IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSY

WILLIAM D. OWENS AN	ID SHELIE OWENS,	CIVIL ACTION
	Plaintiffs,	File No.
VS.		JURY DEMAND
C.R. BARD, INC.		
	Defendant.	

COMPLAINT AND JURY DEMAND

The Plaintiffs, WILLIAM D. OWENS and SHELIE OWENS ("Plaintiffs") by and through the undersigned counsel, hereby file this Complaint against the Defendants, C.R. BARD, INC. in this litigation and states as follows:

At all times material Plaintiffs WILLIAM D. OWENS and SHELIE OWENS were residents of Northumberland, Virginia.

JURISDICTION AND VENUE

- 1. At all times material, Plaintiffs was a resident of Northumberland, Virginia.
- 2. Defendant C.R. BARD, INC. is a New Jersey corporation with its principal place of business in New Jersey.
- 3. At all times relevant herein, the Defendant, C.R. BARD, INC., ("BARD") was conducting business in the State of Virginia and New Jersey. C.R. BARD, INC. is a corporation based out of New Jersey, with its corporate headquarters located at 730 Central Avenue, Murray

Hill, New Jersey. Defendant conducts substantial business in Virgina and is headquartered in New Jersey, and is subject to the personal jurisdiction served by this Court.

4. Jurisdiction is proper in District Court for the District of New Jersey as the amount in controversy exceeds \$75,000 exclusive with interests and costs.

FACTUAL BACKGROUND

- 5. At all times material hereto, the Bard Defendant developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the pelvic mesh products at issue in this matter. By said activities, Bard's Mesh Products were placed into the stream of commerce throughout the United States, including Virginia.
- 6. At all times material to this action, the Bard Defendants designed, patented, manufactured, labeled, marketed, sold and distributed a line of pelvic mesh products. The products by the Bard Defendants were designed primarily for the purposes of treating hernias and pelvic organ prolapse. The Bard's Defendants products at issue in this case were cleared for sale in the U.S. after the Bard Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety of efficacy.
- 7. The Plaintiff was operated on to repair a hernia, during which operation a variety of surgical mesh manufactured, sold and marketed by Defendants was implanted.
- 8. The surgical mesh used in the surgery was known as the "Kugel Hernia Patch" (herein referred to as "Product") and it was designed, manufactured, packaged, labeled, marketed, sold and distributed by Defendant.

- 9. The Product was made of materials which are biologically incompatible with human tissue and react negatively and sometimes dangerously with a large number of those on whom it is used.
- 10. Defendant knew or should have known that their Product was unreasonably harmful.
- 11. The scientific evidence Defendant knew or should have known of demonstrates that the mesh is incompatible with human tissue and often causes a negative immune response in patients implanted with the Product, including Plaintiff.
- 12. In April 2016, the FDA published an article on hernia mesh, identifying "pain, infection, hernia recurrence, adhesion and bowel obstruction" as the most common adverse events associated with hernia mesh implants, as well as other possible complications, like mesh migration and mesh shrinkage.
- 13. The Kugel mesh is marketed to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe and effective, minimally invasive surgical techniques, and is safer and more effective as compared to other products.
- 14. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Product.
- 15. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as the Product.
- 16. The Product was at all times utilized and implanted in a manner foreseeable to and in fact intended by the Defendant, its instructions and procedures for use and its training of the health care providers.

- 17. The Product was implanted in Plaintiff in the same or substantially similar condition as when it left Defendant's possession.
- 18. Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product.
- 19. The Product as designed, manufactured, distributed, sol and/or supplied by Defendant was defective as marketed due to inadequate warnings, labeling and/or inadequate testing.

