

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN CARBON SPINE BOARD,
CERVICAL COLLAR, CPR MASKS
AND VARIOUS MEDICAL TRAINING
MANIKIN DEVICES, AND
TRADEMARKS, COPYRIGHTS OF
PRODUCT CATALOGUES, PRODUCT
INSERTS AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1008

COMMISSION OPINION

I. BACKGROUND

The Commission instituted this investigation on June 24, 2016, based on Laerdal's amended complaint filed on May 19, 2016, and its supplement filed on June 7, 2016. 81 Fed. Reg. 41349-50 (Jun. 24, 2016). The amended complaint, as supplemented, alleges violations of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain carbon spine board, cervical collar, CPR masks and various medical training devices, and trademarks, copyrights of product catalogues, product inserts, and components thereof, by reason of infringement of certain claims of U.S. Patent Nos. 6,090,058 ("the '058 patent") and 6,170,486 ("the '486 patent"), U.S. Copyright Registration Nos. VA 1-879-023 ("the '023 copyright") and VA 1-879-026 ("the '026 copyright"), U.S. Trademark Registration Nos. 3,735,147 ("the '147 trademark") and 3,479,656 ("the '656 trademark"), common law trademarks, and trade dresses; as well as trade dress misappropriation. *Id.* at 41349. The Commission, however, instituted the investigation with respect to only Laerdal's allegations regarding claim 1 of the '058 patent, the '023 and '026

copyrights, the '656 mark, and trade dress misappropriation. *Id.* at 41350.

The Commission's notice of investigation named as respondents Shanghai Evenk International Trading Co., Ltd. ("Evenk"), Shanghai Honglian Medical Instrument, Development Co., Ltd. ("Honglian"), and Shanghai Jolly Medical Education Co., Ltd. ("Jolly"), all of Shanghai, China; Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd. ("Xiehe"), Zhangjiagang New Fellow Med Co., Ltd. ("New Fellow"), Jiangsu Yongxin Medical Equipment Co., Ltd. ("Yongxin Medical Equipment"), and Jiangsu Yongxin Medical-Use Facilities Making Co., Ltd. ("Yongxin Medical-Use"), all of Zhangjiagang City, China; Jiangyin Everise Medical Devices Co., Ltd. ("Everise"), of Jiangyin City, China; Medsource International Co., Ltd. ("Medsource International") and Medsource Factory, Inc. ("Medsource Factory") of PuDong, China; and Basic Medical Supply, LLC ("Basic Medical") of Richmond, Texas. *Id.* at 41350. The Office of Unfair Import Investigations ("OUII") was also named as a party. *Id.* Laerdal accuses the following parties of infringing the following intellectual property rights:

Respondent	'058 patent	'023 and '026 copyrights	'656 mark	Manikin Trade Dress	Spineboard and Cervical Collar Trade Dress
Evenk		X		X	X
Honglian		X		X	X
Jolly		X		X	
Xiehe		X			X
New Fellow		X			X
Yongxin Medical Equipement		X			X
Yongxin Medical-Use		X			X
Everise		X			X
Medsource International	X		X		X
Medsource Factory	X		X		X
Basic Medical	X		X		X

See OUII Main Sub. at 3 (citing Laerdal Amended Cmpl. at ¶¶ 157-420).

All respondents were served with a copy of the amended complaint and the notice of investigation. See OUII Default Motion Response (Oct. 31, 2016) at 3 and Ex. A. On October 20, 2016, Laerdal filed a motion requesting that the ALJ order all respondents to show cause why they should not be found in default for failing to respond to the complaint and notice of investigation. On October 31, 2016, OUII filed a response in support of Laerdal's motion.

On November 7, 2016, the ALJ ordered all of the respondents to show cause why they should not be found in default, and set a response deadline of November 14, 2016. Order No. 5. No responses were filed. On November 21, 2016, the ALJ issued an initial determination ("ID") (Order No. 6) finding all respondents in default pursuant to Commission Rules 210.16 and 210.17. No petitions for review of the ID were filed. On December 1, 2016, Laerdal indicated that it was not seeking a general exclusion order.

