IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

MINERVA SALAZAR, Plaintiff, v. EXACTECH, INC. and EXACTECH US, INC., Defendants.	§ § § § § § § § § §	CIVIL ACTION NO. _____ JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT COURT JUDGE:

COMES NOW, Plaintiff, MINERVA SALAZAR ("Plaintiff"), and files this Plaintiff's Original Complaint complaining of EXACTECH, INC. ("EXACTECH") and EXACTECH US, INC. ("EXACTECH US") (hereafter collectively as "Defendants"), for personal injuries suffered as a proximate result of the implantation of a polyethylene Optetrak Logic PSC Tibial Insert within an Optetrak Logic Total Knee Arthroplasty System ("the Device") and would respectfully show the Court the following:

INTRODUCTION

1. This personal injury action relates to Defendants' misconduct with respect to its design, testing, manufacturing, packaging, storage, labeling, distribution, marketing, or sale of the Optetrak, Optetrak Logic, and Truliant Total Knee Arthroplasty ("TKA") Systems as well as the Vantage Total Ankle Arthroplasty ("TAA") System.[1]

[1] This Complaint will refer to the Truliant TKA as "Truliant" and Vantage TAA Systems as "Vantage," respectfully, and to the Optetrak and Optetrak Logic TKA Systems simply as "Optetrak."

2. For many Americans, the solution to chronic or worsening knee or ankle joint pain is to replace the joint in its entirety. While most knee and ankle joint replacements last for several years, Exactech's Optetrak, Truliant, and Vantage systems fail sooner and more often than others on the market.

3. Exactech admits many of these premature and frequent failures are due to the improper packaging of a component part—the polyethylene insert—which exposes the part to oxygen, causing it to oxidize, and ultimately to deteriorate at an accelerated rate. This eventually leads to premature failure of the entire knee or ankle system and/or other injuries and damages.

4. Because of Exactech's wrongful acts and omissions, including its inadequate packaging of this component part, thousands of patients implanted with Optetrak, Truliant, and Vantage Systems have had to undergo (or likely will have to undergo) significant revision surgeries to remove and replace the defective devices.

5. Indeed, Plaintiff was implanted with the Device, which failed prematurely and caused a severe infection in Plaintiff, resulting in the need for a revision surgery, and causing significant and continuing personal injuries as well as for Plaintiff to incur substantial medical bills and expenses.

6. Accordingly, Plaintiff brings the instant suit, demands judgment against Defendants, and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

7. Plaintiff, Minerva Salazar, is a Texas citizen residing in San Benito, Cameron County, Texas.

8. On July 18, 2017, at Valley Baptist Medical Center in Harlingen, Cameron County, Texas, Plaintiff was implanted with the Device which failed prematurely and caused a severe infection.

9. As a result of the failure of the Device, Plaintiff was forced to undergo revision surgery where her doctor—not knowing the unique risks of the Device—implanted ***another*** polyethylene Optetrak Logic PSC Tibial Insert within an Optetrak Logic Total Knee Arthroplasty System. Due to the complications caused by the first polyethylene Optetrak Logic PSC Tibial Insert within an Optetrak Logic Total Knee Arthroplasty System, Plaintiff spent significant time in the hospital for treatment and recovery from the revision surgery and the implantation of the second polyethylene Optetrak Logic PSC Tibial Insert within an Optetrak Logic Total Knee Arthroplasty System.

10. After the revision surgery, Plaintiff was then transferred from Valley Baptist Medical Center in Harlingen, Texas, to a skilled nursing facility where Plaintiff spent over one month in recovery.

11. Plaintiff has required additional physical therapy, incurred substantial medical bills and expenses, and suffered lost wages, beginning in August 2017, due to Defendants' wrongful acts and omission with respect to the Device. And, because Plaintiff was implanted with another polyethylene Optetrak Logic PSC Tibial Insert within an Optetrak Logic Total Knee Arthroplasty System, she is likely to experience another premature failure (and resulting sequalae) in the future.

12. Defendant, Exactech, Inc., is a Florida Corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

13. Upon information and belief, Defendant Exactech, Inc., designs, tests, develops, manufactures, labels, packages, markets, distributes, or sells orthopedic joint replacements, including the Optetrak, Truliant, and Vantage Systems and related surgical instrumentation, throughout the United States, including in the State of Texas.

14. Upon information and belief, at all relevant times, Defendant Exactech, Inc., was engaged in promoting, distributing, selling, or otherwise introducing its TKA Systems into interstate commerce throughout the United States, including in the State of Texas, and generating substantial revenue as a result.

15. Upon information and belief, Defendant Exactech, Inc., manufactured the Device implanted in Plaintiff.

16. Upon information and belief, Defendant Exactech US, Inc., is a wholly owned subsidiary of Exactech, Inc., with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

17. Upon information and belief, and according to public filings, Defendant Exactech US, Inc., conducts Exactech, Inc.'s U.S. sales and distribution activities.

18. Upon information and belief, Defendant Exactech US, Inc., is engaged in the business of promoting, distributing, selling, or otherwise introducing its TKA Systems into interstate commerce throughout the United States, including in the State of Texas, and generating substantial revenue as a result.

19. Upon information and belief, the Optetrak, Truliant, and Vantage Systems manufactured by Defendant Exactech, Inc., were distributed by Defendant Exactech US, Inc., throughout the United States, including to Plaintiff in Texas.

20. Upon information and belief, Corporation Service Company at 1201 Hays Street, Tallahassee, Florida 32301 is a registered agent of or is authorized to accept service of process for both Exactech, Inc., and Exactech US, Inc.

JURISDICTION AND VENUE

21. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship.

22. This Court has personal jurisdiction over Defendants because each, through its respective employees, agents, and/or sales representatives, have transacted business in the State of Texas and within the District of Texas; solicited residents of the State of Texas; and engaged in the misconduct described in this Complaint, upon information and belief. Accordingly, Defendants both have sufficient minimum contacts with the State of Texas such that it does not offend traditional notions of fair play and substantial justice to have them answer for their misconduct in this Court.

23. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because both Defendants transact and conduct business in Texas, a substantial part of the acts and omissions giving rise to this Complaint occurred in Texas, because Plaintiff was implanted, injured, and revised in Texas, and because Plaintiff is a resident and citizen of Texas.

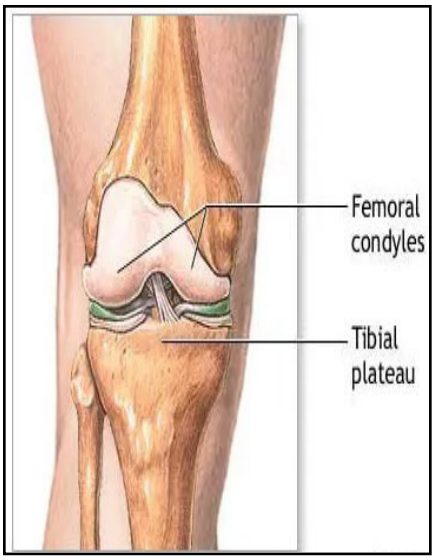
FACTUAL BACKGROUND

Knee Replacement and Components

24. Total knee arthroplasty is a common orthopaedic surgery that involves replacing the

articular surfaces of the joint with smooth metal and highly cross-linked polyethylene plastic.[2]

Knee Joint



25. For example, in a total knee arthroplasty the femoral condyles and tibial plateau of the knee joint are replaced.

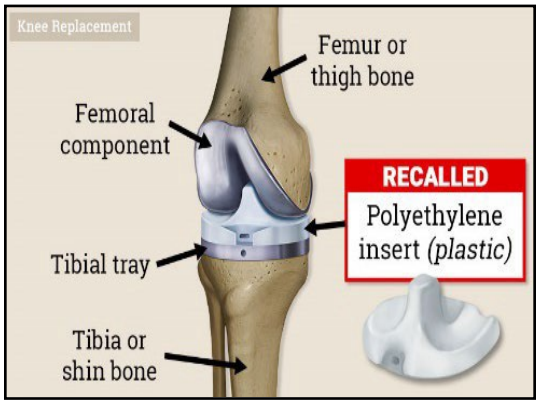
26. Arthroplasty polyethylene inserts are the plastic liners placed between the two metallic surfaces in a fixed-bearing knee or ankle replacement. In essence, these polyethylene inserts serve as cushions—or shock absorbers—between the metal components in knee and ankle replacements.

Exactech® Knee Polyethylene Inserts

27. Exactech's TKA systems are classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. They feature a mix of polyethylene and metal-based components.

[2] For illustrative purposes, below are diagrams of the knee and ankle joints.

28. Exactech's TKA systems are comprised of the following parts: a femoral cap, a tibial tray, and sometimes a patellar cap. The patellar cap and tibial tray are both made of polyethylene.



Properties of Polyethylene and its Use in TKA Systems

29. Polyethylene is a polymer of ethylene—a hydrocarbon—which consists of as many as 200,000 ethylene repeat units. Ethylene is polymerized in the presence of catalysts to make ultra-high molecular weight polyethylene ("UHMWPE"), which is commercially produced as resin powder. The resin powder is then consolidated into rods/sheets from which final inserts found in TKAs are made.

30. Polyethylene is a significant element of TKAs, and its development has undergone considerable changes in the last thirty years. While polyethylene is commonly used in TKAs, there are several concerns with *in vivo* use. Specifically, polyethylene inserts cannot be exposed to oxygen during the packaging and storing process. Exposing polyethylene inserts to oxygen creates a chemical reaction called oxidization, which causes the premature wear or degradation of polyethylene inserts. As such, polyethylene inserts must be handled with a high degree of care when processed, packaged, and stored.

31. The oxidation process is time-dependent and can also occur before the liner is

even implanted in a patient if the liner is exposed to air. Thus, airtight packaging is crucial and requires multiple barriers that adequately prevent oxidation.

32. Wear characteristics of polyethylene are directly influenced by techniques of processing, storing, and packaging methods. These processes are significantly aimed at preventing the oxidation of the polyethylene inserts. Proper packaging and storage prevent oxidation and reduce the risk of failure from strength changes in the polyethylene inserts. Indeed, preventing the oxidation of polyethylene through proper processing, storing, and packaging methods directly prevents the wear of the polyethylene inserts.

33. Wear of polyethylene is a direct cause of component loosening and other component failures. Accordingly, the wear of polyethylene components is likely to cause severe complications, including swelling, grinding, instability, tissue damage, osteolysis, permanent bone loss and other injuries. This ultimately causes the entire systems to fail and patients to need revision surgeries.

The Importance Of Appropriate Packaging Is Well-Understood

34. It is widely understood in the medical device industry that if polyethylene components are exposed to air, they will oxidize and degrade. Accordingly, when manufactured and stored, polyethylene components must and should be packaged in multiple-layered, sufficiently oxygen-resistant vacuum-sealed bags.

35. Indeed, throughout the medical device industry, precautions are taken to ensure polyethylene components are properly packaged to avoid oxidation.

36. For example, the manufacturer Smith & Nephew, which began producing the Salto™ ankle systems in 2006, an ankle replacement system with polyethylene, uses a "double peel

package" when sterilizing and packaging its ankle polyethylene products.

Defendants' False & Misleading Performance Claims

37. Upon information and belief, Defendants represented to doctors, patients, and the general public that its fleet of TKA systems were "excellent," high quality, and reliable. For example, its TKA marketing materials boasted:

> "with a design developing for more than four decades and excellent clinical and laboratory results, surgeons can have confidence in a knee system that continues to demonstrate performance over time. Surgeons around the world continue to document excellent long-term clinical results with the Optetrak family of products."

38. Upon information and belief, Defendants' marketing materials similarly boasted low revisions rates.

39. Upon information and belief, Defendants' marketing materials did not disclose several investigations and ongoing claims that its TAA systems were, in fact, failing much sooner and at much higher rates than others on the market.

Defendants' History of TKA Performance Issues

40. Upon information and belief, as early as 2012, Defendants were aware (or should have been aware) that their TKA systems were failing at a higher rate than promoted due to the oxygenation of the polyethylene components.

41. For example, reports in the Manufacturer and User Facility Device Experience (MAUDE) database in 2012 indicate instances of revision due to "loose tibial component," "aseptic loosening," "pain and visible loosening," "polyethylene deformation," "polyethylene worn," and "pain, limited mobility, knee swelling and sensitivity" caused by loosening in the joint replacement.

42. Additional examples from 2014 list "revision due to tibial loosening," "tibial loosening," "revision of [O]ptetrak knee components due to tibial loosening," "revision due to pain and loosening," and "revision of [O]ptetrak knee components due to aseptic loosening," as well as several reports of "revision of knee components due to tibial loosening," and "revision of [O]ptetrak knee components reportedly due [to] aseptic loosening."

43. And this experience was not unique to U.S. patients. Upon information and belief, according to the 2020 Australian National Joint Replacement Registry, the rate of revision for a TKA utilizing an Optetrak tibial component with a Optetrak-CR femoral component was 8.5% at ten (10) years and 10.2% at ten (10) years when implanted with a Optetrak-PS femoral component; both rates far exceed international guidelines for acceptable revision rates, upon information and belief.

44. Likewise, upon information and belief, the Australian Orthopaedic Association has remarked that the Optetrak TKA Systems have a "higher-than-expected" rate of revision.

45. Upon information and belief, per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Optetrak TKA Systems do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark" because of its high failure rate.

Defendants Were Aware Of The Problem, But Did Nothing

46. Upon information and belief, it is widely recognized and accepted in the medical device industry that reported AERs represent only a small fraction of adverse events associated with and/or caused by a particular device.

47. Despite Defendants' knowledge of early onset failures of their TKA systems,

Defendants continued to design, warrant, manufacture, promote, sell, and distribute them without alerting surgeons or patients of its potential increased risks of early onset failures.

48. Defendants never changed the labeling, marketing materials, or product inserts to adequately and accurately warn patients or doctors of the associated increased risks of early failure due to loosening or polyethylene wear.

49. Exactech did, however, quietly—and without providing information or explanation for its decision to patients, doctors, or the general public—begin replacing the tibial trays of some Optetrak models.

Recent Exactech Recall

50. Finally, in August 2021, Exactech recalled a limited number of its TKA and TAA systems.

51. Upon information and belief, Exactech notified distributors and sales representatives of the limited recall on approximately August 30, 2021, in a letter entitled 'URGENT MEDICAL DEVICE RECALL.' In part, the letter clarified that Exactech was "removing all Knee and Ankle UHMWPE products labeled with an 8- year shelf life and not packaged in EVOH/Nylon bags, in a phased approach over 12 months."[3]

52. Upon information and belief, the actions and timing as to each phase was described as follows:

> **Phase 1:** immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags.
>
> **Phase 2:** between 05/31/2022 to 08/31/2022, returning all remaining knee and

[3] *See* U.S. FOOD & DRUG ADMIN., *Class 2 Device Recall OPTETRAK Comprehensive Knee System* (Oct. 04, 2021) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=189015.

> ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags."[4]

53. Notably, Defendants did not issue any communications to surgeons who had Implanted Optetrak, Truliant, or Vantage Systems with a recalled polyethylene component.

54. Defendants did not issue any communications to patients who had received an Optetrak, Truliant, or Vantage Systems with a recalled polyethylene component.

55. In fact, it took nearly six (6) months for Exactech to notify patients, doctors, and the public that its Optetrak, Truliant, or Vantage Systems were defective and contained faulty polyethylene liners.

56. On February 7, 2022, Exactech issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. **Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, or component fatigue cracking/fracture, all leading to corrective revision surgery.**[5]

57. The "Urgent Medical Device Correction" clarified that Exactech was expanding its recall to now include ***all knee arthroplasty polyethylene inserts packed in non-conforming bags regardless of label or shelf life.*** The components subject to the recall now included:

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[4] *Id.*

[5] *See* Exactech's "Urgent Medical Device Correction" letter, dated Feb. 7, 2022, available online at: https://www.exac.com/wp-content/uploads/2022/02/Exactech-DHCP letter.02.07.2022.pdf.

OPTETRAK®: All-polyethylene CR Tibial Components, All- polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRAK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts; and VANTAGE Fixed-Bearing Liner Components.[6]

58. In its February 7, 2022, correspondence, Exactech advised surgeons that revision surgery should be considered for patients who exhibited symptoms consistent with premature polyethylene wear, like "new or worsening pain, inability to bear weight, grinding or other noise, swelling, or [joint] instability."

Plaintiff's Failed Implant and Subsequent Revision Surgery

59. On July 18, 2017, Plaintiff underwent a TKA on her left knee and was implanted with the Device at Valley Baptist Medical Center, Harlingen, Texas.

60. On July 27, 2017, just nine (9) days after the initial implant, Plaintiff was admitted, again, to Valley Baptist Medical Center, Harlingen, Texas with a severe infection of the left knee replacement—the same knee where Plaintiff was implanted with the Device.

61. On July 31, 2017, Plaintiff was taken to the operating room at Valley Baptist Medical Center for debridement of her left knee and removal of the polyethylene Optetrak Logic PSC Tibial Insert. After removal of the PSC Tibial Insert, Plaintiff's treating surgeon replaced it with an antibiotic spacer. Plaintiff remained in Valley Baptist Medical Center for further observation and treatment of the infection from July 31, 2017 until August 7, 2017, at which time

[6] *Id.*

Plaintiff was—again—taken to the operating room for yet another surgery.

62. As a result of the Device, on August 7, 2017, Plaintiff's left knee was again debrided and the antibiotic spacer that had replaced the defective Optetrak Logic PSC Tibial Insert was then itself replaced with another polyethylene insert into Plaintiff's Optetrak PSC Tibial Insert. Unfortunately, Plaintiff and her doctor—due to Defendants' knowing false representations and intentional material omissions—were unaware of the unique risks posed by the Device, and Plaintiff was implanted with ***another*** Optetrak Logic PSC Tibial Insert. Given the obvious safety risks posed by the Device and this component specifically, it is likely that the second Optetrak Logic PSC Tibial Insert and/or Optetrak Logic TKA system implanted into Plaintiff will also fail, requiring Plaintiff to undergo yet another revision surgery.

63. Because of the failure of the subject Device, Plaintiff has suffered significant and ongoing personal injuries that have limited her activities of daily living, require additional physical therapy, caused substantial medical bills and expenses, as well as other damages.

64. And, because Plaintiff was implanted with another Optetrak Logic PSC Tibial Insert, Plaintiff is likely to experience another premature failure (and resulting injuries and damages) in the future.

65. To this day, Plaintiff continues to experience pain, limited range of motion, and audible noises from her Optetrak Logic TKA System, as well as the fear that the Device and/or the second PSC Tibial Insert will fail again, forcing Plaintiff to undergo further complications and medical intervention.

66. As a direct and proximate result of the defective nature of the Device and the PSC Tibial Insert, Plaintiff has suffered and continues to suffer significant, permanent, and

continuing personal injuries, as described herein.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

67. Defendants willfully, wantonly, or intentionally withheld information from Plaintiff, Plaintiff's healthcare providers, and the public concerning the known hazards associated with its Optetrak, Truliant, and Vantage Systems.

68. Defendants willfully, wantonly, or intentionally withheld safety-related warnings from Plaintiff, Plaintiff's healthcare providers, and the public concerning the known hazards associated with its Optetrak, Truliant, and Vantage Systems.

69. Defendants willfully, wantonly, or intentionally withheld instructions from Plaintiff, Plaintiff's healthcare providers, and the public regarding how to identify, mitigate, or treat known hazards associated with its Optetrak, Truliant, and Vantage Systems.

70. Defendants willfully, wantonly, intentionally conspired, and acted in concert to ignore relevant safety concerns and deliberately not study the long-term safety and efficacy of its Optetrak, Truliant, and Vantage Systems, including the polyethylene liners used in its Optetrak, Truliant, and Vantage Systems.

71. Defendants failed to disclose a known defect in its design, packaging, or delivery of its Optetrak, Truliant, and Vantage Systems, including the polyethylene liners used in its Optetrak, Truliant, and Vantage Systems, and instead affirmatively misrepresented that its TKA systems were as safe as—or even "superior" to—other comparable TKA systems on the market.

72. Due to the absence of any warning or other information by Defendants as to the

significant health and safety risks posed by its Optetrak, Truliant, and Vantage Systems—more specifically, the polyethylene liners used in its Optetrak, Truliant, and Vantage Systems—Plaintiff was unaware that her TKA contained a faulty liner, which was likely to cause a premature failure of the entire joint replacement system. Additionally, this danger was not known to Plaintiff's healthcare providers or to the general public.

73. Given Defendants' deliberate actions designed to deceive or mislead Plaintiff, Plaintiff's healthcare providers, and the general public with respect to the safety and efficacy of Exactech's TKA systems, Defendants are estopped from relying on any statute of limitations defenses.

CAUSES OF ACTION

COUNT I
NEGLIGENCE

74. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

75. At all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Optetrak, Truliant, and Vantage Systems for implantation into patients, such as Plaintiff, by orthopedic surgeons in the United States.

76. At all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Optetrak, Truliant, and Vantage Systems for implantation into patients, such as Plaintiff, by physicians and surgeons in the United States.

77. As medical device manufacturers and distributors, Defendants owed this duty of reasonable care not only to patients, like Plaintiff, but also to doctors, like Plaintiff's implanting physician.

78. Prior to, on, and after the dates of Plaintiff's initial knee replacement surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Device.

79. Following Plaintiff's initial knee replacement surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in failing to recall the Device.

80. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the Optetrak, Truliant, and Vantage Systems.

81. Despite the fact Defendants knew or should have known the Optetrak, Truliant, and Vantage Systems posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Optetrak, Truliant, and Vantage Systems for implantation into consumers.

82. Despite the fact Defendants knew or should have known the Optetrak, Truliant, and Vantage Systems posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Optetrak, Truliant, and Vantage Systems for implantation into consumers without revising any warning language or issuing an earlier recall.

83. Defendants failed to advise surgeons and patients of the need for regular follow-up beyond the ordinary practices after a knee implant as to promptly detect polyethylene degradation

and osteolytic failure and timely revise the device to prevent or at least minimize bone loss, osteolysis, infection, and related injuries and/or other adverse events caused by the Device.

84. Defendants failed to exercise due care under the circumstances, and their gross negligence and recklessness includes the following acts and omissions:

1) Negligently failing to properly package the polyethylene components of the Device;

2) Negligently failing to properly package the polyethylene components of the Device so as to prevent contamination and patient infection;

3) Negligently failing to select appropriate third-parties to package the polyethylene inserts used in the Device;

4) Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Device;

5) Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Device;

6) Negligently failing to properly and thoroughly select the materials that would be used in the Device including avoiding Vitamin E which is universally accepted as an ingredient to minimize oxidation;

7) Negligently failing to test the Device and their attendant parts properly and adequately before releasing the devices to market;

8) Negligently failing to conduct sufficient post-market testing and surveillance of the Device;

9) Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Device in accordance with good practices;

10) Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device;

11) Continuing to negligently manufacture, and distribute the Device after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates;

12) Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device to consumers, including Plaintiff and Plaintiff's

doctors, without an adequate warning of the dangerous risks of the Device;

13) Negligently failing to notify and warn the public, including Plaintiff and Plaintiff's surgeons, of reported incidents involving injury and the negative health effects attendant to the use of the Device;

14) Negligently misrepresenting the safety of the Device;

15) Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Device;

16) Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Device;

17) Negligently failing to exercise due care in the advertisement and promotion of the Device;

18) Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Device;

19) Aggressively promoting the Device without proper warnings of the risk of early failure or material degradation in the average user;

20) Aggressively promoting the Device even after Defendants knew or should have known of the unreasonable risks from implantation;

21) Negligently failing to warn consumers, doctors, users and patients, including Plaintiff and Plaintiff's surgeons, that the Device would contain polyethylene materials not properly packaged and/or in accordance with Defendants' specifications;

22) Negligently diminishing or hiding the risks associated with the implantation of the Device;

23) Negligently failing to recall the Device at an earlier date; and

24) Negligently violating applicable state and federal laws and regulations; and in all other ways.

85. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying,

marketing, selling, advertising, preparing for use, warning of the risks and dangers of the defective implants, and otherwise distributing the Device.

86. As a direct and proximate cause of the foregoing acts, omissions, and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

COUNT II
STRICT LIABILITY: FAILURE TO WARN

87. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

88. At all relevant times, Defendants designed, tested, developed, manufactured, labeled, packaged, marketed, distributed, or sold the Device for implantation into patients, such as Plaintiff, by orthopedic surgeons in the United States.

89. At all times relevant to this action, while Defendants engaged in the business of designing, manufacturing, selling, marketing, promoting, and placing into the stream of commerce the Device, the product contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, such as Plaintiff, and were unfit for their intended use.

90. The Device reached Plaintiff without substantial change in the condition in which it was designed, developed, promoted, manufactured, and sold.

91. At the time and on the occasions in question, the Device was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

92. At all times relevant to the action, the dangerous propensities of the Device were known

to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product, and not known to ordinary consumers.

93. The Device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff and Plaintiff's doctors, because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or their sales force to doctors and patients with or about the Optetrak, Truliant, and Vantage Systems failed to adequately convey the potential risks and side effects of the Optetrak, Truliant, and Vantage Systems and the dangerous propensities of the devices, which risks Defendants knew (or reasonably should have known).

94. The Device was defective due to inadequate, or the absence of, warnings or instructions, including warning stickers, placards, or proper documentation to alert users regarding the hazards posed by the Device.

95. Defendants further failed to adequately disclose the devices' propensity to undergo substantial early polyethylene wear, component loosening or other failure causing serious complications, including grinding, swelling, tissue damage, instability, osteolysis, bone loss and other injuries, as well as the need for revision surgery in patients.

96. Defendants failed to adequately disclose or provide notice of the insufficient packaging of the Device and the likelihood of contamination and patient infection.

97. The instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications regarding the Optetrak, Truliant, or Vantage Systems were additionally defective because they did not provide instructions

concerning how—if at all—the risks associated with the Optetrak, Truliant, or Vantage Systems could be avoided, minimized, detected, or treated.

98. The inadequate warnings for the Device existed when the Device left Defendants' control.

99. Defendants failed to exercise reasonable care to inform Plaintiff, Plaintiff's doctors, and the medical community about dangers regarding the Device.

100. Plaintiff's doctor followed the instructions provided byDefendants with regard to the implantation of the Device.

101. Plaintiff (and Plaintiff's doctor) could not, by the exercise of reasonable care, have discovered these defects and perceived its dangers or avoided injury.

102. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

103. Defendants are strictly liable for providing inadequate warnings accompanying the Device and its component parts, including the packaging of the Device.

COUNT III
STRICT LIABILITY: DESIGN DEFECT

104. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

105. At all relevant times, Defendants designed, tested, developed, manufactured, labeled, packaged, marketed, distributed, or sold the Optetrak, Truliant, and Vantage Systems for implantation into patients, such as Plaintiff, by orthopedic surgeons in the United States.

106. Defendants had a duty to develop, design, and test both the Device and its component

parts, including the respective packaging of each, to produce a product that did not present an unreasonable risk of harm or injury to patients, including Plaintiff.

107. At the time that Defendants designed, tested, manufactured, packaged, promoted, marketed, sold, supplied, distributed and/or serviced the Device, it contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

108. Defendants knew (or reasonably should have known) that the Optetrak, Truliant, and Vantage Systems, as designed, presented an unreasonable risk of harm or injury to patients, including Plaintiff.

109. Defendants knew (or reasonably should have known) that the Optetrak, Truliant, and Vantage Systems were not reasonably safe for its expected, intended, or foreseeable uses as designed by Exactech.

110. The Device reached Plaintiff without substantial change in the condition in which it was sold.

111. At the time and on the occasions in question, the Device was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe, and unreasonably dangerous.

112. The Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by the Defendants reached Plaintiff without substantial change in its condition.

113. As alleged herein, the Defendants knew or had reason to know that the Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, contamination, and/or other

failure causing serious complications including tissue damage, osteolysis, infection and other injuries, as well as the need for revision surgery in patients.

114. The Device, including its component parts and corresponding packaging, was defective as designed because Defendants:

1) developed the Optetrak, Truliant, and Vantage Systems in a manner which resulted in a propensity to undergo substantial early polyethylene wear, component loosening, or other failure modes;

2) failed to design the packaging for the polyethylene components of the Optetrak, Truliant, and Vantage Systems in vacuum bags that contained a secondary barrier layer to prevent the components from undergoing increased oxidation;

3) failed to design the packaging for the polyethylene components of the Optetrak, Truliant, and Vantage Systems in vacuum bags that contained a secondary barrier layer to prevent the components from contamination and patient infection;

4) designed the packaging of the Optetrak, Truliant, and Vantage Systems and their component parts to require materials which were of an inferior grade or quality;

5) failed to conduct adequate testing on component parts, subassemblies, or finished Optetrak, Truliant, and Vantage Systems as packaged and distributed;

6) failed to test an adequate number of samples of Optetrak, Truliant, and Vantage Systems on an ongoing basis to ensure they were safe and performed as designed;

7) failed to take adequate steps to specifically identify failure modes with the Optetrak, Truliant, and Vantage Systems with clarity and to suggest methods to monitor, avoid, or prevent further failures;

8) failed to identify or note the significance of any testing that resulted in failures of the Optetrak, Truliant, and Vantage Systems;

9) failed to take corrective actions to eliminate or minimize further failures of the Optetrak, Truliant, and Vantage Systems;

10) failed to adequately design packaging specifications for the components, subassemblies, or the finished Optetrak, Truliant, and Vantage Systems;

11) designed the polyethylene insert and packaging in a manner that increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery; and

12) otherwise failed to adequately develop, design, or test the Optetrak, Truliant, and Vantage Systems.

