

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF QUEENS

Index No.:
Date Filed:

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ZOE TONE,

SUMMONS

Plaintiff,

**Plaintiff designates
Queens County
as the place of Trial**

-against-

JOEL R. STUDIN, M.D. and
SANOFI-AVENTIS U.S. LLC,

**The basis of venue is:
Plaintiff resides at
72-36 Juno Street
Forest Hills, NY 11375**

Defendants.
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TO THE ABOVE NAMED DEFENDANT(S):

YOU ARE HEREBY SUMMONED to answer the Complaint in this action and to serve a copy of your answer, or, if the Complaint is not served with this Summons, to serve a notice of appearance, on the Plaintiff's Attorney(s) within 20 days after the service of the Summons, exclusive of the day of service (or within 30 days after the service is complete if this Summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the Complaint.

Dated: Garden City, New York
February 18, 2013

FRANK C. PANETTA, ESQ.
MASSIMO & PANETTA, P.C.
Attorney for Plaintiff
99 Quentin Roosevelt Boulevard, Suite 201
Garden City, New York 11530
(516) 683-8880

DEFENDANTS' ADDRESSES:

TO: JOEL R. STUDIN, M.D.
15 Barstow Road
Great Neck, NY 11021
(516) 482-8008

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, New Jersey 08807
(800) 981-2491

or Registered Agent
CORPORATION SERVICE CO.
80 State Street
Albany, New York 12207-2543

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF QUEENS

Index No.:

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ZOE TONE,

**VERIFIED
COMPLAINT**

Plaintiff,

-against-

JOEL R. STUDIN, M.D. and
SANOFI-AVENTIS U.S. LLC,

Defendants.
-----X

Plaintiffs, ZOE TONE, complaining of the Defendants, by her attorneys, MASSIMO & PANETTA, P.C., respectfully alleges, upon information and belief, at all times hereinafter mentioned as follows:

FIRST: At all times hereinafter mentioned, the Plaintiff was and still is a resident of the County of Queens and State of New York.

SECOND: At all times herein mentioned, Defendant, JOEL R. STUDIN, M.D., was a physician duly licensed to practice medicine in the State of New York.

THIRD: At all times herein mentioned, Defendant, JOEL R. STUDIN, M.D., maintained an office at 15 Barstow Road, in the State of New York 11021.

FOURTH: At all times herein mentioned, Plaintiff, ZOE TONE, was a patient of Defendant, JOEL R. STUDIN, M.D. and was treated at said office of Defendant, JOEL R. STUDIN, M.D.

FIFTH: That on or about July 13, 2011 and continuing to on or about, to wit October, 12, 2011, the Plaintiff came under the diagnosis, care and treatment of the Defendant, JOEL R. STUDIN, M.D.

SIXTH: The amount of damages sought in this action exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

SEVENTH: Defendant SANOFI-AVENTIS U.S. LLC is a foreign corporation, duly formed under the laws of Pennsylvania and maintaining offices at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

EIGHTH: At all relevant times, Defendant, SANOFI-AVENTIS U.S. LLC was and is the manufacturer and distributor, of pharmaceuticals, including Sculptra™.

NINTH: SANOFI-AVENTIS U.S. LLC engaged and continues to engage in the research, manufacture and distribution, of among other products, drugs and pharmaceuticals.

TENTH: As a manufacturer of pharmaceuticals with worldwide distribution, Defendant, has sufficient contacts with the State of New York to be subjected to jurisdiction within the State of New York.

ELEVENTH: Among the chemicals and drugs manufactured, advertised and distributed by defendant was the product marketed and registered under the trade name "Sculptra", an injectable "dermal filler" for use on human patients.

**AS AND FOR THE FIRST CAUSE OF ACTION
AGAINST JOEL R. STUDIN, M.D. FOR MEDICAL MALPRACTICE**

TWELFTH: Plaintiff, ZOE TONE repeats, realleges and reiterates paragraphs "FIRST" through "ELEVENTH" with the same force and effect as if hereafter set forth at length.

THIRTEENTH: That on or about July 13, 2011, a Poly-L-Lactic Acid compound approved by the Food & Drug Administration (FDA) for individuals with lipodystrophy¹, namely "Sculptra", was marketed to JOEL R. STUDIN, M.D.'s patients as a "Botox alternative".