On December 20, 2016, the Commission determined not to review the default ID, and sought briefing on the public interest, remedy, and bonding from the parties and the public. Notice (Dec. 20, 2016). The Commission also requested proposed remedial orders from Laerdal and OUII. *Id.* The Commission received main submissions and proposed remedial orders from Laerdal¹ and OUII² on January 5, 2017, a reply submission from Laerdal on January 10, 2017, and a reply submission from OUII on January 12, 2017. The Commission did not receive any submissions from the public.

¹ Complainants' Submission on Remedy, the Public Interest, and Bonding (Jan. 5, 2017) ("Laerdal Main Sub.").

² The Office of Unfair Import Investigation's Submission on Remedy, the Public Interest, and Bonding (Jan. 5, 2017) ("OUII Main Sub.").

II. DISCUSSION

A. Remedy

Section 337 provides that, when the Commission finds a respondent in default, the Commission “shall presume the facts alleged in the complaint to be true.” 19 U.S.C. § 1337(g)(1); *see also* Commission Rule 210.16(c) (“The facts in the complaint will be presumed to be true with respect to the defaulting respondent.”). Those allegations, however, must still show that the respondent violated section 337. *See, e.g., Finkel v. Romanowicz*, 577 F.3d 79, 84 (2d Cir. 2009) (holding that, while a court must accept all factual allegations against a defaulted party as true, a default judgment should only issue if those allegations show that the defaulted party is liable as a matter of law); *Certain Electric Fireplaces, Components Thereof, Manuals for Same, Certain Processes for Manufacturing or Relating to Same and Certain Products Containing Same*, Inv. No. 337-TA-791/826, Comm’n Op. at 11-12 (May 1, 2013) (finding no violation as to defaulting respondents based on breach of contract and tortious interference with contract claims due to insufficient allegations in the complaint).

Here, Laerdal and OUII argue that the appropriate remedy is a limited exclusion order against all eleven respondents and a cease and desist order against Basic Medical³. Laerdal Main Sub. at 1-4, 7; OUII Main Sub. at 4-6. OUII argues that the relief against each respondent should be limited to the particular intellectual property rights that the respondent is alleged to infringe. OUII Main Sub. at 5. We address each type of alleged intellectual property infringement in turn.

1. The '058 Patent

The Commission finds that Laerdal pled sufficient facts to show a violation with respect

³ Laerdal requested a cease and desist order only against domestic defaulting respondent Basic Medical. Laerdal Main Sub. at 7; *see also Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, And Components Thereof*, Inv. No. 337-TA-486, USITC Pub. No. 3625, Comm’n Op. at 17-18 (July 14, 2003).

to claim 1 of the '058 patent, which covers a method of adjusting a cervical collar. Laerdal alleges that Medsource International, Medsource Factory, and Basic Medical induced infringement of the claim by selling cervical collars with instructions to use the cervical collar in an infringing manner. Laerdal Amended Cmpl. at ¶¶ 337-49 and Exs. 38A and 40. Laerdal also alleges that it has a domestic industry through its investments in labor, capital, plant, and equipment for its Stifneck® Select Extrication Collar products that practice claim 1 of the '058 patent. *Id.* at ¶¶ 424-26, Ex. 34, and Ex. 66 ¶ 20. The Commission presumes that these allegations are true, and finds that they establish a violation of section 337.

2. The '656 Mark

The Commission finds that Laerdal pled sufficient facts to show a violation with respect to the '656 mark, which covers the use of the “Pocket Mask” mark in CPR devices. Laerdal alleges that Medsource International, Medsource Factory, and Basic Medical infringe the '656 mark by importing and selling CPR masks with the “Pocket Mask” mark. Laerdal Amended Cmpl. at ¶¶ 393-407. Laerdal further provided screenshots of Medsource International’s and Basic Medical’s websites demonstrating offers for sale of various “Pocket Mask” products, *id.* at Ex. 24 at 24-35, and a Medsource International quote sheet providing pricing for shipping “Pocket Mask” products to the United States, *id.* at Ex. 36. Additionally, Laerdal alleges that it has a domestic industry through its investments in labor, capital, plant, and equipment for CPR masks that bear the '656 mark. *Id.* at ¶¶ 445-446 and Ex. 66 ¶ 27. The Commission presumes that these allegations are true, and finds that they establish a violation of section 337.

3. The '023 and '026 Copyrights

The Commission finds that Laerdal failed to plead sufficient facts to show a violation with respect to its copyrights, which cover two of its product catalogues. *See* '023 copyright (“2000 Lifesavings Products Catalogue”); '026 copyright (“2004 Products Catalogue”). Laerdal

first alleges that various respondents infringe these copyrights by selling spine boards, cervical collars, and manikins. Laerdal Amended Cmpl. at ¶¶ 177; 212; 239; 265; 290; 313. Laerdal, however, has failed to plead facts that show how the sale of spine boards, cervical collars, and manikins constitutes infringement of two copyrights covering catalogues. Spine boards, cervical collars, and manikins are not, for example, a reproduction of a copyrighted catalogue or a derivative work based on a copyrighted catalogue.⁴ Additionally, spine boards, cervical collars, and manikins are useful articles that are subject to copyright protection only to the extent that they have features that would be copyrightable if separated from the article,⁵ but Laerdal failed to make any allegations regarding separable, copyrightable features. In sum, Laerdal's copyrights in its catalogs do not give Laerdal the right to exclude others from making the useful articles depicted in those catalogues.⁶

Laerdal next alleges that various respondents make and sell unauthorized copies of "Laerdal Literature." Laerdal Amended Cmpl. at ¶¶ 176; 178-80; 211; 213-15; 238; 240-42; 264; 266-68; 289; 291-93; 312; 314-16. According to the amended complaint, Laerdal Literature includes "various literature that is used to describe one or more products made by Laerdal (the 'Laerdal Literature'), which includes images, description and photographs of Laerdal's product

⁴ Copyright infringement prohibits, *inter alia*, others from reproducing a copyrighted work and preparing derivative works based on the copyrighted work. 17 U.S.C. § 501 (defining copyright infringement as the violation of any of the exclusive rights of a copyright holder); 17 U.S.C. § 106 (setting forth the exclusive rights of a copyright holder).

⁵ See *Star Athletica, LLC v. Varsity Brands, Inc.*, 137 S.Ct. 1002, 1012 (2017) ("In sum, a feature of the design of a useful article is eligible for copyright if, when identified and imagined apart from the useful article, it would qualify as a pictorial, graphic, or sculptural work either on its own or when fixed in some other tangible medium").

⁶ See 17 U.S.C. § 113(b) ("The title does not afford, to the owner of copyright in a work that portrays a useful article as such, any greater or lesser rights with respect to the making, distribution, or display of the useful article so portrayed . . .").

catalogues, product manuals and on Laerdal's website." *Id.* at ¶ 4.⁷ A section 337 action based on copyright infringement, however, requires "a valid and enforceable United States copyright registered under Title 17." 19 U.S.C. § 1337(a)(1)(B)(i). While Laerdal does allege that respondents infringe the '023 and '026 registered copyrights that cover Laerdal's catalogues, there is no allegation that any of the remaining Laerdal Literature is protected by a registered copyright. *See* Laerdal Amended Cmpl. at ¶¶ (alleging that Laerdal Literature is "entitled to copyright protection"). Thus, Laerdal's allegations regarding copyright infringement that are beyond the infringement of the '023 and '026 copyrights are outside of the scope of the investigation. *See* 81 Fed. Reg. 41350 (limiting Laerdal's copyright claims to the '023 and '026 copyrights).

Laerdal finally alleges that respondents infringed "copyrights to the Laerdal Literature and copyrighted images of Laerdal Infringed Products" by creating their own catalogues containing pictures of their own products. Laerdal Amended Cmpl. at ¶¶ 181; 216; 243; 269; 294; 317. As discussed above, none of these alleged "copyrights to Laerdal Literature" are within the scope of the investigation. Furthermore, Laerdal failed to plead facts showing how the respondents' creation of catalogues using images of their own products constitutes infringement of the '023 and '026 copyrights.

