trial (Permanent Atrial Fibrillation Outcome Study Using Dronedaron on Top of Standard Therapy) and ATHENA trial (which supported Multaq®’s approval for treatment of non-permanent AF).

23. In December of 2011, Multaq®’s drug label was revised with the following changes and recommendations :

- Healthcare professionals should not prescribe Multaq® to patients with AF who cannot or will not be converted into normal sinus rhythm (permanent AF), because Multaq® doubles the rate of cardiovascular death, stroke, and heart failure in such patients.
- Healthcare professionals should monitor heart (cardiac) rhythm by electrocardiogram (ECG) at least once every 3 months. If the patient is in AF, Multaq® should be stopped or, if clinically indicated, the patient should be cardioverted.
- Multaq® is indicated to reduce hospitalization for AF in patients in sinus

rhythm with a history of non-permanent AF (known as paroxysmal or persistent AF).

- Patients prescribed Multaq® should receive appropriate antithrombotic therapy.

24. In September of 2012, the FDA approved some label changes for Multaq®, including certain types of lung disease and pulmonary toxicity as us side effects.

25. Plaintiff Hardin suffered serious drug-induced liver injury secondary to Multaq® ingestion.

26. Plaintiff Clay suffered serious drug-induced liver injury due to his Multaq® ingestion and suffered from heart failure and other cardiovascular problems.

27. Plaintiff Biggs suffered serious drug-induced liver injury due to his Multaq® ingestion.

28. Decedent, James Meyer, suffered serious drug-induced liver injury secondary to Multaq® ingestion.

29. Upon information and belief, Multaq® would never have been ingested by Plaintiffs, and had their physicians known the truth about the dangers and risks of Multaq® and would never have prescribed it.

30. At all relevant times, Defendants were aware of the truth, yet deliberately withheld this from Plaintiffs and their physician.

31. Defendants were negligent in their design, manufacture, formulation, and testing of Multaq®, as well as, tracking adverse events related to Multaq®.

32. As a result of Defendants' negligence, Plaintiffs have sustained damages in an amount to be proved at trial.

FIRST CAUSE OF ACTION

N.C. Gen. Stat. 99B-5: FAILURE TO WARN

33. Plaintiffs repeat, re-allege and incorporate herein by reference, all of the preceding allegations as though set forth in full.

34. Plaintiffs allege that Defendants had an established duty to warn of the dangers in using Multaq®. Defendants knew or should have known of the dangers generally known to the scientific community at the time they manufactured and distributed Multaq®.

35. Defendants failed to provide warning of the dangers of using Multaq®, specifically failing to warn Plaintiffs and their physicians regarding known dangers including the danger of life-threatening liver and cardiovascular injuries. Defendants' failure to warn Plaintiffs and her physician of the dangers of using Multaq® proximately caused Plaintiffs to suffer injuries and damages in a sum in excess of the jurisdictional minimum of this Court.

SECOND CAUSE OF ACTION

N.C. Gen. Stat. § 99B-6: DESIGN DEFECT

36. Plaintiffs repeat, re-allege and incorporate herein by reference, all of the preceding allegations as though set forth in full.

37. Plaintiffs allege that Multaq® was designed in a materially defective manner.

38. In the normal course of their business, Defendants manufactured, designed, distributed, sold, and supplied Multaq®.

39. The Multaq® manufactured, designed, sold, marketed, distributed, supplied

and/or placed in the stream of commerce by Defendants was expected to and did reach consumers, including Plaintiffs, without any alterations or changes.

40. The Multaq® administered to Plaintiffs was defective in design or formulation in at least the following respects:

- (a) When it left the hands of the Defendants, Multaq® was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Plaintiffs or Plaintiffs' physicians;
- (b) Any benefit of Multaq® was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;
- (c) The dosages and/or formulation of Multaq® was unreasonably dangerous;
- (d) There are no patients for whom the benefits of Multaq® outweighed the risks;
- (e) Multaq® was not made in accordance with the Defendants' specifications or performance standards;
- (f) There are no patients for whom Multaq® is a safer and more efficacious drug than other drug products in its class; and/or
- (g) There were safer alternatives that did not carry the same risks and dangers as Multaq®; and
- (h) No reasonable person, aware of the relevant facts, would use or consume Multaq®.

41. The Multaq® administered to Plaintiffs was defective at the time it was distributed by the Defendants or left their control.

