IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., ROCHESTER DRUG CO-OPERATIVE, INC., MEIJER, INC., MEIJER DISTRIBUTION, INC., and AMERICAN SALES COMPANY, LLC,	
Plaintiffs,	**Civ. No. 12-3824 CONSOLIDATED**
v.	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	
Defendants.	

EXHIBITS IN SUPPORT OF DEFENDANT WARNER CHILCOTT'S MOTION TO DISMISS

October 1, 2012

Exhibits Cited in Warner Chilcott's Motion to Dismiss

Exhibit No.	Exhibit Description
1.	Mylan 2011 Form 10-K*
2.	Mylan February 2012 Investor Day Presentation*
3.	RDC Website, About RDC, *available at* http://www.rdcdrug.com/about/
4.	Warner Chilcott 2011 Form 10-K*
5.	Warner Chilcott Form 10-Q Report filed Aug. 3, 2012*
6.	Mayne 2011 Annual Report*
7.	Congressional Budget Office, How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry ix (JULY 1998)*
8.	U.S. Food and Drug Administration, Facts About Generic Drugs, *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm (last updated 9/19/2012)
9.	Sept. 23, 2011 Citizen Petition
10.	Doryx Therapeutic Equivalents, *available at* http://www.accessdata.fda.gov /scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Generics
11.	Plaintiffs Statement of Points of Authority in Opposition to Defendants' Motion to Dismiss *Walgreen*, No. 1:06-cv-02084-RWR, Dkt. No. 35 (D.D.C. May 21, 2007)*
12.	Applesauce Tablet Study
13.	Mylan Press Release, *Mylan Launches First Generic Version of Doryx® 150 mg*, April 30, 2012, *available at* http://investor.mylan.com/releasedetail.cfm?ReleaseID=668717
14.	Mylan Pharmaceuticals, "New Products" Page, available at: http://www.mylanpharms.com/product/new_products.aspx
15.	Application Number A202778, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at: http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=202778&TABLE1=OB_Rx
16.	D. Goldberg, A. Berlin, ACNE AND ROSACEA – EPIDEMIOLOGY, DIAGNOSIS & TREATMENT 15 (2012)*

* Excerpt of cited document attached as Exhibit.

Exhibit No.	Exhibit Description
17.	Mylan Press Release, *Mylan Begins Marketing First Generic Version of BenzaClin Acne Treatment,* Aug. 27, 2009, *available at* http://investor.mylan.com /releasedetail.cfm?releaseid=405704
18.	Mylan Press Release, *Mylan Laboratories Inc. Announces First ANDA Approval for Isotrenoin; Bertek Pharmaceuticals Inc. to Market Amnesteem*, November 11, 2002, *available at* http://investor.mylan.com/releasedetail.cfm?ReleaseID=408179

* Excerpt of cited document attached as Exhibit.

Exhibit 1

10-K 1 d258059d10k.htm FORM 10-K

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☑ **Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2011

OR

☐ **Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from to .

Commission file number 1-9114

MYLAN INC.

(Exact name of registrant as specified in its charter)

Pennsylvania	**25-1211621**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

1500 Corporate Drive, Canonsburg, Pennsylvania 15317
(Address of principal executive offices)
(724) 514-1800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, par value $0.50 per share	The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☑		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the outstanding common stock, other than shares held by persons who may be deemed affiliates of the registrant, as of June 30, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $10,469,135,790.

The number of shares outstanding of common stock of the registrant as of February 15, 2012, was 426,933,895.

INCORPORATED BY REFERENCE

Document	**Parts of Form 10-K into Which Document is Incorporated**
Proxy Statement for the 2012 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2011.	III

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PART I

ITEM 1. Business

Mylan Inc. along with its subsidiaries (collectively, the "Company," "Mylan," "our" or "we") is a fully integrated global pharmaceutical company that develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. Mylan ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in approximately 150 countries and territories. We maintain one of the industry's broadest and highest quality product portfolios, supported by a robust product pipeline and one of the world's largest vertically integrated active pharmaceutical ingredient ("API") operations. Additionally, we operate a specialty business which is focused on respiratory, allergy and psychiatric therapies. Mylan was incorporated in Pennsylvania in 1970.