PLAINTIFF FACTUAL BACKGROUND

- 20. Plaintiff WILLIAM D. OWENS was diagnosed with a ventral hernia in May 14, 2014 2016.
- 21. On May 14, 2014, Plaintiff WILLIAM D. OWENS underwent ventral hernia repair with a Bard Kugel Hernia mesh product.
- 22. Defendants manufactured, sold, and/or distributed the Kugel Products to Plaintiff WILLIAM D. OWENS through his doctors, to be used for treatment of hernia repair.
- 23. In the months following the September 21, 2016 implant of the Kugel mesh, Plaintiff WILLIAM D. OWENS continued to experience chronic abdominal pain, and further experienced several infections, as well as fluid draining from the umbilicus. The mesh continues to cause chronic abdominal pain, infections, and fissures. The mesh will require surgical removal, with an additional surgery to remove the implanted mesh.
- 24. As a result of having the Product implanted, the Plaintiff has experienced significant mental and physical pain and suffering and mental anguish, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, and/or lost income, and other damages.

25. Plaintiffs MARIA and SHELIE OWENS have seen their relationship injured as a

result.

CAUSES OF ACTION COUNT I: NEGLIGENCE

26. Plaintiffs reallege and incorporate by reference every allegation of this

Complaint as if each were set forth fully and completely herein and additionally or in the

alternative, if same be necessary, allege as follows:

27. Defendant had a duty to individuals, including the Plaintiffs, to use reasonable

care in designing, manufacturing, marketing, labeling, packaging and selling their Product.

28. Defendant breached its duty to its customers, including Plaintiffs, by failing to

design, manufacture, market, label, package, and/or sell its Product in such a manner as the

exercise of reasonable care would dictate.

29. Defendant negligently failed to warn or instruct the Plaintiff and/or his health care

providers of the full extent of the risks and hazards known to exist with use of the mesh in a

manner commensurate with the exercise of reasonable care.

30. As a direct and proximate result of the Defendant's negligence, Plaintiffs have

experienced significant physical injury, mental and physical pain and suffering, permanent injury

has undergone medical treatment and will likely undergo further medical treatment and

procedures, has suffered financial or economic loss, including, but not limited to, obligations for

medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY
DESIGN DEFECT

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- 31. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:
- 32. At the time each implanting surgeon implanted the mesh product in patients, Defendants were engaged in the business of selling said product.
 - 33. The Kugel mesh product was defectively designed when sold.
- 34. The Kugel mesh product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in their use.
 - 35. The Kugel mesh product in question was improperly designed in that it was:
 - a. not designed to remain in the human body indefinitely;
 - b. not designed to remain in place and not migrate;
 - c. designed in such a way that could cause infection;
 - d. designed in such a way that the mesh could grow into the patient's skin, causing scar tissue and becoming unremovable.
 - 36. Safer alternative designs were available at the time of sale.
- 37. The mesh product reached Plaintiff's implanting surgeon without substantial change in the condition in which it was sold.
- 38. The defective and unreasonably dangerous condition of the mesh product was the proximate cause of the damages and injuries to Plaintiffs.
- 39. As a direct and proximate result of the mesh product's aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT III: STRICT LIABILITY MANUFACTURING DEFECT

- 40. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:
- 41. The Product implanted in Plaintiff WILLIAM D. OWENS was not reasonably safe for its intended use and was manufactured defectively due to having deviated materially from Defendant's design specifications.
- 42. The deviations from design specs resulted in defective manufacturing which posed unreasonable risks of serious bodily harm to customers, including the Plaintiffs.
- 43. As a direct and proximate of the aforementioned defects, Plaintiffs have experienced mental and physical pain and suffering has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.
- 44. Defendant is strictly liable to the Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY FAILURE TO WARN

- 45. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:
- 46. The Product was not reasonably safe for its intended uses and was defective due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide

sufficient or adequate warnings regarding, among other things, the serious risk of bodily harm posed by the incompatibility of the material used to make the mesh and human blood and tissue or the serious risk of infection or serious scarring.

- 47. As a direct and proximate result of the Product's defects, the Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.
- 48. Defendant is strictly liable to the Plaintiffs for designing, manufacturing, marketing, labeling or packaging and selling a defective Product.