42. The foreseeable risks associated with the design or formulation of Multaq® include, but are not limited to, the design or formulation of Multaq®, which is more dangerous than a reasonably prudent consumer would expect when used in an intended or

reasonably foreseeable manner. There was also a foreseeable risk that Multaq® did not have the benefits claimed by Defendants.

43. The defective and unreasonably dangerous design and marketing of Multaq® was a direct, proximate and producing cause of Plaintiffs' severe liver and cardiovascular injuries.

44. As a direct, legal, proximate, and producing result of the defective and unreasonably dangerous condition of Multaq®, Plaintiffs sustained injuries and damages in a sum in excess of the jurisdictional minimum of this Court.

45. Defendants acted in reckless disregard of the safety of patients, including Plaintiffs so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

NEGLIGENCE

46. Plaintiffs repeat, re-allege and incorporate herein by reference, all of the preceding allegations as though set forth in full.

- (1) A proximate cause of Plaintiffs' injuries and damages is the negligence and misrepresentations of Defendants through their agents, sales representatives/consultants, paid Key Opinion Leaders, servants and/or employees acting within the course and scope of their employment, negligently, carelessly and recklessly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing Multaq®, and including among other things: Negligently and carelessly engaging in the promotion of Multaq® by recommending to physicians, including Plaintiffs' Physicians, and instructing them to use in a manner in which it was unreasonably dangerous;
- (2) Negligently, carelessly and recklessly promoting Multaq®

by instructing, promoting and directing the use of the product in hospitals for treatment of patients in cases not approved by the FDA;

- (3) Negligently, carelessly and recklessly failing to disclose to physicians that the promoted drug can result in serious side effects, including severe liver injuries, cardiac arrest, and death;
- (4) Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with Multaq®;
- (5) Negligently, carelessly and recklessly representing that the use of Multaq® was safe when, in fact, it was unsafe;
- (6) Negligently, carelessly and recklessly promoting Multaq® beyond the narrow and limited uses for which it was approved;
- (7) Negligently, carelessly, and recklessly failing to adequately warn the medical community, the general public, Plaintiffs' physicians and Plaintiffs of the dangers, contra-indications, and side effects from the use of Multaq®;
- (8) Negligently, carelessly and recklessly failing to act as a reasonably prudent drug manufacturer, including:
 - (a) Commissioning studies which misrepresented the risks associated with the use of Multaq®;
 - (b) Compensating the authors of the above studies monetarily for their opinions;
 - (c) Other violations according to proof.

47. Before Plaintiffs were administered Multaq®, Defendants, based upon the state of knowledge as it existed at the time, knew or should have known that such a use could be dangerous and unsafe, and knew or should have known that such a use could result in severe liver injuries.

48. As a direct and proximate result of the acts and conduct of Defendants, Plaintiff has sustained injuries and damages in an amount in excess of the jurisdictional minimum of the Court.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS AND IMPLIED WARRANTIES

49. Plaintiffs repeat, re-allege, and incorporate herein by reference, all of the preceding allegations as though set forth in full.

50. As alleged above, Defendants expressly and impliedly warranted through their direct-to-consumer marketing, label, and sales representatives, that Multaq® was a safe and effective prescription drug. The safety and efficacy of Multaq® constitutes a material fact in connection with the marketing, promotion, and sale of Multaq®.

51. Multaq® manufactured and sold by Defendants did not conform to these express or implied representations because it caused serious, life-threatening, and sometimes fatal injuries to consumers when taken in recommended dosages.

52. In truth, the Multaq® administered to Plaintiff, was not free from such defects nor fit for the purpose for which it was intended to be used, and was, in fact, defectively manufactured and designed and imminently dangerous to the consumers and users, in that the same were capable of causing, and in fact did cause Plaintiffs serious liver injuries while being used in a manner reasonably foreseeable, thereby rendering the same unsafe and dangerous for use by the consumers and users.

53. As a direct, legal, proximate, and producing result of Defendants' breach of warranty, Plaintiffs sustained injuries and damages in a sum in excess of the

jurisdictional minimum of this Court.

54. Defendant acted in reckless disregard of the safety of patients, including Plaintiffs so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

55. Plaintiffs repeat, re-allege, and incorporate herein by reference, all of the preceding allegations as though set forth in full. Plaintiff pleads this Count in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles, including the law of the Plaintiffs' resident State.