Overview

Throughout its history, Mylan has been recognized as a leader in the United States ("U.S.") generic pharmaceutical market. Since 2007, Mylan has transformed itself into an established worldwide pharmaceutical leader and is currently the third largest generic and specialty pharmaceuticals company in the world, in terms of revenue. This transformation has taken place through organic growth and external expansion. Our leadership position in the U.S. generic pharmaceutical industry is the result of our ability to obtain Abbreviated New Drug Application ("ANDA") approvals, as well as our reliable and high quality supply chain. Through the acquisitions of Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited), Merck KGaA's, generics and specialty pharmaceutical business (the "former Merck Generics business"), Bioniche Pharma Holdings Limited ("Bioniche Pharma") and, most recently, the respiratory delivery platform as described below, we have created a horizontally and vertically integrated platform with global scale, augmented our diversified product portfolio and further expanded our range of capabilities, all of which we believe position us well for the future.

In September 2010, Mylan completed the acquisition of 100% of the outstanding equity in Bioniche Pharma, a privately held, global injectable pharmaceutical company. Bioniche Pharma manufactures and sells a diverse portfolio of injectable products across several therapeutic areas for the hospital setting. The addition of Bioniche Pharma has strengthened our position in the institutional marketplace, as it augments the portfolio of products we have historically offered to this sector through certain of our North American subsidiaries.

On December 23, 2011, Mylan completed the acquisition of the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline's Advair® Diskus and Seretide® Diskus incorporating Pfizer Inc.'s, ("Pfizer's") proprietary dry powder inhaler delivery platform (the "Respiratory Delivery Platform"). The acquisition of the Respiratory Delivery Platform fills an important strategic gap in the Company's product portfolio and will expand the Company's focus on difficult-to-produce, limited competition products, and it will serve as a base for Mylan's respiratory franchise. The Respiratory Delivery Platform and scientific expertise will also be used to develop additional branded specialty products, building upon the capabilities and assets that the Company has in place within the Specialty segment. As part of the agreement, Mylan will fund the remaining development and capital requirements to bring the products to market.

Through Mylan Laboratories Limited, an Indian subsidiary, we manufacture and supply low cost, high quality API for our own products and pipeline, as well as for third parties. Mylan Laboratories Limited is one of the world's largest API manufacturers as measured by the number of drug master files ("DMFs") filed with regulatory agencies. Mylan Laboratories Limited is also a leader in supplying API for the manufacturing of antiretroviral ("ARV") drugs, which are utilized in the treatment of HIV/AIDS. Additionally, Mylan Laboratories Limited offers a line of finished dosage form ("FDF") products in the ARV market and manufactures non-ARV FDF products that are marketed by Mylan. Mylan holds approximately 98% ownership and control in Mylan Laboratories Limited.

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Mylan has a robust worldwide commercial presence in the generic pharmaceutical market, including leadership positions in France and Australia and several other key European and Asia Pacific markets, as well as a leading branded specialty pharmaceutical business focusing on respiratory, allergy and psychiatric products.

Currently, Mylan markets a global portfolio of approximately 1,100 different products covering a vast array of therapeutic categories. We offer an extensive range of dosage forms and delivery systems, including oral solids, topicals, liquids and semi-solids. In addition, we focus on those that are difficult to formulate and manufacture and typically have longer product life cycles than traditional generic pharmaceuticals, including transdermal patches, high potency formulations, injectables, controlled release and respiratory delivery products.

Mylan also has one of the deepest pipelines and largest number of products pending regulatory approval in our history. Increased sales volumes and continued leverage of our vertically integrated platform provides substantial operational efficiencies and economies of scale.

We believe that the breadth and depth of our business provides certain competitive advantages over many of our competitors in major markets in which we operate, including less dependency on any single market or product, and, as a result, we are better able to successfully compete on a global basis.

Our Operations

Mylan has two segments, "Generics" and "Specialty." Our revenues are primarily derived from the sale of generic and branded generic pharmaceuticals, specialty pharmaceuticals and API. Our generic pharmaceutical business is conducted primarily in the U.S. and Canada (collectively, "North America"); Europe, the Middle East, and Africa (collectively, "EMEA"); and India, Australia, Japan and New Zealand (collectively, "Asia Pacific"). Our API business is conducted through Mylan Laboratories Limited, which is included within the Asia Pacific region in our Generics Segment. Our specialty pharmaceutical business is conducted by Dey Pharma, L.P. ("Dey"). Refer to Note 12 to Consolidated Financial Statements included in Item 8 in this Form 10-K for additional information related to our segments.

