

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

HARRY MASON,)	
)	
Plaintiff,)	
)	
v.)	CASE NO.:
)	
ASTRAZENECA PHARMACEUTICALS)	
LP; and ASTRAZENECA LP,)	
)	JURY TRIAL DEMANDED
Defendants.)	
)	
)	

COMPLAINT

Plaintiff HARRY MASON for his Complaint alleges as follows:

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff as a direct and proximate result of the Defendants’ negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of the proton pump inhibiting drug known as Nexium and/or other Nexium branded products herein collectively referred to as Nexium.

PARTIES, JURISDICTION, AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between citizens of different States.

3. Venue is properly set in this District pursuant to 28 U.S.C. §1391(b) since Defendants transact business within this judicial district. Likewise, a substantial part of the events

giving rise to the claim occurred within this judicial district.

4. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in the State of Illinois, such that requiring an appearance does not offend traditional notions of fair play and substantial justice. Further, Defendants have maintained registered agents in the State of Illinois.

5. This court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process in that Defendants, acting through their agents or apparent agents, committed one or more of the following:

- a. The transaction of any business within the state;
- b. The making of any contract within the state;
- c. The commission of a tortious act within this state; and
- d. The ownership, use, or possession of any real estate situated within this state.

6. Requiring Defendants to litigate these claims in Illinois does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. All of Plaintiff's claims arise in part from conduct Defendants purposefully directed to Illinois. On information and belief, Defendants' Nexium products are sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, Walgreens, CVS, Schnuck's and Dierberg's, throughout the State of Illinois. On information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Nexium products specifically intended to reach consumers in Illinois, including but not limited to advertisements on local Illinois television programs, advertisements on local Illinois radio broadcasts, advertisements on billboards in Illinois and advertisements in print publications

delivered to consumers in the State of Illinois.

7. Plaintiff's claims arise out of Defendants' design, marketing and sale of Nexium products in the State of Illinois.

8. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, the State of Illinois.

9. Defendant AstraZeneca Pharmaceuticals LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

10. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

11. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in the State of Illinois.

12. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the State of Illinois and derived substantial revenue from such business.

13. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States of America, and the State of Illinois in particular.

14. Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") 21-153 and 21-154 for Nexium (esomeprazole magnesium), and it manufactures and markets Nexium (esomeprazole magnesium) in the United States.

15. At all times relevant hereto Defendant AstraZeneca LP was engaged in the business

of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

16. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in the State of Illinois.

17. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in the State of Illinois and derived substantial revenue from such business.

18. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, and the State of Illinois in particular.

19. Defendants Defendant AstraZeneca LP and AstraZeneca Pharmaceuticals LP shall herein be collectively referred to as “Defendants” or “AstraZeneca.”

20. On information and belief, each Defendant was the agent and employee of each other Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant’s actual and implied permission, consent, authorization, and approval.

FACTUAL ALLEGATIONS

21. Proton pump inhibitors (“PPI”) are one of the most commonly prescribed medications in the United States.

22. More than 15 million Americans used prescription PPIs in 2013, costing more than \$10 billion.

23. However, it has been estimated that between 25% and 70% of these prescriptions have no appropriate indication.

24. Further, twenty five percent of long-term PPI users could discontinue therapy

without developing any symptoms.

25. AstraZeneca sold Nexium with National Drug Code (NDC) numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040.

26. Nexium is AstraZeneca's largest-selling drug and, in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded \$5.7 billion dollars. In 2008, Nexium sales exceeded \$5.2 billion dollars.

27. Nexium (esomeprazole magnesium) is a PPI that works by reducing hydrochloric acid in the stomach.

28. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this product including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

29. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA in association with ingestion of Nexium and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Nexium by as early as 2004. These reports of numerous kidney injuries put Defendants on notice as to the excessive risks of kidney injuries related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

30. Since the introduction of PPIs to the US market in 1990, several observational studies have linked PPI use to serious adverse health outcomes, including hip fracture, community acquired pneumonia, Clostridium difficile infection, acute interstitial nephritis and acute kidney

injury (“AKI”). A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute kidney injuries occurred within 120 days of the patients starting the PPIs.

31. Recent studies have shown the long term use of PPIs was independently associated with a 20% to 50% higher risk of incident chronic kidney disease (“CKD”), after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications. In one of those studies, the use of PPIs for any period of time was shown to increase the risk of CKD by 10%.

32. CKD, also called chronic kidney failure, describes the gradual loss of kidney function. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body.

33. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

34. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often key to avoiding the most negative outcomes.

35. CKD is associated with a substantially increased risk of death and cardiovascular events.

36. CKD is identified by a blood test for creatinine, which is a breakdown product of muscle metabolism. Higher levels of creatinine indicate a lower glomerular filtration rate and as a result a decreased capability of the kidneys to excrete waste products.

37. Creatinine levels may be normal in the early stages of CKD, so the condition may also be discovered by urinalysis. To fully investigate the scope of the kidney damage, various forms of medical imaging, blood tests and a kidney biopsy are employed.

38. Screening of at-risk people is important because treatments exist that delay the progression of CKD.

39. Alternatives to PPIs are and were available that provide the same benefits but act through a different mechanism.

40. One alternative is H2 antagonists, also called H2 blockers, a class of medications that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach.

41. The higher risks of CKD are specific to PPI medications. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with CKD.

42. Similar findings were demonstrated for the outcome of AKI and collectively suggest that PPI use is an independent risk factor for CKD and for AKI.

43. In addition, a study has linked the acute kidney injuries caused by PPIs to a later increased risk of CKD. The study noted that as PPI induced acute kidney disease is often subtle and slowly diagnosed. The delay in diagnosis causes damage to the kidney to be increased and the patient has a higher risk of later developing CKD.

44. Defendants failed to adequately warn against the negative effects and risks associated with Nexium. Defendants have totally failed to provide any warnings regarding CKD.

45. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff. This conduct is fraudulent, unfair, and unlawful.

46. Defendants knew or should have known about the correlation between the use of Nexium and the significantly increased risk of CKD and acute kidney injuries.

47. Despite clear knowledge that Nexium causes a significantly increased risk of CKD and acute kidney injuries, Defendants continued to market and sell Nexium without warning consumers or healthcare providers of the significant risks of CKD and acute kidney injuries.

PLAINTIFFS' USE OF NEXIUM

48. Plaintiff Harry Mason is and was at all times alleged herein a citizen of the State of Illinois and currently resides in Madison County, Illinois.

49. Plaintiff Harry Mason was prescribed Nexium on numerous occasions, including but not limited to, in or about 2006 within Madison County, Illinois. Plaintiff Harry Mason ingested Nexium as directed on or about 2006 within Madison County, Illinois. Plaintiff Harry Mason read and followed the directions regarding the use of Nexium and would not have used Nexium had he been properly appraised of the risks associated with the use of Nexium. Plaintiff Harry Mason suffered kidney failure requiring a kidney transplant while taking Nexium as prescribed in 2006.

TOLLING OF THE STATUTE OF LIMITATIONS

50. Defendants at all relevant times knew or should have known of the problems and defects with Nexium products, and the falsity and misleading nature of Defendants' statements, representations and warranties with respect to Nexium products. Defendants concealed and failed to notify Plaintiff and the public of such defects.

51. Any applicable statute of limitation has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is ongoing.

COUNT 1
STRICT PRODUCT LIABILITY

52. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

53. The Nexium manufactured and/or supplied by Defendants was unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendants failed to perform adequate testing in that adequate testing would have shown that Nexium possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

54. The Nexium manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because Defendants failed to provide adequate warnings to users or consumers of Nexium and continued to aggressively promote Nexium.

55. As the proximate cause and legal result of the defective condition of Nexium as manufactured and/or supplied and/or distributed by Defendant, and as a direct and legal result of the conduct of Defendants described herein, Plaintiff has been damaged.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT 2
STRICT PRODUCT LIABILITY
(Pursuant to Restatement Second of Torts 402a (1965))

56. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

57. The Nexium manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design and formulation of the drug.

58. Alternatively, the Nexium manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of Plaintiff's condition.

59. There existed, at all times material hereto, safer alternative medications.

60. Defendant did not perform adequate testing upon Nexium. Adequate testing would have revealed that Nexium causes serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

61. The Nexium manufactured, designed, marketed, distributed and/or sold by Defendants was unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of Nexium, and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

62. Defendants did not warn the FDA of material facts regarding the safety and efficacy of Nexium, which facts Defendants knew or should have known.

63. The Nexium manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from Nexium, Defendants failed to provide adequate warnings to users or consumers of Nexium and continued to promote Nexium.

64. As a result of the defective condition of Nexium, Plaintiff has suffered damage and injury.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT 3
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

65. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

66. The acts, omissions, and representations of Defendants regarding the manufacturing, distribution and marketing of Nexium as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendant intentionally engaged in extreme and outrageous conduct when it intentionally and/or recklessly marketed Nexium and then intentionally and/or recklessly concealed material information about Nexium's potential serious adverse effects from Plaintiff and Plaintiff's physicians, hospitals, and medical providers.

67. Defendants knew that Plaintiff would suffer mental distress and anxiety upon learning that Nexium possessed a likelihood of serious adverse effects and complications such as life-threatening kidney damage.

68. As a result of Defendants' misconduct, Plaintiff sustained and will continue to sustain emotional and mental distress and anxiety.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT 4
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

69. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

70. Defendants negligently and carelessly manufactured, sold, and distributed Nexium to Plaintiff which was defective.

71. Defendants negligently and carelessly concealed the defective nature of Nexium from Plaintiff, Plaintiff's physicians, hospitals, and medical providers.

72. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of Nexium to Plaintiff, Plaintiff's physicians, hospitals, and medical providers.

73. Defendants' negligence and carelessness directly impacted Plaintiff in that Plaintiff was induced to purchase and ingest the defective and dangerous Nexium.

74. As a direct result of Defendants' misconduct alleged herein, Plaintiff has suffered and will continue to suffer emotional and mental distress and anxiety from the fear of knowing there is a likelihood of serious adverse effects and complications of Nexium use such as life-threatening kidney damage.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

**COUNT 5
COMMON LAW FRAUD**

75. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

76. Defendants made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendants had in their possession adverse drug event reports, drug studies, and other documentation about Nexium and yet made the following misrepresentations:

- a. Misrepresentations regarding the frequency of Nexium-related adverse event reports or occurrences in the Nexium label, package insert or PDR label;
- b. Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Nexium;
- c. Misrepresentations as to the efficacy of Nexium;
- d. Misrepresentations as to the number of adverse events and deaths reported with the use of Nexium;
- e. Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of Nexium.

77. Defendants intended that these misrepresentations be relied upon by physicians, including Plaintiff's physicians, healthcare providers and consumers. Plaintiff did rely upon the misrepresentations that caused Plaintiff's injuries.

78. Defendants' misrepresentations were the proximate and/or producing cause of Plaintiff's injuries.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

**COUNT 6
NEGLIGENCE**

79. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

80. Defendants owed Plaintiff legal duties in connection with its development, manufacture, and distribution of Nexium. Defendants breached those duties, proximately causing Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Nexium. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

- a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that plaintiff would suffer a serious injury or death by ingesting Nexium;
- b. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Nexium in unsafe doses;
- c. Failure to use reasonable care in testing and inspecting Nexium so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
- d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Nexium;

- e. Failure to use reasonable care in the process of manufacturing Nexium in a reasonably safe condition for the use for which it was intended;
- f. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Nexium in unsafe doses; and
- g. Such further acts and/or omissions that may be proven at trial.

81. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

**COUNT 7
NEGLIGENT MISREPRESENTATION**

82. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

83. Defendants failed to communicate to Plaintiff and/or the general public that the ingestion of Nexium could cause serious injuries after it became aware of such risks. Instead, Defendants represented in its marketing that Nexium was safe and effective.

84. Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

- a. Defendants, individually, and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about Nexium in that it made such misrepresentations when it knew or reasonably should have known of the falsity of such misrepresentations.

Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

- b. The above misrepresentations were made to Plaintiff as well as the general public;
- c. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' misrepresentations; and
- d. Consequently, Plaintiff ingested Nexium to Plaintiff's detriment. Defendants' negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

**COUNT 8
FRAUDULENT MISREPRESENTATION**

85. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

86. Defendants are engaged in the business of selling Nexium. By their advertising, labels, or otherwise, Defendants have made a misrepresentation of a material fact concerning the character or quality of Nexium to Plaintiff and the public.

87. Plaintiff justifiably relied on Defendants' misrepresentations in purchasing Nexium. Plaintiff has suffered physical harm proximately caused by Defendants' misrepresentations regarding the character or quality of Nexium.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

**COUNT 9
EXPRESS WARRANTY**

88. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

89. Defendants are merchants and/or sellers of Nexium. Defendants sold Nexium to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Defendants made representations to Plaintiff about the quality or characteristics of Nexium by affirmation of fact, promise and/or description. The representations by Defendants became part of the basis of the bargain between Defendants and Plaintiff. Nexium did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

**COUNT 10
IMPLIED WARRANTY**

90. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

WARRANTY OF MERCHANTABILITY

91. Defendants are merchants and/or sellers of Nexium. Plaintiff purchased Nexium from Defendants and used Nexium for the ordinary purpose for which it is used by consumers. At

the time it was purchased by Plaintiff, Nexium was not fit for the ordinary purpose for which such drugs are used. Nexium was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely. Defendants' breach of their implied warranty of merchantability caused Plaintiffs' injuries and monetary losses.

WARRANTY OF FITNESS

92. Defendants sold Nexium to Plaintiff with the knowledge that Plaintiff was purchasing Nexium for a particular purpose. Further, Defendants knew, or should have known, that Plaintiff was relying on Defendants' skill or judgment to select goods fit for Plaintiff's purpose.

93. Defendants delivered goods that were unfit for Plaintiff's particular purpose and thus breached their implied warranty of fitness. Defendants' failure to select and sell a product which was reasonably safe for its intended use proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff and Class Members demand a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

THE DRISCOLL FIRM, P.C.

By: /s/John J. Driscoll

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