COUNT V BREACH OF EXPRESS WARRANTY

- 49. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:
- 50. Defendant made assurances as described herein to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purposes.
- 51. The Plaintiff WILLIAM D. OWENS and/or his health care provider chose the Product based upon Defendant's warranties and representations regarding the safety and fitness of its product.
- 52. The Plaintiff WILLIAM D. OWENS, individually and/or by and through his health care providers, reasonably relied upon Defendant's express warranties and guarantees that the product was safe, merchantable, and reasonably fit for its intended purposes.

- 53. Defendant breached these express warranties because the Product was unreasonably dangerous and defective as described herein and not as Defendant had represented.
- 54. Defendant's breach of its express warranties resulted in the implantation of an unreasonably dangerous and defective product.
- 55. As a direct and proximate result of Defendant's breach of the aforementioned express warranties, the Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.

COUNT VI BREACH OF IMPLIED WARRANTY

- 56. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:
- 57. Defendant impliedly warranted that the subject mesh was merchantable and was fit for the ordinary purposes for which it was intended.
- 58. When the mesh was implanted in the Plaintiff WILLIAM D. OWENS to treat a hernia, the product was being used for the ordinary purpose for which it was intended.
- 59. Plaintiff, individually and/or by and through his providers, relied upon Defendant's implied warranties of merchantability in consenting to have the subject mesh implanted.

- 60. The Defendant breached these implied warranties of merchantability because the Product implanted in Plaintiff was neither merchantable nor suited for their intended uses as warranted.
- 61. Defendant's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product which placed Plaintiff's health and safety in jeopardy.
- 62. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligation for medical services and expenses, and/or lost income, and other damages.

COUNT VII VIOLATION OF CONSUMER PROTECTION LAWS

- 63. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:
- 64. Plaintiff and Plaintiff's physicians purchased and used the Defendants' Kugel Mesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.
- 65. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Kugel Mesh, and would not have incurred related medical cost and injury.

- 66. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Kugel Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.
- 67. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:
 - a) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have.
 - Advertising goods or services with the intent not to sell them as advertised;
 and,
 - Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.
- 68. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Kugel Mesh. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Kugel Mesh.
- 69. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Kugel Mesh.
- 70. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Kugel Mesh, and would not have incurred related medical costs.

- 71. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.
- 72. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues, as listed below.
- 73. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.
 - 15 U.S.C. §§ 2301-2312
 - Cal Bus. Prof. § 17200, 17500
 - Cal Civ. Code § 1750-1784
- 74. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.
- 75. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Kugel Meshes were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

- 76. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.
- 77. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Kugel Mesh and failed to take any action to cure such defective and dangerous conditions.
- 78. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).
- 79. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.
- 80. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.
- 81. As a direct and proximate result of Defendants' violations of consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VII: LOSS OF CONSORTIUM

- 82. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 83. Plaintiff, SHELIE OWENS, was at all times relevant hereto the spouse of Plaintiff, and as such, lived and cohabitated with her.
 - 84. By reason of the foregoing, Plaintiff, WILLIAM D. OWENS, has incurred

significant expenses for medical care and will continue to be economically and emotionally

harmed in the future.

85. By reason of the foregoing, Plaintiffs were caused to suffer, and Plaintiffs will

continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and

conjugal fellowship, all to the detriment of their marital relationship.

86. By reason of the foregoing, Plaintiffs have suffered injuries and damages as

alleged herein.

WHEREFORE, Plaintiffs WILLIAM D. OWENS and SHELIE OWENS demands

judgment for damages from the Defendant for an amount in excess of Seventy-five Thousand

Dollars (\$75,000.00) together with interest and costs from September 21, 2016.

REQUEST FOR JURY TRIAL

The Plaintiffs herein request trial by jury of all issues triable by right.