Generics Segment

North America

The U.S. generics market is the largest in the world, with generic prescription market revenues of $47.5 billion for the twelve months ended November 2011. Mylan holds the number two ranking in the U.S. generics prescription market in terms of both revenue and prescriptions dispensed. One in every 11 prescriptions dispensed in the U.S. is a Mylan product. Our sales in the U.S. are derived principally through our wholly-owned subsidiary Mylan Pharmaceuticals Inc. ("MPI"), our primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary, as well as through Mylan Institutional ("MI"). MI, a business platform created in 2010, that combined the product lines of Mylan Institutional LLC (formerly Bioniche Pharma USA, LLC) and Mylan Institutional Inc. (formerly UDL Laboratories, Inc.), Mylan's unit dose business, both of which are wholly-owned subsidiaries.

MPI's net revenues are derived primarily from the sale of solid oral dosage and transdermal patch products. MI's net revenues are derived from the sale of its unit dose and injectable product offerings. In the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies, consisting of approximately 340 products, of which approximately 305 are in capsule or tablet form in an aggregate of approximately 740 dosage strengths. Included in these totals are approximately 40 extended release products in a total of approximately 105 dosage strengths.

Also included in our U.S. product portfolio are four transdermal patch products in a total of 18 dosage strengths that are developed and manufactured by Mylan Technologies, Inc. ("MTI"), our wholly-owned

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(2) The 2010 financial data includes the results of Bioniche Pharma from September 7, 2010. Cost of sales in 2010 includes approximately $309.2 million primarily related to the amortization of purchased intangibles from acquisitions.

(3) Cost of sales in 2009 includes approximately $282.5 million primarily related to the amortization of purchased intangibles from acquisitions.

(4) Cost of sales in 2008 includes approximately $415.6 million related to the amortization of purchased intangibles and the amortization of the inventory step-up primarily associated with acquisitions. 2008 also includes a goodwill impairment loss of $385.0 million and impairment charges on certain other assets of $72.5 million.

(5) Effective October 2, 2007, we changed our fiscal year end from March 31st to December 31st. The above periods include Mylan Laboratories Limited (formerly known as Matrix Laboratories Limited) from January 8, 2007 and the former Merck Generics business from October 2, 2007. The 2007 Transition Period represents the period from April 1, 2007 to December 31, 2007.

(6) In addition to the write-off of acquired in-process research and development of $1.27 billion, cost of sales includes approximately $148.9 million related to the amortization of purchased intangibles and the amortization of the inventory step-up primarily associated with the acquisitions of the former Merck Generics business and Mylan Laboratories Limited.

(7) The financial data for 2008 and the 2007 Transition Period have been revised in accordance with the updated accounting guidance regarding noncontrolling interests and accounting related to the outstanding Convertible Notes, which we adopted on January 1, 2009.

(8) Working capital is calculated as current assets minus current liabilities.

ITEM 7. Management's Discussion and Analysis of Financial Condition And Results of Operations

The following discussion and analysis addresses material changes in the financial condition and results of operations of Mylan Inc. and subsidiaries (collectively the "Company," "Mylan" "our" or "we") for the periods presented. This discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the related Notes to Consolidated Financial Statements and our other Securities and Exchange Commission ("SEC") filings and public disclosures.

This Form 10-K may contain "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about our market opportunities, strategies, competition and expected activities and expenditures, and at times may be identified by the use of words such as "may," "could," "should," "would," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "intend," "continue" and variations of these words or comparable words. Forward-looking statements inherently involve risks and uncertainties. Accordingly, actual results may differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the risks described above under "Risk Factors" in Part I, Item 1A. We undertake no obligation to update any forward-looking statements for revisions or changes after the filing date of this Form 10-K.

Executive Overview

Mylan ranks among the leading generic and specialty pharmaceutical companies in the world, offering one of the industry's broadest and highest quality product portfolios, a robust pipeline and a global commercial footprint that spans approximately 150 countries and territories. With a workforce of more than 18,000 employees and external contractors, Mylan has attained leading positions in key international markets through its wide array of dosage forms and delivery systems, significant manufacturing capacity, global scale and commitment to quality and customer service. Through our subsidiary Mylan Laboratories Limited (formerly

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known as Matrix Laboratories Limited), Mylan operates one of the world's largest active pharmaceutical ingredient ("API") manufacturers with respect to the number of drug master files filed with regulatory agencies. This capability makes Mylan one of only two global generics companies with a comprehensive, vertically integrated supply chain. We hold a leading generics sales position in three of the world's largest pharmaceutical markets, those being the United States ("U.S."), France and the United Kingdom ("U.K."), and we also hold leading sales positions in several other key generics markets, including Australia, Belgium, Italy, Portugal and Spain.

Mylan has two segments, "Generics" and "Specialty." Generics primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule, injectable or transdermal patch form, as well as API. Specialty engages mainly in the manufacture and sale of branded specialty nebulized and injectable products. We also report in Corporate/Other certain research and development expenses, general and administrative expenses, litigation settlements, amortization of intangible assets and certain purchase-accounting items, impairment charges, and other items not directly attributable to the segments.

Acquisition of the Respiratory Delivery Platform

On December 23, 2011, we completed the acquisition of the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline's Advair® Diskus and Seretide® Diskus incorporating Pfizer Inc.'s ("Pfizer's") proprietary dry powder inhaler delivery platform (the "Respiratory Delivery Platform"). Advair® Diskus and Seretide® Diskus are inhaled fixed-dose combinations of Fluticasone Propionate and Salmeterol delivered via a dry powder inhaler and are used to treat asthma and COPD (chronic obstructive pulmonary disorder). The acquisition of the Respiratory Delivery Platform fills an important strategic gap in our product portfolio and will expand our focus on difficult-to-produce, limited competition products, and it will serve as a base for our respiratory franchise. The Respiratory Delivery Platform and scientific expertise will also be used to develop additional branded specialty products, building upon the capabilities and assets that we have in place within our Specialty segment. As part of the agreement, we will fund the remaining development and capital requirements to bring the products to market.

This transaction was accounted for as a purchase of a business with a total purchase consideration of approximately $348 million. This amount consisted of an initial cash payment of approximately $22 million, approximately $4 million in assumed liabilities and contingent consideration with an estimated fair value of approximately $322 million to be paid upon the achievement of future development and commercial milestones and the sharing of future profits.

Senior Credit Agreement Refinancing and Receivables Agreement

In November 2011, we entered into a credit agreement (the "Senior Credit Agreement") with a syndication of banks which provided $1.25 billion in U.S. Term Loans (the "U.S. Term Loans") and contains a $1.25 billion revolving facility (the "Revolving Facility," and together with the U.S. Term Loans, the "Senior Credit Facilities"). The proceeds of the U.S. Term Loans and borrowings under the Revolving Facility were used to repay amounts outstanding under the 2007 Amended and Restated Credit Agreement (the "Prior Credit Agreement") and to pay the related fees and expenses of the foregoing transactions.

In February 2012, we entered into an agreement with a syndication of banks to borrow up to $300 million secured by certain U.S. accounts receivable. This agreement has a maturity of three years and is a committed facility.

Financial Summary

For the year ended December 31, 2011, Mylan reported total revenues of $6.13 billion compared to $5.45 billion for 2010. This represents an increase of $679.3 million, or 12.5%. Consolidated gross profit for the

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Under ERISA, a contributor to a multiemployer plan may be liable, upon termination or withdrawal from a plan, for a proportionate share of a plan's unfunded vested liability. If the Company were to withdraw from the Plan or otherwise cease making contributions to the fund, it may trigger a substantial withdrawal liability. Any adjustment for a withdrawal liability would be recorded when it is probable that a liability exists and can be reasonably estimated.

12. Segment Information

Mylan has two segments, "Generics" and "Specialty." The Generics Segment primarily develops, manufactures, sells and distributes generic or branded generic pharmaceutical products in tablet, capsule, injectable or transdermal patch form, as well as API. The Specialty Segment engages mainly in the development, manufacture and sale of branded specialty nebulized and injectable products.

The Company's chief operating decision maker evaluates the performance of its segments based on total revenues and segment profitability. Segment profitability represents segment gross profit less direct research and development expenses and direct selling, general and administrative expenses. Certain general and administrative and research and development expenses not allocated to the segments, as well as net charges for litigation settlements, impairment charges and other expenses not directly attributable to the segments, are reported in Corporate/Other. Additionally, amortization of intangible assets and other purchase accounting related items, as well as any other significant special items, are included in Corporate/Other. Items below the earnings from operations line on the Company's Consolidated Statements of Operations are not presented by segment, since they are excluded from the measure of segment profitability. The Company does not report depreciation expense, total assets and capital expenditures by segment, as such information is not used by the chief operating decision maker.

