UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

EDWARD RINEHART and KARI RINEHART, husband and wife, Plaintiffs, Plaintiffs 3M COMPANY, a Delaware corporation, and ARIZANT HEALTHCARE, INC. a Delaware corporation; Defendants.	NO. COMPLAINT FOR DAMAGES JURY DEMAND (Clerk's Action Required)

Plaintiffs bring this complaint herein against Defendants 3M Company and Arizant Healthcare, Inc. (hereinafter referred to collectively as "Defendants") and allege as follows:

I. INTRODUCTION

1. This is a product liability personal injury case stemming from the design, manufacture, marketing, and maintenance of the Bair Hugger Forced Air Warming device ("Bair Hugger"). As a direct result of the use of Bair Hugger during his knee replacement surgery, Plaintiff Edward Rinehart suffered grievous harm, incurred significant medical bills, and continues

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to suffer to this day.

2. Defendants knew about the risks the Bair Hugger poses to patients, particularly patients such as Plaintiff undergoing implantation surgeries. Despite this knowledge, which Defendants enjoyed for at least the last fifteen years, no attempt has been made to redesign their product or warn healthcare providers of the risks inherent in using a Bair Hugger in an implantation surgery. In fact, Defendants have taken every step to conceal and discredit any scientific studies which might undermine their sales.

II. JURISDICTION AND VENUE

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

4. Venue is proper in this District pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to Plaintiffs' claim occurred in this District, and because Defendants conducted substantial business in this District.

III. PARTIES

5. Plaintiffs Edward Rinehart and Kari Rinehart are husband and wife and are citizens and residents of Thurston County, Washington, and were citizens and residents of the State of Washington at all times relevant to the allegations in this Complaint. Plaintiff Edward Rinehart, upon information and belief, suffered severe and permanent personal injuries as a result of the use of Bair Hugger.

6. Defendant 3M Company is a corporation organized under the laws of the State of Delaware, with a principal place of business in Maplewood, Minnesota. 3M is engaged in the

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business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly, its products, including the Bair Hugger.

7. Defendant Arizant Healthcare, Inc. is a corporation organized under the laws of the State of Delaware. Arizant is a wholly owned subsidiary of Defendant 3M. Arizant conducts business throughout the United States, including the State of Washington.

8. Upon information and belief, each of the Defendants was the representative, agent, servant, partner, predecessor or successor in interest, aider and abettor, co-conspirator and joint venture of each of the remaining Defendants, and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

9. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the Bair Hugger forced air warming blanket.

IV. FACTUAL BACKGROUND

10. Defendants, directly or indirectly through their agents, apparent agents, servants, and/or employees are engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, promoting, marketing, distributing, supplying and/or selling Bair Hugger.

11. Due to the defective design of the Bair Hugger, Plaintiff Edward Rinehart has suffered and will continue to suffer severe and permanent personal injuries, including, but not limited to, impaired mobility and needing to take antibiotics for the rest of his life.

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12. On November 18, 2014 the Bair Hugger was used on Plaintiff Edward Rinehart during the course of Plaintiff's left total knee replacement surgery.

13. The Bair Hugger caused contaminates to be introduced into Plaintiff's open surgical wound, which resulted in an infection.

14. Due to the infection, Plaintiff was required to have additional surgical procedures to remove and replace the polyethylene component and clean the infected area within less than one month from the original implant surgery.

15. Plaintiff now suffers and will continue to suffer from permanent damages as a result of the Bair Hugger induced infection. Indeed Plaintiff's mobility is now impaired, making even the simple movement of walking a challenge.

16. Defendants concealed and continue to conceal their knowledge of the unreasonably dangerous risks of using the Bair Hugger from Plaintiff, other consumers, and the medical community.

17. Moreover, Defendants failed to conduct sufficient and adequate post-marketing surveillance after they began marketing, advertising, distributing, and selling the Bair Hugger.

18. Because of Defendants' actions and omissions, Plaintiff was injured by the use of the Bair Hugger.

19. At all times relevant to the allegations herein, Defendants designed, developed, researched, manufactured, tested, advertised, promoted, sold and/or distributed Bair Hugger for the purpose of warming patients during orthopedic implant surgery.