DATED: September 10, 2018

Melville, New York

By: /s/Nicholas R. Farnolo

Nicholas R. Farnolo, Napoli Shkolnik PLLC 400 Broadhollow Road

Melville, New York 11747

(212) 397-1000

Attorneys for Plaintiffs

Nfarnolo@napolilaw.com

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS William D. Owens and Shelie Owens (b) County of Residence of First Listed Plaintiff Northumberland, VA (EXCEPT IN U.S. PLAINTIFF CASES)			DEFENDANTS	DEFENDANTS		
			C.R.Bard, Inc. County of Residence of First Listed Defendant Union, NJ (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.			
Nicholas Farnolo, Esq. N 400 Broadhollow Road, N		1000				
II. BASIS OF JURISDI	CTION (Place an "X" in O	ne Box Only)	. CITIZENSHIP OF P	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff and One Box for Defendant)	
U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government)	Not a Party)	P	IF DEF 1	PTF DEF	
☐ 2 U.S. Government Defendant	■ 4 Diversity (Indicate Citizensh.)	ip of Parties in Item III)		2 Incorporated and I of Business In A	Another State	
			Citizen or Subject of a Foreign Country	3		
IV. NATURE OF SUIT		dy) PRTS	FORFEITURE/PENALTY	Click here for: Nature of BANKRUPTCY	of Suit Code Descriptions. OTHER STATUTES	
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle Product Liability 360 Other Personal Injury Medical Malpractice CIVIL RIGHTS 440 Other Civil Rights 441 Voting 443 Housing/ Accommodations 445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other 448 Education	PERSONAL INJURY 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage Product Liability PRISONER PETITIONS Habeas Corpus: 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty Other:	□ 625 Drug Related Seizure of Property 21 USC 881 □ 690 Other □ 710 Fair Labor □ 710 Fair Labor Standards Act □ 720 Labor/Management Relations □ 740 Railway Labor Act □ 751 Family and Medical Leave Act □ 790 Other Labor Litigation □ 791 Employee Retirement Income Security Act □ IMMIGRATION □ 462 Naturalization Application □ 465 Other Immigration Actions	422 Appeal 28 USC 158 423 Withdrawal	375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 70 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commodities/Exchange 890 Other Statutory Actions 891 Agricultural Acts 895 Freedom of Information Act 896 Arbitration 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes	
	moved from 3	Appellate Court	Reopened Anothe			
VI. CAUSE OF ACTIO	28 U.S.C. Sec 13	91(b)(2) nuse:	ing (Do not cite jurisdictional sta	unes uniess uiversity);		
VII. REQUESTED IN		IS A CLASS ACTION	DEMAND \$		if demanded in complaint:	
COMPLAINT: VIII. RELATED CASI		J, 1 1100 VII 1	2,000,000.00	JURY DEMAND:	: X Yes □ No	
IF ANY	(See instructions):	JUDGE		DOCKET NUMBER		
DATE 09/10/2018 FOR OFFICE USE ONLY		signature of attor /s/Nicholas R. Far			28 2 2 2	
	MOUNT	APPLYING IFP	JUDGE	MAG, JUE	OGE	

United States District Court

for the District of New Jersey William D. and Shelie Owens Plaintiff(s) Civil Action No. v. C.R.Bard, Inc. Defendant(s) SUMMONS IN A CIVIL ACTION To: (Defendant's name and address) C.R.Bard, Inc. 730 CENTRAL AVE. Murray Hill, New Jersey 07974 A lawsuit has been filed against you. Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Nicholas Farnolo, Esq. Napoli Shkolnik, PLLC 400 Broadhollow Rd. Suite 305 Melville, NY 11747 If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court. Date: Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (1))

This summons for (nam	ne of individual and title, if any)		
received by me on (date)			
☐ I personally served	the summons on the individual at (p	lace)	
		on (date)	; or
☐ I left the summons a	at the individual's residence or usua	l place of abode with (name)	12.3 a e
	, a person of	suitable age and discretion who resi	ides there,
on (date)	, and mailed a copy to the	individual's last known address; or	
☐ I served the summon	ns on (name of individual)		, who is
designated by law to a	accept service of process on behalf	f (name of organization)	
		on (date)	; or
☐ I returned the summ ☐ Other (specify):	nons unexecuted because		; or
(405)			
My fees are \$	for travel and \$	for services, for a total of \$	0.00
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Additional information regarding attempted service, etc: