UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

Lawrence Anderson And Joan Anderson,	Case No. <u>18-cv-2662</u>
Plaintiffs, v.	COMPLAINT AND JURY TRIAL DEMAND
Howmedica Osteonics Corp.,	
Defendant.	

Plaintiffs, Lawrence Anderson and Joan Anderson, for their cause of action against the above-named Defendant, allege and state upon information and belief as follows:

PARTIES, JURISDICTION & VENUE

- 1. Plaintiffs Lawrence Anderson and Joan Anderson are residents of Cold Spring, Minnesota. Plaintiffs are, and at all times relevant to this Complaint were, husband and wife.
- 2. Defendant Howmedica Osteonics Corp. ("HOC") is a corporation organized and existing under the laws of New Jersey, with its principal place of business in Mahwah, New Jersey. Defendant does business throughout the United States, including in the State of Minnesota.
- 3. HOC is a wholly-owned subsidiary of Stryker Corporation ("Stryker"). HOC licenses the Stryker brand name for use on its prosthetic hip devices and pays Stryker a licensing fee.

- 4. This action is properly before the Court because complete diversity of citizenship exists between Plaintiffs and Defendant. In addition, the amount in controversy claimed by Plaintiffs exceeds \$75,000.00. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).
- 5. Defendant is subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendant did (and does) business within the State of Minnesota and has had continuous and systematic contacts with the State of Minnesota, has consented to jurisdiction in the State of Minnesota and/or committed a tort in whole or in part in the State of Minnesota against Plaintiffs as more fully set-forth herein. Upon information and belief, Defendant also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

FACTUAL ALLEGATIONS

A. Total Hip Arthroplasty Procedure

- 6. The hip joint is a ball-and-socket synovial joint formed by the articulation of the rounded head of the femur and the cup-like acetabulum of the pelvis. Both joint surfaces are covered with a strong but lubricated layer of articular hyaline cartilage. Over time, age and wear can break down the cartilage, allowing the femur head to rub directly against the acetabulum resulting in painful joint inflammation and immobility.
- 7. A total hip arthroplasty replaces the body's natural joint with prosthetic components. A typical total hip replacement system consists of four separate components: 1) a femoral stem; 2) a femoral head; 3) a liner; and 4) an acetabular shell. The surgeon removes the patient's natural femoral head, hollows-out the femoral canal, implants the prosthetic femoral stem, and attaches a femoral head to the neck of the stem. The acetabular shell is fixed to the

acetabulum of the pelvis and fitted with a liner. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

B. History of the Secur-Fit HA Femoral Stem and C-Taper LFITTM Femoral Head

- 8. On November 22, 1995, HOC received FDA clearance to sell its Secur-FitTM HA femoral hip stem ("Secur-Fit") in the United States. The Secur-Fit is a tapered non-porous coated femoral stem manufactured from a Ti-6Al-4V substrate material with a coating consisting of Commercially Pure Titanium and Purefix hydroxylapatite.
- 9. The Secur-Fit is designed to be used with a variety of femoral heads, including femoral heads manufactured from either cobalt/chromium or ceramic.
- 10. The material combination of a titanium alloy stem, with a cobalt/chromium femoral head, has been reported to cause fretting and corrosion. Scientists have reported the occurrence of significant fretting and corrosion caused by the combination of dissimilar metals and/or micro-motion at the junction between the stem trunnion and head bore dating back to the 1980s.
- 11. Despite the known problems associated with pairing dissimilar metals and/or micro-motion at the junction between the metal stem and metal head, upon information and belief, Defendant represented and warranted in its marketing materials that its proprietary alloys will not fret or corrode.
- 12. Defendant manufactures, markets, and sells ceramic femoral heads that are compatible with the Secur-Fit. Upon information and belief, a Secur-Fit stem paired with a ceramic femoral head will not experience fretting and corrosion.
- 13. A femoral head commonly paired with the Secur-Fit stem is the C-Taper LFITTM Head, which is fabricated from a cobalt and chromium alloy.

- 14. In 1991, HOC received FDA clearance to sell the C-Taper LFIT™ Head in the United States.
- 15. The LFIT (Low Friction Ion Treatment) manufacturing process embeds nitrogen ions under high energy into the cobalt/chromium surface of large femoral heads, for the purported purpose of improving surface wettability, allowing increased lubrication between components, and decreasing frictional forces.
- 16. A Morse taper (a cone-within-a-cone) is used to mate the C-Taper LFITTM Head with the Secur-Fit stem. The bore (female portion) of the C-Taper LFITTM Head is placed onto the tapered trunnion (male portion) of the Secur-Fit stem and impacted by the surgeon using a Stem Head Impactor tool. The stresses created by compression of the wall of the bore by the trunnion result in a cold-welding or locking of the head/stem taper interface (i.e. taper lock).
- 17. Failure of the taper lock or cold-weld between the C-Taper LFITTM Head bore and Secur-Fit trunnion allows micro-motion of these components and promotes corrosion and fretting.
- 18. The indications for use of both LFIT V40 Heads and Accolade II stems include non-inflammatory degenerative joint disease, such as osteoarthritis and avascular necrosis, and function deformities, such as hip dysplasia.
- 19. At all times material hereto, HOC developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Secur-Fit Stem and C-Taper LFITTM Head, either directly or indirectly, to members of the public within the State of Rhode Island, including hospitals, surgeons, and the Plaintiff.

