

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

Baird Respiratory Therapy, Inc. on behalf
of itself and all others similarly situated,

Plaintiff,

v.

KONINKLIJKE PHILIPS N.V.; PHILIPS
NORTH AMERICA LLC; and PHILIPS RS
NORTH AMERICA LLC,

Defendants.

Case No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Baird Respiratory Therapy, Inc., on behalf of itself, the class, and all others similarly situated as defined below, for their complaint against Defendants Koninklijke Philips N.V. (“Royal Philips”), Philips North America LLC (“Philips NA”), and Philips RS North America LLC (“Philips RS”) (collectively, Royal Philips, Philips NA, and Philips RS are “Philips” or the “Defendants”), allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

INTRODUCTION

1. Plaintiff brings this action on behalf of itself and a proposed nationwide class of durable medical equipment (DME) suppliers who purchased from Philips, directly or indirectly, Philips’ Bi-Level Positive Airway Pressure (“BiPAP”), and/or its Continuous Positive Airway Pressure (“CPAP”) medical devices. In general, each of these devices express air into patients’ airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously while needed.

2. On April 26, 2021, Philips disclosed that the PE-PUR Foam used in certain devices it manufactured may degrade. On June 14, 2021, Philips issued a recall (the “Recall”) of devices containing PE-PUR Foam, noting that it had determined that the PE-PUR Foam was at risk for degradation, resulting in the off-gassing of certain chemicals, and the release of particles which may enter the device’s pathway and be inhaled or ingested by users of such devices. Philips advised Plaintiff to immediately cease selling these devices and to advise customers using Philips BiPAP and CPAP devices immediately discontinue their use of their devices.

3. On June 14, 2021, Philips announced a recall of many of its CPAP/BiPAP machines and its ventilators. These products contain polyester-based polyurethane (“PE-PUR”) foam for sound abatement. Philips announced that the foam may break down and be inhaled or ingested, and the foam may emit volatile organic compounds (“VOCs”) that may be inhaled, result in adverse effects to organs, and cause cancer. Philips explained in an announcement to doctors that these hazards could result in “serious injury which can be life-threatening or cause permanent impairment.”

4. On July 22, 2021, the United States Food and Drug Administration classified the recall of Philips devices containing PE-PUR Foam as a Class 1 recall, the most serious type of recall which is reserved for recalls of devices that may cause serious injuries or death.

5. Prior to June 14, 2021, Plaintiff purchased from Philips, directly or indirectly, Philips CPAP, and/or BiPAP mechanical ventilator devices that are subject to the Recall.

6. Plaintiff seeks to recover damages based on, inter alia, Philips’ negligence, breach of express warranty, and fraud, in connection with Philips’ manufacture, marketing, and sales of recalled devices on behalf of themselves and a nationwide of DME Suppliers.

PARTIES

7. Plaintiff Baird Respiratory Therapy, Inc is a Pennsylvania corporation with its principal place of business in Glenside, Pennsylvania

8. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of Philips NA and Philips RS.

9. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly- owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips’ various lines of business, including Philips RS, in North America.

10. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15296. Philips RS was formerly operated under the business name Respironics, Inc. (“Respironics”). Royal Philips acquired Respironics in 2008.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(d)(2)(A), because this case is a class action where the aggregate claims of all members of the proposed Class exceed \$5,000,000.00, exclusive of interest and costs, and Plaintiff and most members of the proposed Class are citizens of a state different from Defendants.

12. Venue is proper in this judicial District pursuant to 28 U.S.C. §1391(b) and (c) and 18 U.S.C. §1965, because Defendants transact business in, are found in, and/or have agents

in this District, and because some of the actions giving rise to this complaint took place within this District. The Court has personal jurisdiction over the Defendants. Defendants transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons and entities residing in, located in, or doing business throughout the United States, including in this District.

FACTUAL BACKGROUND

I. Continuous Positive Airway Pressure Therapy

13. Sleep apnea is a sleeping disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. These disturbances are called “apneas,” and they may be associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to hypertension, heart attack, or stroke, among other medical ailments.

14. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation.

15. Bi-Level Positive Airway Pressure (“BiPAP”) therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual’s airway.

16. BiPAP is distinguishable from CPAP therapy, however, because BiPAP devices deliver two alternating levels - inspiratory and expiratory - of pressurized air into a person’s

airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

17. Philips developed, marketed, and sold a lineup of CPAP and BiPAP respirator devices under its “Sleep & Respiratory Care” portfolio. Philips has sold millions of these devices in the United States to DME suppliers, including Plaintiff.

18. DME Suppliers then resell these devices to end user patients with a markup on the price they paid Philips and are either partly or fully paid by the end users’ insurance provider, with any shortfall being made up by the end user.