The accounting policies of the segments are the same as those described in Note 2 to Consolidated Financial Statements. Intersegment revenues are accounted for at current market values and are eliminated at the consolidated level.

Presented in the table below is segment information for the periods identified and a reconciliation of segment information to total consolidated information.

(In thousands) **Year Ended December 31, 2011**	**Generics Segment**	**Specialty Segment**	**Corporate / Other[1]**	**Consolidated**
Total revenues				
Third party	$5,579,331	$550,494	$ —	$ 6,129,825
Intersegment	2,480	70,005	(72,485)	—
Total	$5,581,811	$620,499	$ (72,485)	$ 6,129,825
Segment profitability	$1,640,135	$208,215	$ (842,901)	$ 1,005,449

(In thousands) **Year Ended December 31, 2010**	**Generics Segment**	**Specialty Segment[2]**	**Corporate / Other[1]**	**Consolidated**
Total revenues				
Third party	$5,022,554	$427,968	$ —	$ 5,450,522
Intersegment	40,116	61,772	(101,888)	—
Total	$5,062,670	$489,740	$ (101,888)	$ 5,450,522
Segment profitability	$1,398,264	$122,694	$ (799,374)	$ 721,584

Exhibit 2

Mylan®
Seeing
is believing

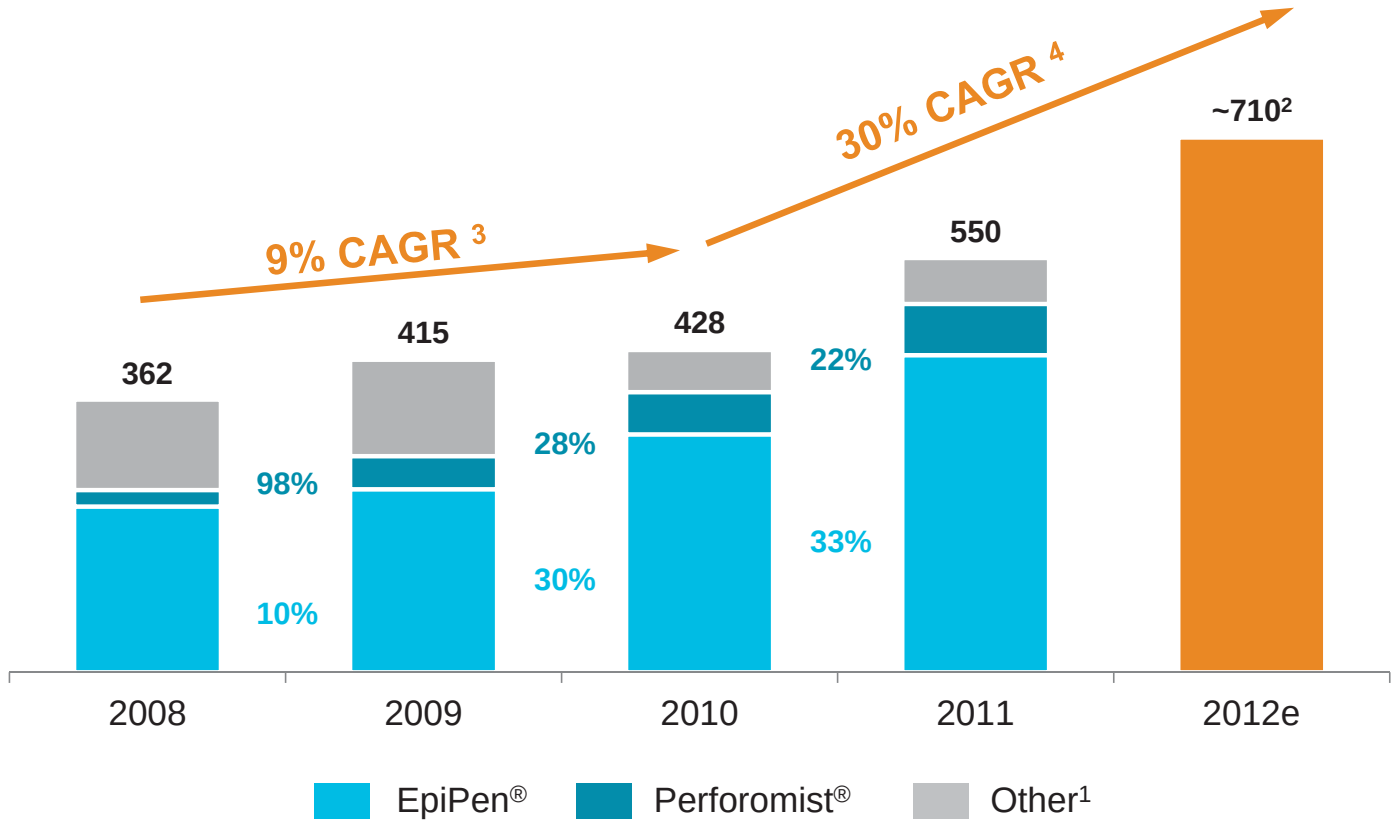
Mylan Investor Day

Kris King
Vice President,
Global Investor Relations

Mylan Specialty: Total Revenue Growth

Total Revenue

($ millions)



1. Other includes Mylan generics, Sandoz, Accuneb, Duoneb, devices, Zyflo, Chiesi, Curosurf, Cyanokit and Somerset
2. ~30% growth 2012 vs. 2011 3. CAGR from 2008 to 2010 4. CAGR from 2010 to 2012

Mylan®
Seeing is believing

Exhibit 3

About RDC

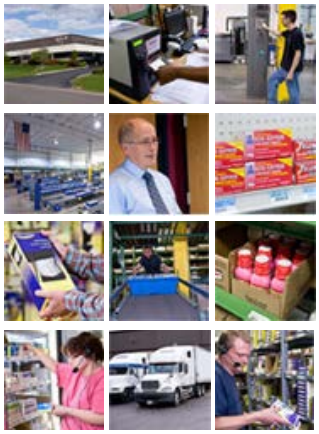
RDC is a true dividend-paying regional wholesale drug cooperative – a marriage of a traditional drug distribution company, a buying cooperative, and a private long-term investment structure formed for the sole benefit of pharmacist-entrepreneurs. We were founded in 1905 and currently rank as the 8th largest full-line distributor in the US.

Our company strives to provide the best possible service through user-friendly technology, professional sales representation, and a level of personal attention rarely found in today's wholesale environment. On a daily basis, we distribute a complete inventory of pharmaceuticals, HBC's and Home Health Care supplies to community retail pharmacies, long-term care pharmacies, and home health care stores. Our current geographical presence encompasses northeastern metropolitan and rural marketplaces surrounding Buffalo, Rochester, Syracuse, Albany, Watertown, Scranton, New York City, Long Island, Philadelphia, Pittsburgh, Newark, Atlantic City, and Cleveland.

RDC stockholders enjoy many unique benefits. But ownership is not required to buy product – in fact, 75% of our customer base is not invested. So, if you are simply looking for a traditional wholesale partner, consider this your invitation to open an account and do business with us just as you would with any other supplier. We're confident you'll see a difference and gain peace of mind about supporting a company that

Our Board Members
Our History
Our Customers
Store Resource Center
Store Promotion Center

TAKE A PHOTO TOUR:



promotes your profession.

Please use the links on the right to learn more about RDC. If you're already a customer, we'd be pleased to hear from you – just take a moment and let us know how we're doing.

Exhibit 4

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2011

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 0-53772

WARNER CHILCOTT PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**98-0626948**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

1 Grand Canal Square, Docklands
Dublin 2, Ireland
(Address of principal executive offices)

Registrant's telephone number, including area code: +353.1.897.2000
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Ordinary Shares, $0.01 par value	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of ordinary shares held by non-affiliates as of June 30, 2011 was approximately $4,137.7 million, using the closing price per share of $24.13, as reported on The NASDAQ Global Market as of such date. Ordinary shares held by our executive officers and directors and certain shareholders as of June 30, 2011 have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of January 30, 2012, the number of the registrant's ordinary shares, par value $0.01 per share, outstanding was 249,337,918.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K ("Annual Report") is incorporated by reference from the registrant's proxy statement to be filed pursuant to Regulation 14A with respect to the registrant's Annual Meeting of Shareholders to be held on May 8, 2012.

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Item 6. Selected Financial Data.