C. Plaintiff Allegations

- 20. On January 10, 2011, Plaintiff Lawrence Anderson underwent left total hip arthroplasty as a result of advanced left hip arthritis. At that time, Plaintiff's surgeon implanted a Cluster Acetabular Shell with a Trident® Insert, and a Secur-Fit femoral stem with a C-Taper Head.
- 21. Just over 1 year after his total hip arthroplasty, Plaintiff began experiencing significant discomfort and stiffness in his left lateral hip. A report issued by CentraCare Laboratory Services on June 29, 2016 revealed a serum *cobalt level of 4.9ng/mL* and serum *chromium of 1.1 ng/mL*. In addition, the MARS MRI taken July 5, 2016 shows effusion suspect for ALTR. Based upon these findings, Plaintiff's provider scheduled revision surgery.
- Plaintiff underwent partial revision surgery on October 29, 2016, at which time Plaintiff's surgeon encountered severe tissue necrosis and black sludge corrosion at the interface of the trunnion interfece. This was excised and the trunnion was felt in good enough condition to be retained. The surgeon notes "some necrotic tissue going up the iliopsoas bursa was debrided and necrotic capsular tissue." A Stryker X3 liner was then placed into the Trident® PSL® Acetabular Shell, and a C-Taper LFITTM Head and Biolox Delta Taper wer impacted onto the Secur-Fit trunnion.
- 23. Plaintiff's elevated serum cobalt and chromium persisted for a time after revision surgery. On a report from CentraCare Laboratory Services dated April 19, 2017, Plaintiff's cobalt serum level was 0.5ng/mL and his chromium level was 0.7ng/mL.

25. As a direct and proximate result of HOC placing the above-referenced implants into the stream of commerce, Plaintiff has suffered, and continues to suffer, both injuries and damages including, but not limited to, past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE FEDERAL REQUIREMENTS

- 26. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.
- 27. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.
- 28. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any of its medical devices may have caused or contributed to death or serious injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a

device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360 (i).

- 29. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR § 803.50.
- 30. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 CFR § 803.52.
- 31. Pursuant to federal regulations, manufacturers must report any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events. *See* 21 CFR § 803.53.
- 32. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals.

 FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed

by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR § 806.

- 33. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance. See 21 CFR § 820.
- 34. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when

unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." *See* 21 CFR § 814.

37. Specifically, it is believed that with respect to C-Taper LFIT™ Head in combination with the Secur-Fit femoral stem, the Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and, sold a misbranded and adulterated product.

CLAIMS FOR RELIEF

COUNT 1 NEGLIGENCE

- 38. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.
- 39. Defendant designed, manufactured, marketed, detailed, and advertised, both to physicians and consumers, Secur-Fit stems and C-Taper LFITTM Heads.
- 40. As a result, Defendant had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom these devices would be implanted, including Plaintiff.
- 41. Defendant failed to use reasonable and due care for the safety and well-being of those in whom Secur-Fit stems and C-Taper LFITTM Heads would be implanted, including Plaintiff, and is therefore negligent in the following respects:

- Defendant failed to adequately design and manufacture these devices to insure
 that they would not corrode, fret, deteriorate and induce metallosis in patients.
 Defendant's failures include, but are not limited to, the following:
 - i. Recommending use of components designed and manufactured with incompatible metals; namely, the combination of the titanium alloy in the Secur-Fit stem with the cobalt-chromium in the C-Taper LFITTM Head;
 - ii. Poor design of the bore of the C-Taper LFITTM Head such that it resulted in taper lock failure, micro-motion of the Secur-Fit trunnion within the C-Taper LFITTM Head bore, corrosion and fretting;
 - iii. Poor manufacturing practices such that the C-Taper LFITTM Head bore and Secur-Fit trunnion did not "fit" the way in which they were intended to fit, resulting in taper lock failure, micro-motion, corrosion and fretting;
 - iv. Failing to establish and maintain adequate procedures to ensure that the specified design requirements for C-Taper LFITTM Heads were met during the manufacturing process;
 - v. Failing to limit the type of femoral head components it recommended for use with the Secur-Fit stem to those that would not promote micromotion, taper lock failure, corrosion and fretting; and

- vi. A combination of the above factors which resulted in metallosis,

 Adverse Local Tissue Reaction ("ALTR"), soft tissue and bony
 necrosis, pain and premature failure of the device.
- b. Upon information and belief, Defendant made affirmative representations that these devices would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer, including Plaintiff and Plaintiff's surgeon;
- c. Defendant failed to manufacture C-Taper LFITTM Heads to FDA-cleared and/or Defendant's own internal specifications such that the taper lock between the C-Taper LFITTM Head bore and the Secur-Fit trunnion failed, resulting in micro-motion, fretting and corrosion, and causing metallosis and ALTR in patients, including Plaintiff;
- d. Defendant had actual knowledge prior to marketing Secur-Fit stems in combination with C-Taper LFITTM Heads that a titanium alloy stem performed poorly when paired with cobalt/chromium head. Defendant also had knowledge at the time the Secur-Fit was introduced to the market that other HOC devices made of titanium alloy were experiencing corrosion, fretting, and failure at the trunnion-bore interface. Nevertheless, Defendant either suppressed or ignored such knowledge, and marketed the C-Taper LFITTM Heads as compatible with Secur-Fit stems, knowing full-well that these two dissimilar metals historically performed poorly after implantation and were causing harm to patients when utilized in various hip implant devices.

- 42. Defendant, as manufacturer, supplier and seller of these orthopedic components had superior knowledge and owed a duty of care to their customers, orthopedic surgeons, and to the patients themselves in whom Secur-Fit / C-Taper LFITTM Head combinations were being implanted.
- 43. Defendant breached its duty of care, and the conduct outlined above demonstrates Defendant's failure to exercise reasonable and appropriate care.
- 44. It was foreseeable that this wrongful conduct and these omissions would lead to premature failure of the Secur-Fit / C-Taper LFITTM Head combination, and cause severe, permanent, debilitating injuries to patients, including Plaintiff.
- 45. As a direct and proximate result of Defendant's negligence, Plaintiff suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

COUNT 2 STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

- 46. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.
- 47. The C-Taper LFITTM Head implanted into Plaintiff's hip, in combination with the Secur-Fit stem, was defective and unreasonably dangerous for its intended use as a hip prosthesis at the time it left HOC's control.
- 48. The Secur-Fit stem is designed in such a way that when used as intended with a C-Taper LFITTM Head, the combination causes serious, permanent, and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein. Defendant acted unreasonably in its design of the Secur-Fit stem in

combination with the C-Taper LFITTM Head in that it failed to adopt a safer design that was practical and feasible. Such reasonable alternative design would have prevented or substantially reduced the risk of harm to Plaintiff without substantially impairing the usefulness, practicality, or desirability of the product.

- 49. Defendant's Secur-Fit stem, in combination with the C-Taper LFIT™ Head, does not perform as safely as orthopedic surgeons and ordinary consumers would expect when used as intended or in a manner reasonably foreseeable to Defendant.
- 50. The risks of using the Secur-Fit stem, in combination with an C-Taper LFITTM Head, outweigh the benefits of using these devices.
- 51. There were safer alternative designs to the Secur-Fit/ C-Taper LFITTM Head combination implanted in Plaintiff which in reasonable probability would have prevented or significantly reduced the risk of the personal injuries suffered by Plaintiff without substantially impairing the product's utility and such safer alternative designs were economically and technologically feasible at the time the Secur-Fit stem and C-Taper LFITTM Head left the control of Defendant by the application of existing or reasonably achievable scientific knowledge.
- 52. As a direct and proximate result of the design defects in the Secur-Fit/ C-Taper LFITTM Head combination, Plaintiff suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

COUNT 3 STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

53. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

- 54. The Secur-Fit/ C-Taper LFITTM Head combination was designed for implantation into the human body and anticipated to function for fifteen or more years. The Secur-Fit/ C-Taper LFITTM Head combination was also designed to be compatible with human tissue and bone.
- 55. The Secur-Fit/ C-Taper LFITTM Head combination implanted in Plaintiff, however, failed and was explanted in *less than eight years*.
- 56. The C-Taper LFITTM Head implanted into the Plaintiff was manufactured in a substandard and defective manner, such that either:
 - a. The bore within the C-Taper LFITTM Head was poorly machined or fashioned so that it could not achieve the desired taper lock or cold-weld with the trunnion of the Secur-Fit stem;
 - b. The bore within the C-Taper LFITTM Head was fashioned in such a manner that it did not maintain structural integrity when implanted in a biologic environment;
 - c. The bore within the C-Taper LFITTM Head was fashioned in such a manner that it did not maintain structural integrity when mated with a titanium alloy trunnion; and/or
 - d. The specified design requirements for C-Taper LFITTM Heads were not met during the manufacturing process.
- 57. As a direct and proximate result of the manufacturing defects in the C-Taper LFITTM Head, Plaintiff suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

