

Mallinckrodt plc  
Form 8-K  
July 29, 2015

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported):

July 29, 2015

Mallinckrodt public limited company

(Exact name of registrant as specified in its charter)

Ireland

001-35803

98-1088325

(State or other jurisdiction  
of incorporation)

(Commission  
File Number)

(I.R.S. Employer  
Identification No.)

Perth House, Millennium Way, Chesterfield,  
Derbyshire, United Kingdom,

S41 8ND

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

+44.124.626.3051

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))



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**Item 8.01 Other Events.**

**Inomax Patents: Inter Partes Review ("IPR") Proceedings**

In February 2015 and March 2015, the U.S. Patent and Trademark Office ("USPTO") issued Notices of Filing Dates Accorded to Petitions for IPR petitions filed by Praxair Distribution, Inc. concerning ten patents covering Inomax. Patent Owner Preliminary responses for all of the IPR petitions were filed in May 2015 and June 2015. On July 29, 2015 the USPTO Patent Trial and Appeal Board ("PTAB") issued rulings denying the institution of four of the five IPR petitions challenging the five patents expiring in 2029. The PTAB also issued a ruling on July 29, 2015 that instituted the IPR proceeding in the fifth of this group of patents and the PTAB is statutorily required to complete the IPR process on that patent within one year. The timing for the USPTO to determine whether to grant the petition(s) to institute an IPR in the second set of five patents that expire in 2031 is within three months of receiving the Patent Owner Preliminary Response(s) filed in late June 2015.

**Mallinckrodt Inc. v. U.S. Food and Drug Administration ("FDA") and United States of America**

In November 2014, the Company filed a Complaint for Declaratory and Injunctive Relief ("the Complaint") in the U.S. District Court for the District of Maryland Greenbelt Division against the FDA and the United States of America for judicial review of what the Company believes is the FDA's inappropriate and unlawful reclassification of the Company's Methylphenidate HCl Extended-Release tablets USP (CII) ("Methylphenidate ER") in the Orange Book: Approved Drug Products with Therapeutic Equivalence ("Orange Book"). In its complaint, the Company asked the court to: issue an injunction to (a) set aside the FDA's reclassification of the Company's Methylphenidate ER products from freely substitutable at the pharmacy level (class AB) to presumed to be therapeutically inequivalent (class BX) in the Orange Book and (b) prohibit the FDA from reclassifying the Company's Methylphenidate ER products in the future without following applicable legal requirements; and issue a declaratory judgment that the FDA's action reclassifying the Company's Methylphenidate ER products in the Orange Book is unlawful. The Company concurrently filed a motion with the same court requesting an expedited hearing to issue a temporary restraining order ("TRO") directing the FDA to reinstate the Orange Book AB rating for the Company's Methylphenidate ER products on a temporary basis. The court denied the Company's motion for a TRO. In December 2014, the FDA filed a motion to dismiss the Complaint with the district court. The Company filed its opposition to the motion to dismiss in January 2015, and concurrently filed a motion for summary judgment. On July 29, 2015, the court granted the FDA's motion to dismiss with respect to three of the five counts in the Complaint and granted summary judgment in favor of the FDA with respect to the two remaining counts. The Company is evaluating its options with respect to the court's decision, including a possible appeal to the U.S. Court of Appeals for the Fourth Circuit.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Mallinckrodt public limited company

*July 29, 2015*

By: *Kenneth L. Wagner*

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*Name: Kenneth L. Wagner*

*Title: Vice President and Corporate Secretary*