56. Defendants failed to disclose a known defect and affirmatively misrepresented that Multaq® was safe for its intended use. Further, Defendants actively concealed the true risks associated with the use of Multaq®. Neither Plaintiffs nor Plaintiffs' prescribing physicians had knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of Defendants' concealment of and misrepresentations regarding the true risks associated with Multaq®, Plaintiffs could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

57. Thus, because Defendants fraudulently concealed the defective nature of Multaq® and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

58. Additionally, and alternatively, Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that Multaq® caused the appreciable harm

sustained by Plaintiffs. Plaintiffs did not have actual or constructive knowledge of facts indicating to a reasonable person that Plaintiffs were the victim of a tort. Plaintiffs were unaware of the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiffs' lack of knowledge was not willful, negligent or unreasonable.

59. Additionally, and alternatively, Plaintiffs and Defendants entered into a tolling agreement that suspended any statute of limitations and expressly agreed to waive and relinquish any right to assert that the time prescribed by the applicable statute of limitations expired.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as follows:

1. For costs of suit incurred herein;
2. For compensatory and general damages according to proof;
3. For punitive damages;
4. For special and incidental damages according to proof;
5. For pre-judgment interest according to law and proof;
6. For interest on all sums found to be due and owing, said interest accruing at the legal rate from the date of the incident;
7. For such other and further relief as the court deems just and proper.

DATED: January 25, 2016

By: /s/ Gregory L. Jones

Gregory L. Jones
NC Bar 13001
1319 Military Cutoff Rd
Suite CC #138
Wilmington NC 28405
910-619-1100
greg@gregjoneslaw.com

Robert L. Salim (LA #11663)
Lisa L. Causey (LA #33767)
SALIM-BEASLEY, LLC
1901 TEXAS STREET
NATCHITOCHEs, LA 71457
PHONE: (318) 352-5999
FAX: (318) 352-5998
Email: robertsalim@cp-tel.net
Email: lcausey@salim-beasley.com

Attorneys for Plaintiff

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 NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
Amanda Ruth Hardin, et al.

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

(c) Attorneys (*Firm Name, Address, and Telephone Number*)
Robert L. Salim, Lisa Causey-Streete, Salim-Beasley, LLC, 1901 Texas Street, Natchitoches, LA 71457; Gregory L. Jones, 1319 Military Cutoff Rd., Ste. CC 138, Wilmington, NC 28405

DEFENDANTS
Sanofi-Aventis U.S. LLC, et al.

County of Residence of First Listed Defendant Sommerset
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (*If Known*)

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

1 U.S. Government Plaintiff

2 U.S. Government Defendant

3 Federal Question
(U.S. Government Not a Party)

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*)

	PTF	DEF		PTF	DEF
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	LABOR	SOCIAL SECURITY	
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	
			IMMIGRATION	FEDERAL TAX SUITS	
			<input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (*Do not cite jurisdictional statutes unless diversity*):
28 U.S.C. §1391(a) and 18 U.S.C. §1965

Brief description of cause:
This is a products liability case arising out of severe liver injuries as a result of ingesting Multaq® (dronedarone).

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ _____ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

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

DATE: 01/25/2016 SIGNATURE OF ATTORNEY OF RECORD: /s/Gregory L. Jones

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

for the

Middle District of North Carolina

Ruth Amanda Hardin, et. al.

Plaintiff

v.

Sanofi-Aventis U.S. LLC and Aventis
Pharmaceuticals Inc.

Defendant

Civil Action No. 1:16-cv-62

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Aventis Pharmaceuticals Inc.
Corporation Service Company
327 Hillsborough Street
Raleigh, NC 27603-1725

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Robert L. Salim
Lisa Causey-Streete
Salim-Beasley, LLC
1901 Texas Street
Natchitoches, LA 71457

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. 1:16-cv-62

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify):* _____ .

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____ .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT

for the

Middle District of North Carolina

Ruth Amanda Hardin, et. al.

Plaintiff

v.

Sanofi-Aventis U.S. LLC and Aventis
Pharmaceuticals Inc.

Defendant

Civil Action No. 1:16-cv-62

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Sanofi-Aventis U.S. LLC
Corporation Service Company
327 Hillsborough Street
Raleigh, NC 27603-1725

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Robert L. Salim
Lisa Causey-Streete
Salim-Beasley, LLC
1901 Texas Street
Natchitoches, LA 71457

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

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Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: