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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. DR. REDDY'S LABORATORIES, INC., Defendant.	Civil Action No. 17-13219

COMPLAINT

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

INTRODUCTION

1. The United States seeks civil penalties and other relief, as appropriate, against the defendant, Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") for its knowing violations of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§ 2051 et seq., relating to the unlawful importation, manufacture, and distribution of prescription drugs that did not comply with the mandatory requirements promulgated under the Poison Prevention Packaging Act ("PPPA"), 15 U.S.C. §§ 1471–77.

2. Since the 1970s, the PPPA has protected children from the accidental ingestion of household oral prescription drugs by authorizing standards that require those drugs to be in special packaging that is child resistant ("child-resistant" packaging). Dr. Reddy's sold prescription drugs that should have been in child-resistant packaging. Engineers at Dr. Reddy's concluded that the packages for those drugs would not pass the tests required to prove child resistance. Instead of notifying the Consumer Product Safety Commission — let alone the public — that its drugs put children at risk, Dr. Reddy's quietly began changing its drug packaging while continuing to sell the drugs in untested packaging. Dr. Reddy's actions were unlawful; Dr. Reddy's knowingly violated the CPSA.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331, 1345, 1355(a) and 15 U.S.C. §§ 2069(a), 2071(a).

4. Venue in this district is proper under 28 U.S.C. §§ 1391(b), (c), and 1395(a).

DEFENDANT

5. Dr. Reddy's is a corporation organized and existing under the laws of New Jersey. Dr. Reddy's is located at 107 College Road East, Princeton, NJ, 08540, in southern Middlesex County (south of Raritan River).

6. Dr. Reddy's operates as the North American subsidiary of Dr. Reddy's Laboratories Limited, a corporation headquartered in Hyderabad, Telangana, India.

7. Dr. Reddy's imports, manufactures, and distributes throughout the United States household oral prescription drugs.

8. Dr. Reddy's is an importer, manufacturer, and distributor of products that are subject to the requirements of the CPSA, the PPPA, and the regulations issued thereunder.

POISON PREVENTION PACKAGING ACT

9. Congress passed the PPPA in 1970 and authorized the Consumer Product Safety Commission ("CPSC" or "Commission") to establish special packaging standards for household substances when "special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance." 15 U.S.C. § 1472(a).

10. The PPPA defines "household substance" to include "any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household." 15 U.S.C. § 1471(2). This definition includes prescription drugs. *See* 15 U.S.C. § 1471(2)(B).

11. The PPPA defines "special packaging" in part as "packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time." 15 U.S.C. § 1471(4).

12. Regulations promulgated pursuant to authority granted by the PPPA set forth mandatory standards for special packaging, including a detailed child test protocol used to determine if special packaging meets required effectiveness specifications. 16 C.F.R. §§ 1700.15, 1700.20. Children between 42 and 51 months of age perform the actual tests, and a test failure for the prescription drug packaging at issue in this case — unit packaging or "blister packages" — depends on the toxicity of the packaged drug. 16 C.F.R. § 1700.20(a)(2).

13. Oral prescription drugs are substances requiring special packaging. 16 C.F.R. § 1700.14(a)(10).

CONSUMER PRODUCT SAFETY ACT

14. The CPSA prohibits the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States of any product or substance that is regulated under the CPSA or any other Act enforced by the Commission that is not in conformity with an applicable consumer product safety rule or similar rule, regulation, standard, or ban under any other Act enforced by the Commission. 15 U.S.C. § 2068(a)(1).

15. The CPSA requires every manufacturer, distributor, and retailer of a product over which the Commission has jurisdiction to immediately report to the Commission upon obtaining information reasonably supporting the conclusion that such product fails to comply with any rule, regulation, standard, or ban under the CPSA or any Act enforced by the Commission; contains a defect which could create a substantial product hazard; or creates an unreasonable risk of serious injury or death, unless such manufacturer, distributor, or retailer has actual knowledge that the Commission has been adequately informed of such failure, defect, or risk. 15 U.S.C. § 2064(b)(2)–(4).

16. Under the Commission's regulations, "immediately" means "within 24 hours" after a company has obtained the requisite information. 16 C.F.R. § 1115.14(e). The regulations permit initial reports to be made to the CPSC by telephone or in writing. 16 C.F.R. § 1115.13(b), (c).

17. Knowledge of product safety related information is imputed to a company when an employee of the company, capable of appreciating the significance of the information, receives it. 16 C.F.R. § 1115.14(b).

18. The failure to furnish information required by 15 U.S.C. § 2064(b) is a prohibited act under the CPSA. 15 U.S.C. § 2068(a)(4).

19. The CPSA also requires that every manufacturer of a product which is subject to a consumer product safety rule under the CPSA or similar rule, ban, standard, or regulation under any other Act enforced by the Commission and which is imported for consumption or warehousing or distributed in commerce (and the private labeler of such product if such product bears a private label) shall issue a certificate which shall certify, based on a test of each product or upon a reasonable testing program, that such product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA or any other Act enforced by the Commission, and shall specify each such rule, ban, standard, or regulation applicable to the product. 15 U.S.C. § 2063(a)(1).

20. The failure to furnish a certificate as required by 15 U.S.C. § 2063(a)(1) is a prohibited act under the CPSA. 15 U.S.C. § 2068(a)(6).

21. Any person who knowingly violates 15 U.S.C. § 2068 is subject to civil penalties. 15 U.S.C. § 2069(a)(1). The CPSA defines "knowingly" as "(1) the having of actual knowledge, or (2) the presumed having of knowledge deemed to be possessed by a reasonable man who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations." 15 U.S.C. § 2069(d).

22. On August 14, 2008, the Consumer Product Safety Improvement Act of 2008 ("CPSIA"), Pub. L. No. 110-314, 122 Stat. 3016, amended the CPSA to, amongst other things, make PPPA violations prohibited acts subject to civil penalties and to make applicable the mandatory reporting under 15 U.S.C. § 2064(b) and the requirement for conformity certification under 15 U.S.C. § 2063(a) to prescription drugs required to be in child-resistant packaging.

23. The Commission stayed enforcement of the CPSIA's conformity certification requirements until February 10, 2010. The Commission's public notice of the lifting of the stay informed manufacturers that products subject to the PPPA and its regulations would require testing and certificates of general conformity for all products manufactured after February 10, 2010. 74 Fed. Reg. 68,588, 68,591 (Dec. 28, 2009).

FACTS

24. Dr. Reddy's manufactured and imported the prescription drugs ciprofloxacin, fluoxetine, ondansetron, risperidone, and sumatriptan packaged in individual blister packs ("Subject Products") from its parent company in India. The Subject Products were in oral dosage forms and were sold for the consumption or use by individuals at home. Dr. Reddy's imported and distributed for sale the Subject Products to retail pharmacies throughout the United States.

25. In or around November 2010, Dr. Reddy's employees requested that its parent company in India manufacture placebo samples of its currently marketed prescription drugs packaged in blister packs so Dr. Reddy's could test those packages for child resistance.

26. In or around February 2011, Dr. Reddy's packaging engineers authored a report entitled "Risk Analysis on current Rx Blister Products" that discussed the requirements of the CPSA and the PPPA. This report outlined the PPPA's child test protocol for determining compliance with the PPPA's child-resistant packaging standards and discussed the ramifications to Dr. Reddy's of a

failed test, including that Dr. Reddy's would have to report the failure to the Commission and face a possible civil "fine" for marketing a non-compliant product. The packaging engineers, aware of the significance of the information they outlined in the report, presented the report to other employees of Dr. Reddy's.

27. The Risk Analysis report recommended that Dr. Reddy's immediately change the packaging of certain Subject Products rather than proceed to testing, due to the expectation that the existing packaging of those products would fail the child test protocol.

28. In a section entitled "Overdose Stories," the Risk Analysis report identified the harm that could come to children from the accidental ingestion of prescription drugs by describing the symptoms and medical treatment, including hospitalization, of children who had ingested drugs with the same active pharmaceutical ingredients as some of the Subject Products.

29. The Risk Analysis report warned that Dr. Reddy's was not in compliance with the CPSIA for any of the Subject Products, and that if caught, Dr. Reddy's would have to "accept the consequences." The Risk Analysis report further warned that Dr. Reddy's lack of required certificates for the Subject Products put Dr. Reddy's prescription drug business at risk.

30. Following the packaging engineers' presentation of the Risk Analysis report to other Dr. Reddy's employees, Dr. Reddy's began developing replacement packaging for the Subject Products.

31. Even though Dr. Reddy's recognized it needed to change and test the packaging for the Subject Products, it continued to distribute the Subject Products in the existing, untested packaging.

32. On or about May 12, 2011, Dr. Reddy's received from India placebo samples of at least two of the Subject Products in the existing, untested packaging. Dr. Reddy's did not subject

the packaged placebos to the child test protocol to ascertain whether the packaging complied with the PPPA's mandatory standards for child resistance despite having requested placebo samples for that very purpose.

33. On February 22, 2012, Dr. Reddy's told the Commission that placebo samples had been or were in the process of being created to test replacement packaging for the Subject Products.

34. On April 2, 2012, Dr. Reddy's submitted a report to the Commission pursuant to 15 U.S.C. § 2064(b) concerning a prescription drug with the same active pharmaceutical ingredient as one of the Subject Products. In that report, Dr. Reddy's represented to CPSC that the blister packaging for that prescription drug had failed the child test protocol, and because that packaging was similar to the existing, untested packaging for one of the Subject Products, the Subject Product's packaging also may not comply with the PPPA's mandatory standard for child-resistant packaging.

35. On May 31, 2012, the Commission issued a Notice of Non-Compliance to Dr. Reddy's concerning the Subject Products.

36. On June 14, 2012, Dr. Reddy's represented to the Commission that it had ceased distribution of the Subject Products by and between March 30, 2012, and June 1, 2012.

COUNT 1

37. The United States re-alleges and incorporates by reference paragraphs 1–36 as if set forth fully herein.

38. Dr. Reddy's did not comply with the PPPA's child test protocol requirements in 16 C.F.R. § 1700.20(a) to ensure that the Subject Products complied with the PPPA's mandatory child-resistant packaging standards.

39. Dr. Reddy's acted "knowingly" within the meaning of the CPSA because it either had actual knowledge of the Subject Product's noncompliance or could have obtained such knowledge upon the exercise of due care. 15 U.S.C. § 2069(d).

40. Separately as to each individual package of the Subject Products sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States, Dr. Reddy's knowingly violated 15 U.S.C. § 2068(a)(1) by selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States products that were not in conformity with a consumer product safety rule or similar rule, regulation, standard, or ban under an Act enforced by the Commission, namely, the PPPA.

COUNT 2

41. The United States re-alleges and incorporates by reference paragraphs 1–36 as if set forth fully herein.

42. After August 14, 2008, the date the CPSIA was enacted, Dr. Reddy's obtained information that reasonably supported the conclusion that the Subject Products failed to comply with the PPPA; contained a defect which could create a substantial product hazard; or created an unreasonable risk of serious injury or death. However, Dr. Reddy's failed to report immediately to the Commission as required by the CPSA. 15 U.S.C. § 2064(b).

43. Dr. Reddy's acted "knowingly" within the meaning of the CPSA because it either had actual knowledge of the failure to comply, defect, or risk, or could have obtained such knowledge upon the exercise of due care. 15 U.S.C. § 2069(d).

44. Separately as to each individual package of the Subject Products sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States, Dr. Reddy's knowingly violated 15 U.S.C. § 2068(a)(4) by failing to immediately inform the CPSC upon

obtaining information that reasonably supported the conclusion that the Subject Products failed to comply with a rule, regulation, standard or ban under the CPSA or any other Act enforced by the Commission, namely, the PPPA; contained a defect which could create a substantial product hazard; and created an unreasonable risk of serious injury or death. These violations began from the time Dr. Reddy's obtained the information about the failure to comply, defect, or risk, and continued until Dr. Reddy's had actual notice that the Commission was adequately informed.

COUNT 3

45. The United States re-alleges and incorporates by reference paragraphs 1–36 as if set forth fully herein.

46. After August 14, 2008, the date the CPSIA was enacted, Dr. Reddy's knew that the CPSIA imposed additional requirements for general conformity certification and that the Subject Products were subject to those requirements.

47. After February 10, 2010, the date CPSC lifted its stay of enforcement, Dr. Reddy's did not furnish general conformity certifications pursuant to 15 U.S.C. § 2063(a) certifying, based on a test of each product or upon on a reasonable testing program, that the Subject Products complied with all rules, bans, standards, or regulations applicable to the products under the CPSA or an Act enforced by the Commission, namely, the PPPA.

48. Dr. Reddy's acted "knowingly" within the meaning of the CPSA because it either had actual knowledge of the failure to furnish certificates or could have obtained such knowledge upon the exercise of due care. 15 U.S.C. § 2069(d).

49. For each of the Subject Products, Dr. Reddy's knowingly violated 15 U.S.C. § 2068(a)(6) by failing to furnish a certificate as required by the CPSA.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests this Court:

I. Assess civil penalties against Dr. Reddy's in accordance with 15 U.S.C. § 2069 for each separate violation and for all related series of violations alleged in Counts 1–3 of this Complaint;

II. Award injunctive relief as appropriate; and

III. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated this 18th day of December, 2017.

Respectfully submitted,

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