

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC.,  
Petitioner

v.

WARNER CHILCOTT COMPANY, LLC.,  
Patent Owner

---

Case IPR2015-00682  
Patent 7,704,984

---

**PATENT OWNER PRELIMINARY RESPONSE  
PURSUANT TO 35 U.S.C. § 313 AND 37 C.F.R. § 42.107**

**LIST OF EXHIBITS**

Exhibit	Document
2001	Opinion from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J. Jan. 17, 2014)
2002	Opinion from <i>Warner Chilcott Co., LLC v. Lupin Ltd., et al</i> , Nos. 2014-1267, -1273 (Fed. Cir. Oct. 22, 2014)
2003	Excerpts of Trial Transcripts from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J. Oct. 7-17, 2013)
2004	Speroff, L. & P.D. Darney, A Clinical Guide for Contraception (4th ed. 2005) (PTX 83 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2005	Speroff, L. & Darney, P.D., A Clinical Guide for Contraception (3d ed. 2001) (PTX 82A from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2006	Prescribing Information for Lo Loestrin Fe
2007	van Heusden, A.M., Fauser, B.C.J.M., “Activity of the pituitary-ovarian axis in the pill-free interval during use of low-dose combined oral contraceptives,” <i>Contraception</i> , 1999; 59:237-243. (DTX 507 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2008	Teichmann, A.T., et al., “The influence of the dose of ethinyl estradiol in oral contraceptives on follicle growth,” <i>Gynecol. Endocrinol.</i> 1995; 9:299-305. (DTX 477 <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2009	U.S. Patent 5,980,940 (JTX 16 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2010	Kaunitz, A., Oral Contraceptive Estrogen Dose Considerations, 58 <i>Contraception</i> 15S (1998) (PTX 48 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2011	Darney, P., OC Practice Guidelines: Minimizing Side Effects, 42 <i>Int’l J. Fertility &amp; Women’s Med.</i> 158 (Suppl. 1 1997) (PTX 21 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2012	Thorneycroft, I. & Cariati, S., Ultra-Low-Dose Oral

Exhibit	Document
	Contraceptives: Are They Right for Your Patient?, <a href="http://www.medscape.com">www.medscape.com</a> , July 3, 2001 (PTX 99 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2013	Akerlund et al., Comparative Profiles of Reliability, Cycle Control and Side Effects of Two Oral Contraceptive Formulations Containing 150 mcg Desogestrel and Either 30 or 20 mcg Ethinyl Estradiol, 100 <i>Brit. J. Obstet. Gynecol.</i> 832 (1993) (PTX 1 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2014	Marut, E., Oral Contraceptives; Who, Which, When, and Why, 82 <i>Postgraduate Medicine</i> , 1987
2015	U.S. Patent No. 4,292,315 (PTX 112 <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2016	Serfaty, D., The 20 Microgram Ethinyl Estradiol Plus 150 Microgram Desogestrel Pill Multicenter Study on 235 Women for 6 Months, 18 <i>Contraception-fertilite sexualite</i> 407 (1990) (PTX 78) from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2017	Lammers et al., Double-blind comparative acceptability study with two combined oral contraceptives containing 20 µg ethinylestradiol plus desogestrel or norethisterone acetate, in Optimizing the estrogen dose in oral contraceptives 67-74 (1992) (PTX 52 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2018	Task Force on Oral Contraceptives, A randomized, double-blind study of six combined oral contraceptives, 25 <i>Contraception</i> 231 (Mar. 1982) (PTX 97 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2019	Bounds, et al., A Randomized Double-Blind Trial of Two Low Dose Combined Oral Contraceptives, 86 <i>Brit. J. Obstetrics</i> 325 (1979) (PTX 10 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2020	Szarewski, A. & Guillebaud, J., Contraception: A User's Handbook (1998) (PTX 93 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2021	U.S. Patent 4,921,843 (JTX 15 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))

Exhibit	Document
2022	Excerpts from the Deposition Transcript of Kurt Barnhart, M.D. (7/30/2013) from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.)
2023	Miscellaneous Exhibits introduced at trial by Lupin Ltd. and Amneal Pharmaceuticals in <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.)
2024	Sullivan et al., Effect of 21-day and 24-day oral contraceptive regimens containing gestodene (60 µg) and ethinyl estradiol (15 µg) on ovarian activity, 72 <i>Fertility &amp; Sterility</i> 115 (July 1999) (PTX 91 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2025	Gestodene Study Group 324, Cycle control, safety and efficacy of a 24-day regimen of gestodene 60 µg/ethinylestradiol 15 µg and a 21- day regimen of desogestrel 150 µg/ethinylestradiol 20 µg, 4 <i>Eur. J. Contraception &amp; Reproductive Health Care</i> 17 (Suppl. 2 1999) (PTX 37 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2026	Endrikat, J., et al., “Double-blind, multicenter comparison of efficacy, cycle control, and tolerability of a 23-day versus a 21-day low-dose oral contraceptive regimen containing 20 mcg ethinyl estradiol and 75 mcg gestodene,” <i>Contraception</i> , 2001; 64:99-105. (DTX 520 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2027	Szarewski, A. & Guillebaud, J., <i>Contraception: A User’s Guide</i> (3d ed. 2004) (PTX 92 from <i>Warner Chilcott Co., LLC v. Lupin Ltd. et al.</i> , Civ. A. Nos. 11-05048, 12-2928 (D.N.J.))
2028	Complaint of Warner Chilcott Co., LLC. in <i>Warner Chilcott Co. LLC v. Mylan, Inc. et al.</i> , Civ. No. 3:13-06560 (D.N.J.)
2029	Answer and Counterclaims of Mylan in <i>Warner Chilcott Co. LLC v. Mylan, Inc. et al.</i> , Civ. No. 3:13-06560 (D.N.J.)
2030	Scheduling Order in <i>Warner Chilcott Co. LLC v. Mylan, Inc. et al.</i> , Civ. No. 3:13-06560 (D.N.J.)
2031	Thomas MA. <i>Contraception. Conn’s Current Therapy</i> , pp. 1123-8, 2001.
2032	Thomas MA: <i>Fertility Control and Contraception. Gynecology &amp; Obstetrics, A Longitudinal Approach. Chapter III:185-207, 1993.</i>

**TABLE OF CONTENTS**

	<b>Page(s)</b>
I. Introduction.....	1
II. Background.....	5
A. The '984 Patent and Lo Loestrin.....	5
B. Prior Litigation Concerning the '984 Patent.....	7
C. Petitioner’s Concurrent Obviousness Challenge to the '984 Patent.....	11
D. Combination Oral Contraceptives.....	12
III. Level of Ordinary Skill in the Art .....	15
IV. Claim Construction Under “Broadest Reasonable Interpretation” .....	15
V. Petitioner Has Not Shown a Reasonable Likelihood That at Least One Claim of the '984 Patent Is Unpatentable.....	15
A. Ground 1: Petitioner Has Failed to Show That Claims 1-9 Are Unpatentable over the '868 Publication and the '050 Patent and/or the '394 Patent in Further View of Sulak and the “General Knowledge in the Art”.....	15
1. A POSA would not have reason to make a COC with 5-15 µg EE in light of concerns about an increased risk of amenorrhea (absence of withdrawal bleeding).....	17
2. Cycle control and efficacy concerns would also have prevented a POSA from selecting 5-15 µg EE in combination with NA or norethindrone.....	19
3. A POSA would not have seen a reason to use the 24/2/2 administration scheme of the '984 patent.....	34
B. Ground 2: Petitioner Has Failed to Show That Claims 1-9 Are Unpatentable over the '381 Publication and the '050 Patent	

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.