FOURTEENTH: That on or about July 13, 2011, September 7, 2011 and October 12, 2011 Defendant, JOEL R. STUDIN, M.D. performed a series of injections of a dangerous drug for a purpose it was neither intended for, nor safe for commonly referred to as "off-label" usage, willful and wantonly recklessly ignoring the manufacturer's warnings.

¹ Commonly known as suffering from gaunt or shallow cheeks related to fat loss.

FIFTEENTH: Defendant, JOEL R. STUDIN, M.D., performed treatment in a manner that deviated from the standard of care; his lack of knowledge about the drug deviated from what a prudent doctor would know about said drug prior to injecting it; JOEL R. STUDIN, M.D. treated Plaintiff's complications in a negligent manner, he misdiagnosed or failed to diagnose Plaintiff correctly and as a result, Plaintiff suffered severe and permanent injuries all without any fault or lack of care on the part of the Plaintiff.

SIXTEENTH: Said occurrence was due to the wanton, willful, and or gross negligence of the Defendant, JOEL R. STUDIN, M.D., in improperly performing said injections, in intentionally failing to follow the manufacturer's directions, with conscious disregard or lack of care on the part of the Plaintiff herein. This wanton behavior was both unethical and a deviation from the standard of care.

SEVENTEENTH: As a result and by reason of the foregoing, Plaintiff sustained severe internal as well as external injuries, including, but not limited to, disfigurement, severe physical pain, mental anguish as a result thereof, upon information and belief some or all of these injuries are of a permanent and lasting nature.

EIGHTEENTH: Plaintiff has been prevented from performing her usual activities; and Defendants have caused Plaintiff to expend sums of money for medical care due to said negligence.

NINETEENTH: Plaintiff, ZOE TONE, seeks punitive damages in addition to monetary damages, in an amount in excess of the jurisdictions of all lower courts which would otherwise have jurisdiction.

AS AND FOR A SECOND CAUSE OF ACTION
AGAINST JOEL R. STUDIN, M.D. FOR FAILING TO PROVIDE
INFORMED CONSENT ABOUT OFF-LABEL USE

TWENTIETH: Plaintiff repeats, reiterates and realleges each and every allegation contained in those paragraphs of the Complaint marked and designated "FIRST" through "NINETEENTH" with the same force and effect as if hereafter set forth at length.

TWENTY-FIRST: Defendant, JOEL R. STUDIN, M.D., willfully failed to inform the Plaintiff of the risks, hazards and alternatives connected with the procedures utilized, so that an informed consent could be given.

TWENTY-SECOND: Reasonably prudent persons in the Plaintiff's position would not have undergone the procedures, if they had been fully informed of the risks, hazards and alternatives connected with said procedures, not limited to the frequent skin eruptions, inflammatory reaction, granulomas and lumps and bumps present in trials. Said information was available in the medical community and a reasonable medical doctor should have advised Plaintiff of same.

TWENTY-THIRD: Defendant, JOEL R. STUDIN, M.D., intentionally and willfully deceived Plaintiff in order to gain her approval of the procedure and increase his personal revenue by advising her it was a safe "wrinkle filler". The failure to adequately and fully inform the Plaintiff of the procedures is a proximate cause of the injury Plaintiff sustained.

TWENTY-FOURTH: As a consequence of the foregoing, Plaintiff was willfully and intentionally deceived and was unable to give informed consent to the procedures Defendant, JOEL R. STUDIN, M.D., performed on Plaintiff, ZOE TONE.

TWENTY-FIFTH: The dollar amount of the damages sought, punitive and monetary, exceed the jurisdiction of all lower courts which would otherwise have jurisdiction.

AS AND FOR A THIRD CAUSE OF ACTION
AGAINST JOEL R. STUDIN, M.D. FOR GROSS NEGLIGENCE

TWENTY-SIXTH: Plaintiff repeats, reiterates and realleges each and every allegation contained in those paragraphs of the Complaint marked and designated "FIRST" through "TWENTY-FIFTH" with the same force and effect as if hereafter set forth at length.

TWENTY-SEVENTH: Due to the aforementioned the acts constituting "off-label" injections of Sculptra, Plaintiff was negligently and recklessly injured by a drug known to cause papules and nodules.

TWENTY-EIGHTH: The injections, were improperly done by JOEL R. STUDIN, M.D., were done without testing a site on ZOE TONE 's body and were done in a negligent manner.