115. The Device and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together the implant, the Device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Device were in a condition not suitable for proper and intended use.

116. The Device and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

117. Feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Device was designed and packaged and offered for sale in the market.

118. For example, Defendants could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH), like other manufacturers in the industry do, to prevent the polyethylene components from undergoing increased oxidation.

119. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by the Defendants.

120. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when

they were used and operated in a manner that was foreseeable to the Defendants.

121. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived its dangers or avoided injury.

122. The Defendants are strictly liable for the defective design of the Device; defective design of the packaging of the Device; the distribution, marketing, and/or sale of the Device; and the injuries sustained by Plaintiff.

123. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff sustained serious personal injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

COUNT IV
STRICT LIABILITY – MANUFACTURING DEFECT

124. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

125. At all relevant times, Exactech designed, tested, developed, manufactured, labeled, packaged, marketed, distributed, or sold the Optetrak, Truliant, and Vantage Systems for implantation into patients, such as Plaintiff, by orthopedic surgeons in the United States.

126. Exactech had a duty to manufacture, pack, and distribute the Optetrak, Truliant, and Vantage Systems, including their component parts, in a manner that prevented unreasonable risk of harm or injury to patients, including Plaintiff.

127. Exactech knew (or reasonably should have known) that its Optetrak, Truliant, and Vantage Systems were defective as manufactured.

128. The Optetrak, Truliant, and Vantage Systems, as manufactured, were not reasonably

safe as manufactured, packaged, or distributed by Exactech.

129. The Optetrak, Truliant, and Vantage Systems, including their component parts, were defective as manufactured because Exactech:

1) packaged the polyethylene components of the Optetrak, Truliant, and Vantage Systems in vacuum bags that contained a secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent the components from oxidizing before they were implanted;

2) failed to design the packaging for the polyethylene components of the Optetrak, Truliant, and Vantage Systems in vacuum bags that contained a secondary barrier layer to prevent the components from contamination and patient infection;

3) selected materials to package the Optetrak, Truliant, and Vantage Systems, which were of an inferior grade or quality;

4) failed to set appropriate manufacturing specifications to ensure that the Optetrak, Truliant, and Vantage Systems performed safely, appropriately, and as intended;

5) failed to periodically test to ensure that the Optetrak, Truliant, and Vantage Systems as manufactured met Exactech's intended specifications;

6) failed to establish internal quality control protocols and procedures to ensure that the Optetrak, Truliant, and Vantage Systems as manufactured met Exactech's intended specifications;

7) failed to comply with internal quality control protocols and procedures to ensure that the Optetrak, Truliant, and Vantage Systems as manufactured met Exactech's intended specifications;

8) failed to take corrective actions to eliminate or minimize further failures of the Optetrak, Truliant, and Vantage Systems;

9) failed to select appropriate third-parties to package the polyethylene inserts used in the Optetrak, Truliant, and Vantage Systems;

10) failed to properly supervise and monitor the packaging of the polyethylene inserts used in the Optetrak, Truliant, and Vantage Systems; and

11) otherwise failed to adequately manufacture, package, or distribute the Optetrak, Truliant, and Vantage Systems.

130. The manufacturing defects in the Optetrak, Truliant, and Vantage Systems existed when the devices left Exactech's control.

131. Plaintiff's doctors implanted the Optetrak, Truliant, or Vantage Systems in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Exactech.

132. The Optetrak, Truliant, and Vantage Systems, including their component parts, which were manufactured, packaged, or distributed by Exactech, reached patients, like Plaintiff, without substantial change in condition.

133. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defect and perceived its dangers or avoided injury.

134. Exactech is strictly liable for the defective manufacture of its Optetrak, Truliant, and Vantage Systems, the distribution, marketing, or sale of the defectively manufactured Optetrak, Truliant, and Vantage Systems and the injuries sustained by Plaintiff.

135. As a direct and proximate result of one or more of these wrongful acts or omissions of Exactech, Plaintiff sustained serious personal injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

COUNT V
NEGLIGENT MISREPRESENTATION

136. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

137. Defendants made statements concerning material facts which Defendants may have believed to be true but which in fact were false, or otherwise omitted material facts, including but not limited to:

1) Representing to the orthopedic community, and Plaintiff's surgeon, prior to implantation into Plaintiff's body, that the PSC Tibial Insert within the Device performed better than the competitors' Highly Cross Linked Polyethylene;

2) Defendants knew the PSC Tibial Insert within the Device was failing at a high rate and failed to disclose this information to Plaintiff and/or Plaintiff's surgeon prior to installation of the GXL;

3) Defendants knew that other patients experienced problems with the Device, including but not limited to, osteolysis, loosening of the components, deterioration of the polyethylene, and reports of significant pain, all prior to the installation of the Device in Plaintiff, and failed to disclose such information to Plaintiff and/or Plaintiff's surgeon;

4) Defendants represented to Plaintiff and/or Plaintiff's surgeon, prior to the implantation of the PSC Tibial Insert within the Device, that the PSC Tibial Insert was clinically proven to reduce wear when, in fact, no clinical trials were submitted for approval by the FDA;

5) Defendants misrepresented the success rate of the PSC Tibial Insert within the Device to Plaintiff's surgeon; and

6) Defendants failed to disclose to Plaintiff's surgeon, prior to the installation of the Device in Plaintiff's body, that they were aware of and/or witnessed revision surgeries in which the Device failed, including becoming loose, causing osteolysis, and causing excessive wear.