II. Philips’ Sleep & Respiratory Care Devices Were Endangering its Users

19. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled “Regulatory Update,” that device user reports had led to a discovery that the type of PE-PUR “sound abatement” foam Philips used to minimize noise in several CPAP and BiPAP respirators posed health risks to its users. Specifically, Philips disclosed that “the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature.”

20. Over a month later, on June 14, 2021, Philips announced that it was recalling several models of BiPAP, CPAP, and mechanical ventilator devices “to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices.”

21. The list of the devices Philips recalled (the “Recalled Devices”) include:

Philips CPAP and BiLevel PAP Devices Subject to Recall	
Device Name/Model	Type
Philips E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips DreamStation ASV	Continuous Ventilator, Non-life Supporting
Philips DreamStation ST, AVAPS	Continuous Ventilator, Non-life Supporting
Philips SystemOne ASV4	Continuous Ventilator, Non-life Supporting
Philips C Series ASV, S/T, AVAPS	Continuous Ventilator, Non-life Supporting
Philips OmniLab Advanced Plus, In-Lab Titration Device	Continuous Ventilator, Non-life Supporting
Philips SystemOne (Q Series)	Non-continuous Ventilator
Philips DreamStation, CPAP, Auto CPAP, BiPAP)	Non-continuous Ventilator
Philips DreamStation GO, CPAP, APAP	Non-continuous Ventilator
Philips Dorma 400, 500, CPAP	Non-continuous Ventilator
Philips REMStar SE Auto, CPAP	Non-continuous Ventilator

22. In a post-recall email to Plaintiff and presumably all other DME suppliers noted herein, Philips has admitted that the Recalled Products are defective and unsafe, and thus instructed the suppliers not to resell any of the Recalled Plaintiff currently in their respective inventories.

III. Philips Unreasonably Delayed Its Recall

23. Philips has not disclosed when it first received reports from users of its Sleep & Respiratory Care devices “regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask).”

24. Several facts support the assertion that Philips knew of the issue of the degradation of PE-PUR foam well in advance of issuing the recall. First, Philips’ own language admits that the recall was issued in response to “several complaints” it had received regarding black particles and debris in the airways of the Recalled Devices. Second, posts on message boards and

YouTube channels such as the website apneaboard.com and the YouTube channel *CPAP Reviews* complained about problems now known to be consistent with the degradation of PE-PUR foam, including black particles in the airways of the Recalled Devices.

25. Thus, as a result of user reports, Philips was aware of the degradation of the PE-PUR sound abatement foam used in the Recalled Devices yet continued to manufacture and sell the Recalled Devices to Plaintiff and other DME suppliers with such awareness for a significant period of time. During this period, Philips unreasonably and unjustly profited from the sale of the Recalled Devices.

26. In fact, it was only after the early April 2021 release of the Philips Respironics DreamStation 2, a breathing device which does not contain the dangerous PE-PUR Foam, that Philips publicly admitted the problems with the Recalled Devices in a regulatory filing. As detailed above, it was not for another seven weeks that Philips officially recalled the Recalled Devices.

27. Although Philips has recently announced a repair and replace program for the end user patients, it has offered no relief or compensation to DME suppliers that have the Recalled Devices.

28. Plaintiff seeks a refund relating to the acquisition of its Recalled Devices, non-defective replacement devices that are currently in its inventory, and all other appropriate damages.

CLASS ACTION ALLEGATIONS

29. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3).

30. Plaintiff seeks class certification on behalf of a class defined as follows (the “Class”):

All DME suppliers in the United States and its territories which, from the beginning of any applicable limitations period through June 14, 2021, purchased or leased for resale the Recalled Products (the “Class”).

31. Plaintiff reserves the right to modify or refine the definition of the Class based upon discovery of new information and in order to accommodate any of the Court’s manageability concerns.

32. Excluded from the Class are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendants and Defendants’ predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which any Defendants or their parents have a controlling interest, as well as Defendants’ current or former employees, agents, officers, and directors; (c) persons who properly execute and file a timely request for exclusion from the Class; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiff and Defendants; and (f) the legal representatives, successors, and assigns of any such excluded persons.

33. **Ascertainability.** The proposed Class is readily ascertainable because it is defined using objective criteria such that Class members can determine if they are part of the Class. Further, the Class can be readily identified through records maintained by Defendants.

34. **Numerosity (Rule 23(a)(1)).** The proposed Class is so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class, as herein identified and described, is not known, but sales figures indicate that DME suppliers have purchased thousands of the Philips Recalled Devices.

35. **Commonality (Rule 23(a)(2)).** Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class members,

including the following:

- a) whether Defendants owed a duty of care to Plaintiff and the Class;
- b) whether Defendants knew or should have known of the defects associated with the PE-PUR Foam used for sound abatement posed health risks;
- c) whether Defendants wrongfully represented that the PE-PUR Foam used for sound abatement in the Recalled Devices was safe;
- d) whether the Recalled Devices retained any value post-recall;
- e) whether Defendants wrongfully represented that the Recalled Devices were safe to use;
- f) whether Defendants wrongfully failed to disclose that the PE-PUR Foam used for sound abatement in the Recalled Devices posed health risks to Recalled Device users;
- g) whether Defendants' representations in advertising, warranties, packaging, and/or labeling were false, deceptive, and misleading;
- h) whether those representations were likely to deceive Plaintiff and the Class;
- i) whether Defendants had knowledge that those representations were false, deceptive, and misleading;
- j) whether Defendants breached their express warranties;
- k) whether Defendants breached their implied warranties;
- l) whether Defendants have been unjustly enriched;
- m) whether Defendants made negligent and/or fraudulent misrepresentations and/or omissions;
- n) whether Plaintiff and the members of the Class are entitled to actual, statutory, and

punitive damages; and

- o) whether Plaintiff and members of the Class are entitled to declaratory and injunctive relief.

36. **Typicality (Rule 23(a)(3)).** Plaintiff's claims are typical of the claims of the other members of the proposed Class. Plaintiff and members of the Class suffered injuries as a result of Philips' wrongful conduct that is uniform across the Class.

37. **Adequacy (Rule 23(a)(4)).** Plaintiff has and will continue to fairly and adequately represent and protect the interests of the Class. Plaintiff has retained counsel competent and experienced in complex litigation and class actions. Plaintiff has no interest that is antagonistic to those of the Class, and Defendants have no defenses unique to Plaintiff. Plaintiff and its counsel are committed to vigorously prosecuting this action on behalf of the members of the Class, and they have the resources to do so. Neither Plaintiff nor Plaintiff's counsel have any interest adverse to those of the other members of the Class.

38. **Substantial Benefits.** This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy and joinder of all members of the Class is impracticable. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the Courts and Defendants, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court. Class

treatment will create economies of time, effort, and expense and promote uniform decision-making.

39. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

40. Class certification is also appropriate under Fed. R. Civ. P. 23(b)(2) because Defendants acted or refused to act on grounds generally applicable to the Class, so that final injunctive relief or corresponding declaratory relief is appropriate as to the Class as a whole. Plaintiff reserves the right to revise the foregoing class allegations and definitions based on facts learned and legal developments following additional investigation, discovery, or otherwise.

FIRST CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY On Behalf of the Class

41. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

42. Philips marketed and sold the Recalled Devices into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiff and the Class for resale to end users.

43. Philips expressly warranted, advertised, and represented to Plaintiff and the Class that the Recalled Devices were safe and appropriate for human use.

44. Philips made these express warranties regarding the Recalled Devices quality and fitness for use in writing through its website, advertisements, and marketing materials and on the Recalled Devices' packaging and labels. These express warranties became part of the

basis of the bargain that Plaintiff and the Class entered into upon purchasing the Recalled Devices.

45. Philips' advertisements, warranties, and representations were made in connection with the sale of the Recalled Devices to Plaintiff and the Class. Plaintiff and the Class relied on Philips' advertisements, warranties, and representations regarding the Recalled Devices in deciding whether to purchase Philips' products.

46. Philips' Recalled Devices do not conform to Philips' advertisements, warranties, and representations in that they were unfit for use, are not safe, and defective.

47. Philips therefore breached its express warranties by placing Recalled Devices into the stream of commerce and selling them to purchasers like Plaintiff and the Class, when their use had dangerous effects and was unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for use as marketed by Philips.

48. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, but nowhere on the package labeling or on Philips' websites or other marketing materials did Philips warn Plaintiff and members of the Class or their end-user customers of the dangerous PE-PUR Foam used in the Recalled Devices.

49. Instead, Philips concealed the defects associated with the PE-PUR Foam used in the Recalled Devices and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations were true.

50. The adverse health effects associated with use of the Recalled Devices existed when they left Philips' possession or control and were sold to Plaintiff and members of the Class. The dangers associated with use of the Recalled Devices were undiscoverable by

Plaintiff and members of the Class at the time of purchase of the Recalled Devices.

51. As manufacturers, marketers, advertisers, distributors, and sellers of Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

52. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations to induce Plaintiff and members of the Class to rely on such representations.

53. Philips' affirmations of fact and promises were material, and Plaintiff and members of the Class reasonably relied upon such representations in purchasing the Recalled Devices.

54. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiff or members of the Class.

55. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice of the defects associated with the PE-PUR Foam in the Recalled Devices and that it was unsafe. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the Recalled Devices but failed to do so until now.

56. As a direct and proximate result of Philips' breaches of express warranty, Plaintiff and members of the Class have been damaged because they purchased Recalled Products that they are unable to resell. Plaintiff and members of the Class did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for the Recalled Devices.

57. Plaintiff and the Class seek actual damages, injunctive and declaratory relief,

attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their express warranties and resulting breach.

SECOND CLAIM FOR RELIEF

**FRAUDULENT MISREPRESENTATION
On Behalf of the Class**

58. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

59. Philips falsely represented to Plaintiff and the Class that the Recalled Devices were fit for use by Plaintiff's and the Class's customers.

60. Philips intentionally, knowingly, and recklessly made these misrepresentations to induce Plaintiff and the Class to purchase Recalled Devices.

61. Philips knew that its representations about the Recalled Devices were false in that the Recalled Devices contained PE-PUR Foam and were therefore defective and that could cause adverse health effects to Plaintiff's customer-users of the Recalled Devices which does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead Plaintiff and the Class.

62. Plaintiff and the Class did in fact rely on these misrepresentations and purchased Recalled Devices to their detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, Plaintiff's and the Class's reliance on Philips' misrepresentations was justifiable.

63. As a direct and proximate result of Philips' conduct, Plaintiff and the Class have suffered actual damages in that they purchased Recalled Devices that are currently sitting in their inventories and cannot be resold, and not conform to the Recalled Devices' labels, packaging, advertising, and statements.

64. Plaintiff and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

THIRD CLAIM FOR RELIEF

**FRAUD BY OMISSION
On Behalf of the Class**

65. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

66. Philips concealed from and failed to disclose to Plaintiff and the Class of the defects associated with the Recalled Devices and the use of Recalled Devices is accompanied by a risk of adverse health effects that does not conform to the products' labels, packaging, advertising, and statements.

67. Philips was under a duty to disclose to Plaintiff and the Class the true safety, quality, characteristics, fitness for use, and suitability of the Recalled Devices because: (1) Philips was in a superior position to know the true state of facts about its products; (2) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of Recalled Devices for use by individuals; and (3) Philips knew that Plaintiff and the Class could not reasonably have been expected to learn or discover that Recalled Devices were misrepresented in the packaging, labels, advertising, and websites prior to purchasing Recalled Devices for resale.

68. The facts concealed or not disclosed by Philips to Plaintiff and the Class were material in deciding whether to purchase Recalled Devices.

69. Plaintiff and the Class justifiably relied on the Philips' omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of Recalled Devices, which is inferior when compared to how Recalled Devices are advertised and represented by Philips.

70. As a direct and proximate result of Philips' conduct, Plaintiff and the Class have suffered actual damages in that they purchased Recalled Devices that are currently sitting in their inventories and cannot be resold, and not conform to the Recalled Devices' labels, packaging, advertising, and statements.

71. Plaintiff and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

FOURTH CLAIM FOR RELIEF

UNJUST ENRICHMENT On Behalf of the Class

72. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

73. Plaintiff and the Class conferred substantial benefits on Philips through their purchase of the Recalled Devices. Philips knowingly and willingly accepted and enjoyed these proceeds from the sales of their Recalled Devices and obtained benefits from Plaintiff and the Class.

74. Philips either knew or should have known that the payments rendered by Plaintiff and the Class were given with the expectation that the Recalled Devices would be fit for resale and use and that they have the qualities, characteristics, and suitability for use represented and warranted by Philips when they were not. As such, it would be inequitable for Philips to retain the benefit of the payments under these circumstances.

75. Philips' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Philips to retain the benefits without payment of the value to Plaintiff and the Class.

76. Plaintiff and the Class are entitled to recover from Philips all amounts wrongfully collected and improperly retained by Philips, plus interest thereon.

77. Plaintiff and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, pray for judgment against Philips as to each and every count, including:

- A. An order certifying this action and the Class requested herein as a class action, designating Plaintiff as the representatives of the Class, and appointing Plaintiff's counsel as counsel to the Class;
- B. An order declaring that Defendants' actions constitute: (i) breach of express warranty; (ii) fraudulent misrepresentation; and (iii) fraud by omission, and that Philips is liable to Plaintiff and members of the Class, as described herein, for damages arising therefrom;
- C. An order declaring that Defendants have been unjustly enriched by Plaintiff through their purchases of the Recalled Devices;
- D. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendants from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendants' past conduct;
- E. A judgment awarding Plaintiff and members of the Class all appropriate damages, in an amount to be determined at trial;
- F. A judgment awarding Plaintiff and members of the Class pre-judgment and post-judgment interest, as permitted by law;
- G. A judgment awarding Plaintiff and members of the Class costs and fees, including attorneys' fees, as permitted by law; and

H. Grant such other legal, equitable, or further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable.

DATED: March 9, 2022.

Respectfully submitted,

/s/ Marc H. Edelson

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