TWENTY-NINTH: The preparation of both Sculptra and/or Plaintiff was improperly done by JOEL R. STUDIN, M.D., constituting gross negligence.

THIRTIETH: The dollar amount of the damages sought exceeds the jurisdiction of all lower courts which would otherwise have jurisdiction.

AS AND FOR A FOURTH CAUSE OF ACTION AGAINST
JOEL R. STUDIN, M.D. FOR RECKLESSNESS IN HIS
WILFUL WANTON DISREGARD

THIRTY-FIRST: Plaintiff repeats, reiterates and realleges each and every allegation contained in those paragraphs of the Complaint marked and designated "FIRST" through "THIRTIETH" with the same force and effect as if hereafter set forth at length.

THIRTY-SECOND: By injecting Sculptra™, a Poly-L-Lactic Acid, known to cause adverse reactions in patients and have dire consequences, to an unsuspecting Plaintiff, JOEL R. STUDIN, M.D. was reckless and grossly negligent. JOEL R. STUDIN, M.D. knew or had reason to know that said adverse consequences were likely to occur, yet proceeded recklessly.

THIRTY-THIRD: Defendant engaged in willful and wanton behavior that put profit above the health of his patient when he engaged in a second and third round of Sculptra™ injections on a patient that was not suffering from lipodystrophy and whose skin was not tested.

THIRTY-FOURTH: As a result of the foregoing, Plaintiff is entitled to punitive damages.

THIRTY-FIFTH: As a result of the foregoing, the dollar amount sought exceeds the jurisdiction of all lower courts.

AS AND FOR A FIRST CAUSE OF ACTION
AGAINST SANOFI-AVENTIS U.S. LLC
FOR PRODUCTS LIABILITY

THIRTY-SIXTH: Plaintiff repeats, reiterates and realleges each and every allegation contained in those paragraphs of the Complaint marked and designated "FIRST" through "THIRTY-FIFTH" with the same force and effect as if hereafter set forth at length.

THIRTY-SEVENTH: SANOFI-AVENTIS U.S. LLC knew or had reason to know their product "Sculptra" was and is dangerous, as it causes nodules, papules, granulomas or skin reactions.

THIRTY-EIGHTH: The negligence of SANOFI-AVENTIS U.S. LLC consisted, among other things, of negligently, carelessly and recklessly testing and manufacturing, of which said negligent design, manufacture greatly caused plaintiff's injuries; negligently and carelessly putting an inherently dangerous product on the market and failing to provide a reasonably safe drug in which to rely; otherwise failing to exercise that degree of care and caution which a reasonably prudent manufacturer of drugs would have exercised with regard to protecting the safety of the users of its product; and was otherwise careless and negligent.

THIRTY-NINTH: The defect in the drug was hidden and/or not disclosed, misrepresented at the FDA fast track hearing, therefore, plaintiff did not and, by the exercise of reasonable care, could not discover it, nor could she, by exercising such reasonable care, have

perceived the danger.

FORTIETH: SANOFI-AVENTIS U.S. LLC marketed and distributed the drug in the State of New York illegally and violated FDA rules by marketing to doctors directly for off-label use, despite knowing it was a dangerous and had a multitude of known side-effects.

FORTY-FIRST: By reason of the wrongful, willful, unlawful, reckless and negligent acts of defendants, plaintiff has sustained serious temporary and permanent injuries, has suffered severe mental shock, has been compelled to secure medical aid and medicines in an effort to cure or minimize her injuries, and will require further medical aid and assistance for an indefinite period of time, all to his her substantial damage. Plaintiff further demands to be compensated for her medical needs, past, present and future.

FORTY-SECOND: The amount of damages sought in this action exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

AS AND FOR A SECOND CAUSE OF ACTION
AGAINST SANOFI-AVENTIS U.S. LLC
FOR PRODUCTS LIABILITY

FORTY-THIRD: Plaintiff, repeats, reiterates and realleges each and every allegation contained in those paragraphs of the Complaint marked and designated as "FIRST" through "FORTY-SECOND" with the same force and effect as if hereafter set forth at length.

FORTY-FOURTH: In manufacturing, packaging, selling and distributing the drug "Sculptra", Defendant warranted to the public and to Plaintiff that "Sculptra" was fit for use as an injectable, was at least of a quality which would pass without objection in the trade, was at least fit for the ordinary purposes for which such product was manufactured, and in all other respects was of merchantable quality.