20. Upon information and belief, there are over 50,000 Bair Hugger units currently in use across the United States.

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21. The Bair Hugger consists of a disposable blanket that is connected to a portable heater/blower by a flexible hose. The Bair Hugger system is positioned over (or in some cases under) surgical patients during surgery, and keeps patients warm by blowing hot air on the patient's exposed skin.

22. The hot air accumulates under the surgical blanket and escapes the blanket either below the surgical table or at the head end of the surgical table. The escaped hot air creates airflow currents that flow against the downward air flow of the operating room. As this warmed air rises, it deposits bacteria from the floor of the operating room onto the surgical site.

23. Between 2002 and 2009, Defendants reduced the efficiency of the Bair Hugger air filtration blowers, which drastically reduced the safety of such blowers.

24. As a result, the internal airflow pathways of the Bair Hugger blowers became contaminated with pathogens. The pathogens incubate and proliferate within the internal airflow paths of the Bair Hugger blowers.

25. The pathogens are then expelled from the interior of the Bair Hugger blower by the outward airflow, travel through the hose into the disposable blanket and escape into the operating room.

26. Since at least 2009, Defendants have been aware of the pathogenic contamination of the airflow paths of the Bair Hugger.

27. Despite their knowledge to the contrary, Defendants have actively and aggressively marketed the Bair Hugger as safe in both general and orthopedic surgeries.

28. In September of 2009, Defendants falsely represented to the Food and Drug Administration ("FDA") that the Bair Hugger's filtration system meets High Efficiency Particulate

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Air ("HEPA") standards. HEPA standards require that an air filter be capable of removing 99.97% of all particles 0.3 microns or larger. The Bair Hugger filter is marketed as HEPA compliant. However, the filter is only capable of removing less than 65% of all such particles. At the time Defendants made these representations, they had actual knowledge that the statements were false.

29. In June of 1997, Defendants admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." Defendants further addressed the Bair Hugger's risk of contamination by stating that the risk of contamination is obviated because all "Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent [sic] air from migrating toward the surgical site." Defendants' statement, however, was and is patently false. In fact, a number of Bair Hugger blankets that are marketed as safe for use in surgeries do not utilize a taped edge. Instead, those blankets blow contaminated air directly toward the surgical site.

30. Moreover, Defendants' statement that the taped barrier would prevent the contaminated air from escaping the device is untrue because it ignores the fact that the warm air from the Bair Hugger rises against the general downward airflow of the operating room. The tape barrier does not prevent the Bair Hugger from facilitating the movement of pathogens from the floor of the operating room to the surgical site. At the time Defendants made these statements, Defendants had actual knowledge of their falsity.

31. Furthermore, Defendants make the following misrepresentations on their website, http://www.fawfacts.com/laminar_airflow/ (last visited December 23, 2015):

a. Contamination mobilized by the convection currents generated by the Bair Hugger cannot reach the surgical site because "[a]ir velocity within the operating room is many times stronger than that of a forced air warming blanket";

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b. "The air emerging from the blanket is directed downward by the surgical drape and, emerges under the operating room table and is drawn away through the laminar system's return air inlets"; and

c. "It's been suggested that warm air rising above the Bair Hugger blanket could interfere with the downward laminar flow toward the surgical site. It should be noted that the Bair Hugger warming unit delivers less than one percent of the airflow of a laminar flow system and the momentum of the downward air is far greater than the upward momentum imparted to the air above the blanket."

32. Defendants' statements in the preceding paragraphs are false. Defendants' statements disguise the fact that the true issue with the Bair Hugger is not the strength of the airflow in a laminar system, but instead the hot temperature of the air generated by the Bair Hugger. The cold air generated by the operating room has a higher density than the hot air generated by the Bair Hugger. The cold air falls to the floor of the operating room and forces the contaminated air at the floor of the operating room (now warmed by the waste heat from the Bair Hugger) to rise into the sterile field and surgical site. Contrary to Defendants' advertisement, the warm air rises and is not "drawn away" from the surgical site.

33. In as early as 2010, Defendants advertised the Bair Hugger in multiple medical publications, available at http://sca94852107ebf47b.jimcontent.com/download/version/1372595687/module/6710032887/name/AJIC-R-1.pdf (last visited December 28, 2015), and made the following false and misleading claims:

> "While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems."

Prior to and after Defendants' statement, published scientific research has demonstrated the

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inaccuracy of this statement. The Bair Hugger generates an exhaust that creates convective airflow patterns which disrupt the laminar flow of the operating room.

34. In July of 2012, Defendants' public relations and communications specialist, Greta Deutsch, stated "some conductive-warming manufacturers have alleged that forced-air warming increases bacterial contamination of operating rooms or interrupts laminar airflow. These accusations have no factual basis." Indeed, this statement ignored numerous published studies documenting the adverse effects the Bair Hugger has on laminar airflow.

35. Defendants should have been prompted to redesign or discontinue the Bair Hugger in light of the numerous peer-reviewed publications and studies identifying the critical defects of the Bair Hugger. These publications include, but are not limited to, the following:

a. Albrecht M, et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2010;39:321-8;

b. Leaper D, et al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev*. 2009;1(2):e28;

c. McGovern, P.D., et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br*. 2012;93-B(11):1537-1544;

d. Legg, A. et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg-Br.* 2012;94- B:254-6;

e. Belani, K., et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesthesia & Analgesia* 2012 (prepublication on-line) 2013;117(2):406-411;

f. Dasari, K.B., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anesthesia* 2012;67:244249.

36. Defendants were aware that their representations were false at the time they were

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made. Nonetheless, Defendants continued to mislead healthcare providers regarding the safety of the Bair Hugger.

37. Despite the numerous scientific studies to the contrary, Defendants chose not to alter the design of the Bair Hugger or to warn physicians of the dangers associated with the device. Instead, Defendants chose to "double down" on their efforts to market and promote their defective product.

38. Plaintiff's physician reasonably relied upon Defendants' representations and advertisements to Plaintiff's detriment. Any reasonable physician would not use the Bair Hugger if he or she was fully aware of the risks associated with it.

39. As a direct and proximate result of the failure of Defendants' Bair Hugger to maintain the sterility of the surgical site and Defendants' wrongful conduct, Plaintiff has incurred damages, including severe and permanent personal injuries, medical expenses and other economic and non-economic damages.

V. CAUSES OF ACTION

COUNT I: NEGLIGENT MISREPRESENTATION

40. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

41. Defendants made negligent misrepresentations regarding the Bair Hugger including, but not limited to, the following:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger has been tested and found to be safe and effective for the warming of patients during orthopedic implant surgery; and

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b. Defendants represented that Bair Hugger was safer than other patient warming systems.

42. Defendants made the foregoing representations without having reasonable grounds for believing them to be true. The representations made by Defendants were false, in that the Bair Hugger is not safe, fit, and effective for human use.

43. The foregoing representations were made directly by Defendants, sales representatives, and other authorized agents of Defendants, in publications and other written materials that were directed to Plaintiff, the general public, and healthcare providers, with the intention of inducing reliance on the misrepresentations, thereby promoting the sale and use of the Bair Hugger.

44. Plaintiff and Plaintiff's physicians did, in fact, reasonably rely upon the representations. In the absence of the representations, the Bair Hugger would not be used in implantation surgeries such as the one at issue in this case.

45. As a result of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severe bodily injuries and damages.

COUNT II: FRAUD

46. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

47. As a result of Defendants' research or testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including, but not limited to, assuring Plaintiff, healthcare providers, and the FDA, that the Bair Hugger was safe and effective for use as a means to warm patients during orthopedic surgeries.

48. Defendants intentionally represented that the Bair Hugger has been tested and

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found to be safe and effective for the warming of patients during orthopedic implant surgery, and that the Bair Hugger was safer than other patient warming systems.

49. Defendants had a duty to disseminate truthful information to the general public, including Plaintiff, and a parallel duty not to deceive the general public and Plaintiff, as well as the Plaintiff's respective healthcare providers.

50. The information distributed by Defendants to Plaintiff, the general public, and healthcare providers contained false representations that Bair Hugger was safe and effective for use as a means to warm patients during orthopedic surgeries.

51. Defendants' representations were all false and misleading.

52. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to Defendants, and results demonstrating that the Bair Hugger was not safe as a means of warming patients during orthopedic surgeries.

53. Defendants' representations were made with the intent that healthcare providers and patients, including Plaintiff, would rely upon them.

54. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and healthcare providers to induce and encourage the sale of Bair Hugger.

55. At the time the representations were made, Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and safety concerns associated with the use of the Bair Hugger.

56. Plaintiff did not discover the true facts with respect to the dangerous and serious health and safety concerns associated with the use of the Bair Hugger, nor Defendants' false

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representations regarding the same, nor could Plaintiff with reasonable diligence have discovered the true facts.

57. Plaintiff and Plaintiff's physician did in fact rely upon the representations. In the absence of Defendants' representations, the Bair Hugger would not be used in implantation surgeries such as the one at issue in this case.

58. Defendants' conduct was fraudulent and deceitful, and was committed willfully, wantonly and/or purposefully to induce Plaintiff.

59. As a result of the foregoing acts and omissions, Plaintiff suffered serious physical injury, harm, and damages and will continue to suffer such harm and damages in the future.

COUNT III: WASHINGTON PRODUCTS LIABILITY ACT

60. Plaintiffs hereby incorporate by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

61. At all times relevant to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Bair Hugger.

62. At all times relevant to this action, the Bair Hugger was expected to reach, and did reach, consumers in the State of Washington and throughout the United States, including Plaintiff and Plaintiff's physicians herein without substantial change in the condition it was sold.

63. In violation of the Washington Products Liability Act, RCW 7.72, et seq., at the time the Bair Hugger left control of Defendants, it was defective and not reasonably safe. These defects include, but are not limited to, the following:

a. Defendants are strictly liable to Plaintiff for his injuries and damages because at

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the time of manufacture, and at the time the Bair Hugger left the control of Defendants, the likelihood that the Bair Hugger would cause injury or damage similar to that suffered by Plaintiff, and the seriousness of such injury or damage had been known by Defendants for at least fifteen years and outweighed the burden on Defendants to design a product that would have prevented Plaintiff's injuries and damages and outweighed the adverse affect that an alternative design that was practical and feasible would have on the usefulness of the subject product.

b. The Bair Hugger was unsafe to an extent beyond that which would be contemplated by an ordinary consumer, in one or more of the following particulars: the propensity of the Bair Hugger to cause convention currents that disrupt the generally downward airflow of the operating room makes the Bair Hugger dangerous when used in the way it is ordinarily used and is unsafe to an extent beyond that which would be contemplated by an ordinary consumer; in the alternative, the propensity of the Bair Hugger's internal airflow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens makes the Bair Hugger not reasonably safe when used in the way it is ordinarily used and is dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

c. The subject product manufactured and/or supplied by Defendants was defective in design in that, an alternative design exists that would prevent severe and permanent injury. In particular, the development of body warming device without the effects of the Bair Hugger. The product was not reasonably safe in design under the

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Washington Product Liability Act.

d. The subject product manufactured and/or supplied by Defendants was not reasonably safe because Defendants did not provide an adequate warning or instruction about the product. At the time the subject product left Defendants' control, it possessed a characteristic that may cause damage, and Defendants failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product. The product is not safe and causes severe and permanent injuries. The product was not reasonably safe because the warning was inadequate and Defendants could have provided adequate warnings or instructions.

e. The subject product manufactured and/or supplied by Defendants was not reasonably safe because adequate warnings or manufacturer instructions were not provided after the product was manufactured and when Defendants learned of, or should have learned of, the dangers connected with the subject product.

f. The subject product manufactured and/or supplied by Defendants was not reasonably safe because it did not conform to an express warranty made by Defendants regarding the product's safety and fitness for use. Defendants expressly warranted that the Bair Hugger was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested. Defendants did not disclose the material risks that the Bair Hugger could cause severe and permanent injury. Defendants' express warranty regarding the subject product induced Plaintiff and Plaintiff's physicians

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to use the product, and Plaintiff's damage was proximately caused because Defendants' express warranty was untrue. The product was not reasonably safe because of nonconformity to express warranty under the Washington Product Liability Act.

64. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

COUNT IV: VIOLATION OF WASHINGTON CONSUMER PROTECTION ACT

65. Plaintiff hereby incorporates by reference the allegations of this Complaint contained in each of the preceding paragraphs as if fully stated herein.

66. Defendants violated the Washington Consumer Protection Act.

67. Defendants engaged in unfair or deceptive acts or practices including, but not limited to, the following:

a. engaging in acts and practices by willfully failing and refusing to timely report information that reasonably suggested the Bair Hugger, like that used on the Plaintiff, may cause or contribute to death or serious injury when used in implantation surgeries;

b. representing knowingly or with reason to know that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;

c. representing knowingly or with reason to know that the Bair Hugger and its filtration system is of a particular standard, quality, or grade when it differs materially from that representation;

d. representing knowingly or with reason to know that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect;

e. falsely stating, knowingly or with reason to know, that services or repairs are not needed.

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68. Defendants' unfair and deceptive acts or practices described above were committed in the course of Defendants' trade or commerce.

69. Defendants' unfair and deceptive acts or practices described above affected public interest.

70. Defendants' violation of the Washington CPA, whether individually or in combination, caused Plaintiff's injuries and damages as set forth herein.

VI. DAMAGES

71. Plaintiff incorporates herein by reference, as though fully set forth at length, each and every allegation and statement contained in the foregoing paragraphs.

72. As a direct and proximate result of Defendants' tortious conduct and breach of duties as set forth herein, Edward Rinehart sustained serious injuries.

73. The serious injuries sustained by Edward Rinehart are painful, permanent, and disabling, and have necessitated extensive medical care and treatment in the past and will continue to necessitate extensive medical care and treatment in the future.

74. As a direct and proximate result of his serious injuries, Edward Rinehart has sustained pain and suffering, both physical and mental, and with reasonable probability will continue to experience pain and suffering, both physical and mental, in the future.

75. As a further direct and proximate result of his injuries, Edward Rinehart has sustained disability, and loss of enjoyment of life, and will continue to sustain disability and loss of enjoyment of life in the future.

76. As a further direct and proximate result of his injuries, Edward Rinehart has sustained medical expenses, out of pocket expenses, and costs. With reasonable probability, he

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will continue to sustain medical expenses, life care expenses, and other out of pocket costs and expenses in the future as a result of his serious injuries.

77. As a direct and proximate result of Defendants' tortious conduct and breach of duties as set forth herein, Plaintiff Kari Rinehart, spouse of Edward Rinehart, has sustained and will continue to sustain a loss of consortium.

78. Plaintiffs are entitled to damages in an amount to be proved at trial, together with interest thereon and costs.

79. WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as hereinafter set forth.

PRAYER FOR RELIEF

Plaintiffs respectfully request judgment against all Defendants as follows:

1. General damages, as shall be determined at the time of trial;

2. Special damages to be shown at the time of trial, including all pre-judgment interest allowed by law;

4. Punitive or exemplary damages according to proof at the time of trial;

5. Treble damages in the maximum amounts permitted by RCW 19.86.090;

6. Costs of suit incurred herein;

8. For such other and further relief as the Court may deem just and proper.

Dated: February 2, 2016

LAW OFFICES OF JAMES S. ROGERS

/ s James S. Rogers
/ s Elizabeth J. Donaldson
James S. Rogers, WSBA #5335

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DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a jury trial of six (6) as provided by Rule 38(a) of the Federal Rules of Civil Procedure.

DATED this 2nd day of February, 2016.

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/ s James S. Rogers
/ s Elizabeth J. Donaldson

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