Additionally, Laerdal has failed to allege that it has a domestic industry in the catalogues protected by the copyrights. Section 337(a)(3) requires that a complainant show investment "with respect to the articles protected by the . . . copyright" Here, the '023 and '026 copyrights protect Laerdal's 2000 and 2004 catalogues, but Laerdal failed to allege that it made

⁷ *See also id.* at ¶ 105 ("Laerdal created literature that is used to describe one or more products made by Laerdal (hereinafter, the 'Laerdal Literature.')

investments with respect to those catalogues. Laerdal instead alleges that it has a domestic industry in its copyrighted BaXstrap® Spineboard products and four manikins,⁸ but those products are not protected by the '023 and '026 copyrights.

Accordingly, the Commission finds that, even when it presumes that the pleaded facts are true, Laerdal has failed to show that any respondent has violation section 337 with respect to the '023 and '026 copyrights.

4. The Trade Dress Misappropriation Claims

The Commission finds that Laerdal failed to plead sufficient facts to show a violation with respect to its alleged trade dress rights. First, Laerdal failed to plead that it suffered the requisite harm to support a finding of violation. A violation of section 337 based on trade dress infringement requires a showing that the infringement has the effect or threat of substantially injuring or preventing the establishment of a domestic industry.⁹ *See Certain Electric Skin Care Devices, Brushes and Chargers Therefor, and Kits Containing the Same*, Inv. No. 337-TA-959, Comm'n Op. at 11 (Feb. 13, 2017); 19 U.S.C. § 1337(a)(1)(A)(i)-(ii). Laerdal's Amended Complaint contains no such allegation.¹⁰

⁸ Laerdal Amended Cmpl. at ¶¶ 422, 432, 434, 437, 440, 443.

⁹ Here, the notice of investigation limits the investigation to whether there is an injury under 19 U.S.C. § 1337(a)(1)(A)(i). 81 Fed. Reg. 41350.

¹⁰ Laerdal's Amended Complaint instead alleges that the respondents' actions "are unlawful under 19 U.S.C. § 1337(a)(1)(A) in that they constitute unfair methods of competition and unfair acts in the importation of articles that constitute infringement and misappropriation of at least one of Laerdal's Trade Dresses or infringe Laerdal's Trademarks[.]" Laerdal Amended Cmpl. at ¶ 22. Laerdal further alleges that "the continued, unauthorized reproduction of Laerdal's trade dress in connection with the sale, marketing and distribution of [Respondent] Infringing Products and related materials threaten to cause Laerdal actual injury to its goodwill and reputation, and loss of control over Laerdal Trade Dress rights in the domestic market." Laerdal Amended Cmpl. at 48-49, 55, 61, 66, 72, 76, 94-95. Neither of these allegations, even when presumed to true, demonstrates that the trade dress infringement or misappropriation has "the threat or effect . . . to destroy or substantially injure an industry in the United States."

Second, Laerdal failed to specify the elements that constitute its trade dress. A party seeking to assert trade dress infringement must “articulate the design elements that compose the trade dress.” *Yurman Design, Inc. v. PAJ, Inc.*, 262 F.3d 101, 117 (2d Cir. 2001).¹¹ Laerdal alleges that it has the following trade dresses:

- (1) The trade dress for Laerdal’s BaXstrap® SpineBoards is characterized by and includes, without limitation, the distinctive shape of the item, curvature, number, placement and shape of the openings, spatial relationship of the length to the width and thickness, and use of bright colors. Laerdal Amended Cmpl. at ¶ 118;
- (2) The trade dress for Laerdal’s Stifneck Select Extrication Collars is characterized by and includes, without limitation, the distinctive shape of the item, curvature, number, placement and shape of the openings, spatial relationship of the length and circumference to the width and thickness, and/or use of contrasting colors. *Id.* at ¶ 118;
- (3) The trade dress for Laerdal’s [Junior Manikins, Anne Manikins, Baby Anne Manikins, Baby Manikins] is characterized by and includes, without limitation, the distinctive shape of the item, [facial features,] [mouth opening,] musculature, position of the body, angle and positioning of the extremities, [openings,] arrangement, shape and placement of internal parts, placement of outside hooks, and the types of plastic [and metal parts] used for different components and clothing. *Id.* at ¶¶ 128, 134, 139, 143.

Because these alleged trade dresses are not only vague but also “without limitation,” the Commission finds that Laerdal has failed to allege a protectable trade dress.¹²

¹¹ See also *Fair Wind Sailing, Inc. v. Dempster*, 764 F.3d 303, 309 (3d Cir. 2014) (“it is the plaintiff’s duty to ‘articulat[e] the specific elements which comprise its distinct dress.’”) (internal citation omitted).

¹² Commission remedial orders involving trade dresses contain substantially more specificity than Laerdal’s alleged trade dresses. See, e.g., *Certain Ink Markers and Packaging Thereof*, Inv. No. 337-TA-522, USITC Pub. No. 3971, General Exclusion Order (Oct. 25, 2005); *Certain Digital Multimeters*, Inv. No. 337-TA-588, USITC Pub. No. 4210, General Exclusion Order (May 14, 2008); *Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, and Components Thereof*, Inv. No. 337-TA-486, USITC Pub. No. 3625, Limited Exclusion Order

Third, Laerdal failed to plead sufficient facts to show that its asserted trade dresses are not functional. Under the Lanham Act, “the person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional.” 15 U.S.C. § 1125(a)(3). Laerdal’s amended complaint asserts without explanation that its products “utilize non-functional trade dress[.]” Laerdal Amended Cmpl. at ¶¶ 122, 127, 133, 138, 143. While the Commission must accept the factual allegations as true, this allegation is a legal conclusion that is unsupported by facts. The Commission finds that many of the alleged trade dress elements of the spine boards,¹³ cervical collars,¹⁴ and training manikins¹⁵ are functional.

(July 2003); *Certain Electronic Skin Care Devices, Brushes and Chargers Therefor, And Kits Containing Same*, Inv. No. 337-TA-959, Limited Exclusion Order, Ex. 1 at 12 (Feb. 6, 2017).

¹³ A spine board performs the function of enabling the transportation of an injured human while immobilizing the spine. Laerdal Amended Cmpl. at ¶ 14. Accordingly, the spine board must be slightly larger than a human, so the alleged trade dresses in the “distinctive shape of the item” and “spatial relationship of the length to the width and thickness” are both functional. *See* Laerdal Amended Complaint at Ex. 26. Additionally, Laerdal’s own documentation states that the “curvature, number, placement and shape of the openings” is functional. *See id.* (advertising “[e]xtra large and multiple handholds accommodate flexibility to assist for a more secure rescue,” “[s]ecure immobilization with both adult and paediatric strap holes,” and “[r]aised handholds make it easy to pick up”).

¹⁴ A cervical collar performs the function of securing the head support of an injured human. Laerdal Amended Cmpl. at ¶ 14. Accordingly, the cervical collar must fit around a human head, so the alleged trade dresses in the “distinctive shape of the item, curvature, number, placement and shape of the openings, spatial relationship of the length and circumference to the width and thickness” are all functional. *See* Laerdal Amended Complaint at Ex. 26. Additionally, Laerdal’s own documentation shows that the “curvature, number, placement and shape of the openings” are functional. *See id.* (advertising “[l]arge trachea opening allows access for carotid pulse checks and advanced airway procedures,” and “[u]nique large rear panel opening allows for c-spine palpation, drainage, and visualization”).

¹⁵ A medical-training manikin performs the function of simulating a human for the purpose of practicing medical procedures. Accordingly, the medical training manikins must have features similar to a human body, so the alleged trade dress in “distinctive shape of the item,” “facial features,” “mouth opening,” “musculature,” “position of the body,” “angle and positioning of the extremities,” “openings,” and “arrangement, shape and placement of the internal parts” are functional.

Accordingly, the Commission finds that, even when the pleaded facts are presumed true, Laerdal has failed to show that any respondent has violated section 337 with respect to its alleged trade dresses.