FORTY-FIFTH: Defendant breached its warranty in that the product "Sculptra" was lethal, toxic, damaging and not fit for human use without causing severe harm and injury, and was not of a merchantable quality.

FORTY-SIXTH: As a result of the injection of "Sculptra" plaintiff suffered disfigurement, severe physical pain and mental anguish, all of which are of a permanent nature.

FORTY-SEVENTH: Plaintiff also developed and continues to develop solidified particle deposits, necessitating removal and caused by the toxic elements present in "Sculptra" which injuries continue to the present time.

FORTY-EIGHTH: The injuries sustained by Plaintiff, ZOE TONE, have prevented her from pursuing her usual daily duties and vocation, and plaintiff will be unable to perform them for an indefinite period of time.

FORTY-NINTH: As a result of defendant's breach of warranty, plaintiff has been damaged in a sum that exceeds the jurisdiction of all lower courts for all causes of action to be determined upon the trial of this case together with interest, costs and disbursements as set forth by law and as against the Defendants punitive damages equal to three times the amount of compensatory damages.

AS AND FOR A THIRD CAUSE OF ACTION
AGAINST SANOFI-AVENTIS U.S. LLC FOR
WILFUL WANTON RECKLESSNESS

FIFTIETH: Plaintiff, repeats, reiterates and realleges each and every allegation contained in those paragraphs of the Complaint marked and designated as "FIRST" through "FORTY-NINTH" with the same force and effect as if hereafter set forth at length.

FIFTY-FIRST: Defendant, SANOFI-AVENTIS U.S. LLC. was and is a foreign corporation, duly formed under the laws of France and having its principle place of business in the United States at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

FIFTY-SECOND: At all relevant times, defendant was and still is a merchant engaged in the, research and development, manufacture and distribution, among other products, of drugs and pharmaceuticals.

FIFTY-THIRD: At all relevant times, by defendant marketing and distributing drugs and pharmaceuticals and putting said pharmaceuticals and drugs in the stream of commerce, consented to the jurisdiction of the laws of the State of New York.

FIFTY-FOURTH: Among the chemicals and drugs researched developed, manufactured, advertised and distributed by Defendant, was the product marketed and registered under the trade name "Sculptra" for use in the treatment of patients with facial depressions or deficits.

FIFTY-FIFTH: It is well-established law that punitive damages may be awarded when a defendant's conduct is so reckless or wantonly negligent with an intentional disregard of the rights of others. SANOFI-AVENTIS U.S. LLC. knew or had reason to know that the drug, which is inherently dangerous was going to be used "off-label". They themselves violated FDA rules and marketed a drug directly for off-label use to physicians such as Dr. Amy Newberger.

FIFTY-SIXTH: It was reckless and egregious to market a drug they had known to cause granulomas and papules and other side and to have conscious disregard for the general welfare of the public.

FIFTY-SEVENTH: Defendant boasts that it "contribute[s] to human health and the quality of life", and "Shortening or improving the identification, validation and approval of products by using cutting-edge science, technologies, quality processes and data". Yet it robbed this Plaintiff of any semblance of a life. Said denigration of Plaintiff's life was proximately caused by Sculptra™ being approved by the Food and Drug Administration by willful deceit or deception and by a willful and wanton disregard as to the health and safety of the public. Said misleading and falsely representing data in violation of FDA rules and guidelines has taken quality of life away from Plaintiff.

FIFTY-EIGHTH: In manufacturing, packaging, selling and distributing the drug "Sculptra" defendant(s) warranted to the public and to plaintiff that "Sculptra" was fit for use as

an injectable, was at least of a quality which would pass without objection in the trade, was at least fit for the ordinary purposes for which such product was manufactured, and in all other respects was of merchantable quality.

FIFTY-NINTH: Defendant breached its warranty in that the product "Sculptra" was lethal, toxic, damaging and not fit for human use without causing severe harm and injury, and was not of a merchantable quality.

SIXTIETH: As a result of the injection of "Sculptra" plaintiff suffered disfigurement, severe physical pain and mental anguish, all of which are of a permanent nature.

SIXTY-FIRST: Plaintiff also developed and continues to develop solidified particle deposits, necessitating removal and caused by the toxic elements present in "Sculptra" which injuries continue to the present time.

SIXTY-SECOND: The injuries sustained by plaintiff have prevented her from attending to her usual daily duties and vocation, and plaintiff will be unable to perform them for an indefinite period of time.

SIXTY-THIRD: Defendants all represented and advertised that "Sculptra" was safe and effective as an alternative to surgery or other injectable drugs, despite knowing or having reason to know that it was not; as a result, it was reasonable for Plaintiff, ZOE TONE, to rely on said representations of all Defendants and to use the product, "Sculptra", and therefore, the implied warranties extended to plaintiff.

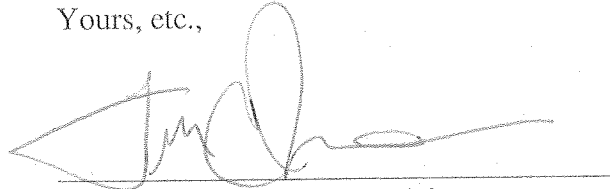
SIXTY-FOURTH: As a result of Defendant's breach of warranty, Plaintiff has been damaged in a sum that exceeds the jurisdiction of all lower courts.

WHEREFORE, Plaintiffs demands judgment against all Defendants in an amount that exceeds the jurisdictional limit of all lower courts which would otherwise have jurisdiction for all causes of action to be determined upon the trial of this case, including, but not limited to her

medical expenses, pain and suffering and for punitive damages against all Defendants, together with interest, costs and disbursements as set forth by law against the Defendants.

Dated: Garden City, New York
February 18, 2013

Yours, etc.,

A handwritten signature in black ink, appearing to read 'Frank C. Panetta', written over a horizontal line.

FRANK C. PANETTA, ESQ.
MASSIMO & PANETTA, P.C.

Attorneys for Plaintiffs
99 Quentin Roosevelt Boulevard, Suite 201
Garden City, New York 11530

TO: JOEL R. STUDIN, M.D.
15 Barstow Road
Great Neck, NY 11021
(516) 482-8008

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, New Jersey 08807
(800) 981-2491

or **Registered Agent**
CORPORATION SERVICE CO.
80 State Street
Albany, New York 12207-2543

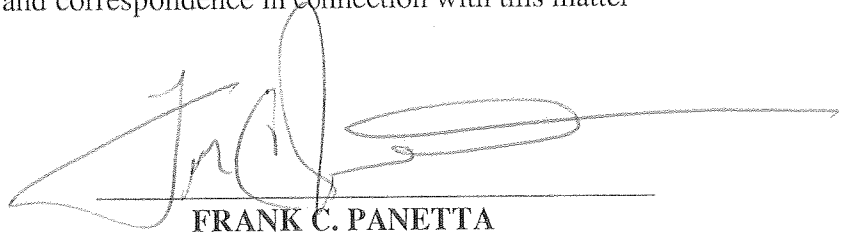
VERIFICATION

STATE OF NEW YORK)
 ss.:)
COUNTY OF NASSAU)

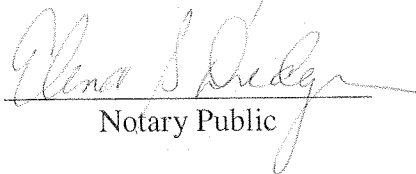
The undersigned, **FRANK C. PANETTA**, is an attorney and partner of the firm of MASSIMO & PANETTA, with offices at 99 Quentin Roosevelt Boulevard, Suite 201, Garden City, New York 11530, County of Nassau, duly admitted to practice law in the Courts of the State of New York, states:

That Deponent is the attorney of record for Plaintiff in the within action. That Deponent has read the foregoing SUMMONS AND VERIFIED COMPLAINT and knows the contents thereof. That same is true to the Deponent's own knowledge, except as to those matters therein stated to be alleged on information and belief, and that as to those matters, Deponent believes it to be true.

Deponent further states that the reason this Verification is made by Deponent and not by Plaintiff is that Plaintiff does not reside within the County of Nassau which is the County where MASSIMO & PANETTA have their offices (Plaintiff resides in the County of Queens, State of New York, 72-36 Juno Street, Forest Hills, New York 11375). That the source of Deponent's information, and the grounds of Deponent's belief as to all matters herein, not therein stated upon knowledge, are records, reports and correspondence in connection with this matter reviewed by your Deponent.


FRANK C. PANETTA

Sworn to before me this
18 day of February, 2013.


Notary Public

ELENA S. DREDGER
Notary Public, State Of New York
No. 02DR6007395
Qualified in Nassau County
Commission Expires Jan. 25, 2015