<u>COUNT 4</u> <u>STRICT PRODUCTS LIABILITY – FAILURE TO WARN</u>

- 58. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.
- 59. Defendant knew or should have known that the C-Taper LFITTM Heads it manufactured and distributed contained a manufacturing defect in the Head's bore which would prevent the Secur-Fit trunnion from achieving the desired taper lock and result in taper lock failure and micro-motion. Defendant also knew or should have known that the titanium alloy used in the Secur-Fit stem was incompatible with the cobalt-chromium in the C-Taper LFITTM Heads which, in the presence of taper lock failure and micro-motion, would lead to galvanic and crevice corrosion and fretting, and cause metallosis and ALTR in patients.
- 60. Defendant had a duty to warn surgeons about the risk of taper lock failure with its C-Taper LFITTM Heads, and to warn surgeons about the risk of resulting micro-motion, corrosion, fretting, metallosis, and ALTR in patients who were implanted with this device.
- 61. Defendant breached that duty by providing inadequate warnings (or no warnings at all) to surgeons that use of an C-Taper LFIT™ Head with a Secur-Fit stem could result taper lock failure, corrosion and fretting, and cause substantial injury to the surgeon's patients.
- 62. If Defendant had warned orthopedic surgeons about the risk of taper lock failure with its C-Taper LFITTM Heads, and that the resulting micro-motion would increase the risk of corrosion and fretting at the trunnion-bore interface, and that such corrosion and fretting could lead to metallosis and ALTR in their patients, orthopedic surgeons (including Plaintiff's surgeon) would not have implanted the Secur-Fit stem with an C-Taper LFITTM Head, and Plaintiff would

not have developed metallosis and ALTR, and would not have had to undergo a revision surgery less than eight years after her index surgery.

63. As a direct and proximate result of Defendant's failure to warn, Plaintiff suffered all or some of the following: severe physical pain and suffering; emotional distress; mental anguish; loss of the capacity for the enjoyment of life; and incurred medical expenses. These damages have occurred in the past and will continue into the future.

COUNT 5 LOSS OF CONSORTIUM

- 64. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.
- 65. As a further direct result of Defendant's acts, omission, and/or breach of duties as described and alleged above, Plaintiff Joan Anderson has lost, and will in the future lose, her husband's companionship, aid, comfort, society, services, protection and consortium, all to her damage in an amount greater than \$75,000.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment in their favor as follows:

- 1. Awarding actual damages to Plaintiff incidental to the purchase and use of the Secur-Fit/ C-Taper LFITTM Head system in an amount to be determined at trial;
- 2. Awarding the past and future costs of treatment for Plaintiff's injuries caused by the Secur-Fit/ C-Taper LFITTM Head system;
 - 3. Awarding damages for Plaintiff's physical pain and suffering;
 - 4. Awarding damages for Plaintiff's mental and emotional anguish;
 - 5. Awarding pre-judgment and post-judgment interest to Plaintiff;

- 6. Awarding, if the Court allows an amended complaint on Plaintiff's motion, punitive damages;
 - 7. Awarding the costs and expenses of this litigation to Plaintiff;
 - 8. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and
 - 9. For such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: September 13, 2018 MESHBESHER & SPENCE, LTD.

By: /s/ Andrew L. Davick
Andrew L. Davick (MN # 332719)
Ashleigh E. Raso (MN #393353)
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Attorneys for Plaintiffs

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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.)

purpose of initiating the civil d	ocket sheet. (SEE INSTRUC	TIONS ON NEXT PAGE OF T	HIS FORM.)	, , , , , , , , , , , , , , , , , , ,		
I. (a) PLAINTIFFS Lawrence Anderson and Joan Anderson			DEFENDANTS Howmedica Osteonics Corp.			
(b) County of Residence of First Listed Plaintiff Stearns (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorneys (Firm Name, Address, and Telephone Number) Andrew L. Davick, Anthony J. Nemo, Ashleigh E. Raso, Meshbesher & Spence, 1616 Park Avenue, Minneapolis, MN 5540			County of Residence of First Listed Defendant Bergen (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED. Attorneys (If Known)			
612-339-9121						
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)			II. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintify (For Diversity Cases Only) and One Box for Defendant)			
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government Not a Party)		PTF DEF Citizen of This State PTF DEF PTF DEF			
☐ 2 U.S. Government Defendant	✓ 4 Diversity (Indicate Citizenship of Parties in Item III)		Citizen of Another State			
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