5. Conclusion

For the reasons discussed above, the Commission has determined that Laerdal sufficiently plead a violation of section 337 with respect to claim 1 of the '058 patent and the '656 mark, but has not shown a violation of section 337 with respect to the '023 copyright, '026 copyright, or the trade dresses. Because the only respondents alleged to infringe claim 1 of the '058 patent and the '656 mark are Medsource International, Medsource Factory, and Basic Medical, the Commission has determined that the appropriate remedy is a limited exclusion order against products of Medsource International, Medsource Factory, and Basic Medical that infringe claim 1 of the '058 patent or the '656 mark. The Commission has also determined that a cease and desist order against Basic Medical with respect to claim 1 of the '058 patent and the '656 mark is appropriate.¹⁶

B. Public Interest

Section 337(g)(1) provides that, if section 337(g)(1)(A)-(E) are satisfied, the Commission shall issue the appropriate limited exclusion order or cease and desist order “unless, after considering the effect of such exclusion or order upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the Commission finds that such exclusion or order should not be issued.” 19 U.S.C. § 1337(g)(1).

¹⁶ As noted above, Laerdal did not seek a CDO against Medsource International or Medsource Factory.

Laerdal contends that the public interest factors do not weigh against issuing a remedy. Laerdal argues that a remedy will not impact the supply of cervical collars in the United States because: (1) the three affected respondents may sell cervical collars that adjust in a way that does not practice claim 1 of the '058 patent, and (2) Laerdal has the capacity to fulfill the demand created by the exclusion of infringing cervical collars. Laerdal Main Sub. at 6-7. Laerdal further argues that a remedy would not impact the supply of CPR masks in the United States because the affected respondents may sell CPR masks under a different trademark. *Id.* at 6. OUII agrees that the public interest factors do not weigh against issuing a remedy. OUII Main Sub. at 6-7.

Having examined the record of this investigation, the Commission finds no evidence to indicate that the remedial orders would have an impact upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. The relief is limited to three related respondents, and there is no evidence that Laerdal could not fulfill any demand created by the remedy. Accordingly, the Commission has determined that consideration of the public interest factors does not preclude issuance of the Commission remedy.

C. Bonding

During the 60-day period of Presidential review, imported articles subject to remedial orders are entitled to conditional entry under bond. 19 U.S.C. § 1337(j)(3). The amount of the bond is specified by the Commission and must be an amount sufficient to protect the complainant from any injury. *Id.*; 19 C.F.R. § 210.50(a)(3). In cases where the record does not contain sufficient evidence upon which to base a determination of the appropriate amount of the bond despite a complainant's effort to adduce such evidence, the Commission has set a 100

percent bond. *See Certain Sortation Systems, Parts Thereof, and Products Containing Same*, Inv. No. 337-TA-460, USITC Pub. No. 3588, Comm'n Op. at 21 (Feb. 19, 2003).

Both Laerdal and OUII argue that the bond should be set at 100 percent of entered value because the respondents defaulted. Laerdal Main Sub. at 8; OUII Main Sub. at 7. The Commission generally sets the bond at 100 percent of entered value when a party defaults. *Certain Composite Wear Components and Welding Products Containing Same*, USITC Pub. No. 4251, Inv. No. 337-TA-644, Comm'n Op. at 25 (Aug. 2011). The Commission has therefore determined that a 100 percent bond is appropriate.

III. CONCLUSION

For the reasons set forth in this opinion, the Commission has determined that the appropriate remedy in this investigation is: (1) a limited exclusion order preventing the importation and sale by Medsource International, Medsource Factory, and Basic Medical of articles that infringe claim 1 of the '058 patent or the '656 mark, and (2) a cease and desist order against Basic Medical. The Commission has also determined to set the bond amount during the period of Presidential review at one hundred (100) percent of entered value.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: June 14, 2017

**CERTAIN CARBON SPINE BOARD, CERVICAL COLLAR,
CPR MASKS AND VARIOUS MEDICAL TRAINING
MANIKIN DEVICES, AND TRADEMARKS, COPYRIGHTS
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Inv. No. 337-TA-1008

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION** has been served by hand upon the Commission Investigative Attorney, Monica Bhattacharyya, Esq., and the following parties as indicated, on **June 14, 2017**.



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