7) Representing the PSC Tibial Insert within the Device to have lower wear propensities than comparable products.

8) Representing that the PSC Tibial Insert within the Device liner would last for a lifetime

9) Representing the PSC Tibial Insert within the Device to have better longevity than comparable products.

10) Failing to inform Plaintiff and the public of the risk of injury after being informed of the increased rate of wear related adverse events with Defendants' other "enhanced" polyethylene products.

11) Failing to inform Plaintiff and the public of any potential risks related to Defendants' increased knowledge of problems associated with the PSC Tibial Insert within the Device until Defendants had already designed and released a marketable replacement for the PSC Tibial Insert.

12) Doing all of the above with the intent of selling more knee replacements and creating demand for Defendants' systems by using deceptive or untrue statements of fact about the safety and benefits of the Device, including its PSC Tibial Insert.

138. Defendants were negligent in making such statements because they knew or should have known the statements were false or omitted material information.

139. In making these statements, Defendants intended or expected that another would rely on the statements.

140. Plaintiff, through Plaintiff's surgeon and his or her agents, justifiably relied on the false statements.

141. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff sustained serious personal injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

COUNT VI
BREACH OF EXPRESS WARRANTY

142. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

143. Prior to Plaintiff's initial knee replacement surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

144. Defendants expressly warranted the Device was a safe and effective orthopedic device.

145. At the time the Defendants manufactured, marketed, sold and/or distributed the Device,

they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Device.

146. The express warranties represented by the Defendants were a part of the basis for Plaintiff's use of the Device, and Plaintiff and Plaintiff's surgeon relied on these warranties in deciding to implant the Device.

147. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which the Device was to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

148. The Device does not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely and caused Plaintiff to suffer an infection which necessitated Plaintiff to undergo revision surgery.

149. At the time the Defendants marketed, sold and/or distributed the Device, Defendants expressly warranted that the Device, including all of its component parts, were safe and merchantable for their intended use.

150. Plaintiff and Plaintiff's implanting physician reasonably relied upon the Defendants' express warranties.

151. Plaintiff used the Device for its intended purpose, and in a reasonably foreseeable manner.

152. The Device manufactured and sold by the Defendants, did not conform to the Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

153. As a direct and proximate result of the Defendants' acts and omissions, including breach of express warranty, Plaintiff was implanted with the Device and sustained serious personal

injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

COUNT VII
BREACH OF IMPLIED WARRANTY

154. Plaintiff re-alleges and incorporates by reference all matter stated elsewhere in this pleading as if fully set forth herein, and at length.

155. Prior to Plaintiff's initial knee replacement surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

156. Defendants impliedly warranted, through its marketing, advertising, distributors, and sales representatives, that the Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

157. In fact, the Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

158. The Device manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly manufactured, treated to prevent oxidation, and packaged and stored as to avoid premature degradation of component materials and to prevent contamination and patient infection.

159. Plaintiff and/or Plaintiff's surgeon reasonably relied upon the skill and judgment

of the Defendants as to whether the Device was of merchantable quality and safe for its intended and particular use and purpose.

160. Contrary to such implied warranties, the Device was not of merchantable quality or safe for its intended and particular use and purpose, because Defendants failed to prevent the components from undergoing increased oxidation and/or contamination and causing patients to experience substantial early polyethylene wear, component loosening, infection, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

161. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff was implanted with the Device and sustained serious personal injuries and resulting damages in the past, and which will continue in the future, including pain and suffering, physical impairment, mental anguish, medical expenses, lost wages and loss of earning capacity.

COUNT VIII
EXEMPLARY DAMAGES

162. Defendants' conduct described herein, when viewed objectively from the standpoint of Defendants at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Moreover, Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others. Further, Defendants acted with malice, oppression, and a conscious disregard for Plaintiff and the general public's safety, who accordingly request that the trier of fact, in the exercise of sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others and deter Defendants and others from engaging in similar conduct

in the future. Furthermore, the aforesaid wrongful conduct was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of Defendants. Therefore, Plaintiff seeks exemplary damages in an amount to be determined by the jury.

JURY TRIAL DEMAND

163. Plaintiff hereby respectfully requests a trial by jury and submits the appropriate fee.

PRAYER

164. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear and answer herein, and that upon final hearing hereof, Plaintiff have judgment against Defendants for all damages to which she is entitled under the laws of the State of Texas, which amount exceeds the minimum jurisdictional limits of this Court; for pre-judgment interest in accordance with law and/or at the highest legal rate; for interest on the judgment; for costs of suit; for exemplary damages; and for such other and further relief, either at law or in equity, to which Plaintiff has shown or will show herself justly entitled.

Respectfully submitted,

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