The following table sets forth our selected historical consolidated financial data. The selected consolidated financial data as of December 31, 2011 and 2010 and for the years ended December 31, 2011, 2010, and 2009 presented in this table have been derived from our audited consolidated financial statements and related notes included elsewhere in this Annual Report. The selected consolidated financial data as of December 31, 2009, 2008 and 2007, and for the years ended December 31, 2008 and 2007 presented in this table are derived from our audited consolidated financial statements and related notes which are not included in this Annual Report.

The selected consolidated financial data set forth below should be read in conjunction with, and is qualified by reference to, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Notes to the Consolidated Financial Statements included elsewhere in this Annual Report and in previously filed Annual Reports on Form 10-K.

(dollars and share amounts in thousands, except per share amounts)	Year Ended December 31, 2011(1)	2010(1)	2009(1)	2008	2007
Statement of Operations Data:					
Total revenue[2]	$2,728,106	$2,974,482	$1,435,816	$ 938,125	$ 899,561
Costs and expenses:					
Cost of sales (excluding amortization of intangible assets)[3]	356,144	492,801	320,278	198,785	185,990
Selling, general and administrative	923,925	1,090,351	436,384	192,650	265,822
Restructuring costs[4]	103,780	—	—	—	—
Research and development	107,796	146,506	76,737	49,956	54,510
Amortization of intangible assets	596,305	652,920	312,172	223,913	228,330
Impairment of intangible assets[5]	—	—	—	163,316	—
(Gain) on sale of assets[6]	—	—	(393,095)	—	—
Net interest expense[7][8][9]	339,923	284,448	124,617	93,116	117,618
Income before taxes	300,233	307,456	558,723	16,389	47,291
Provision for income taxes	129,087	136,484	44,605	24,746	18,416
Net income / (loss)	$ 171,146	$ 170,972	$ 514,118	$ (8,357)	$ 28,875
Per Share Data[10][11][12]:					
Earnings / (loss) per ordinary share—basic	$ 0.68	$ 0.68	$ 2.05	$ (0.03)	$ 0.12
Earnings / (loss) per ordinary share—diluted	$ 0.67	$ 0.67	$ 2.05	$ (0.03)	$ 0.12
Dividends per share[7]	$ —	$ 8.50	—	—	—
Weighted average shares outstanding—basic	252,047	251,302	250,565	249,807	248,916
Weighted average shares outstanding—diluted	254,313	253,851	251,219	249,807	250,454
Balance Sheet Data (at period end):					
Cash and cash equivalents	$ 616,344	$ 401,807	$ 539,006	$ 35,906	$ 30,776
Total assets[3][4][5][6][7][8]	5,030,029	5,651,989	6,054,114	2,582,891	2,884,974
Total debt[6][7][8][9]	3,862,796	4,678,664	3,039,460	962,557	1,200,239
Shareholders' equity / (deficit)[7][10][11][12]	69,131	(65,642)	1,889,093	1,349,920	1,354,420

(1) On October 30, 2009, pursuant to the purchase agreement dated August 24, 2009 (as amended, the "Purchase Agreement"), between us and P&G, we acquired PGP from P&G for $2,919 million in cash and the assumption of certain liabilities in the PGP Acquisition. Under the terms of the Purchase Agreement, we acquired P&G's portfolio of branded pharmaceutical products, prescription drug pipeline, manufacturing facilities in Puerto Rico and Germany and a net receivable owed from P&G of approximately $60 million. We recorded adjustments to the fair value of our assets and liabilities as of the date of the PGP Acquisition. This resulted in a significant increase to intangible assets, including in-process research & development ("IPR&D"). During 2009, 2010 and 2011, the following items were included in our operating results:

- total revenues and the related cost of sales for PGP products beginning October 30, 2009;
- a charge of $106 million in the year ended December 31, 2010 and $74 million in the year ended December 31, 2009 in cost of sales attributable to a purchase accounting adjustment increasing the opening value of the inventories acquired in the PGP Acquisition that was recorded as that inventory was sold during each respective period;
- SG&A and R&D expenses from PGP, including transaction costs and transition services expenses paid to P&G;

Exhibit 5

10-Q 1 d355772d10q.htm FORM 10-Q

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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2012

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 0-53772

WARNER CHILCOTT PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**98-0626948**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1 Grand Canal Square, Docklands
Dublin 2, Ireland
(Address of principal executive offices)

+353.1.897.2000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.)
Yes ☐ No ☒

As of July 20, 2012, the registrant had 250,482,397 ordinary shares outstanding.

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The following table presents total revenues by product for the quarters and six months ended June 30, 2012 and 2011:

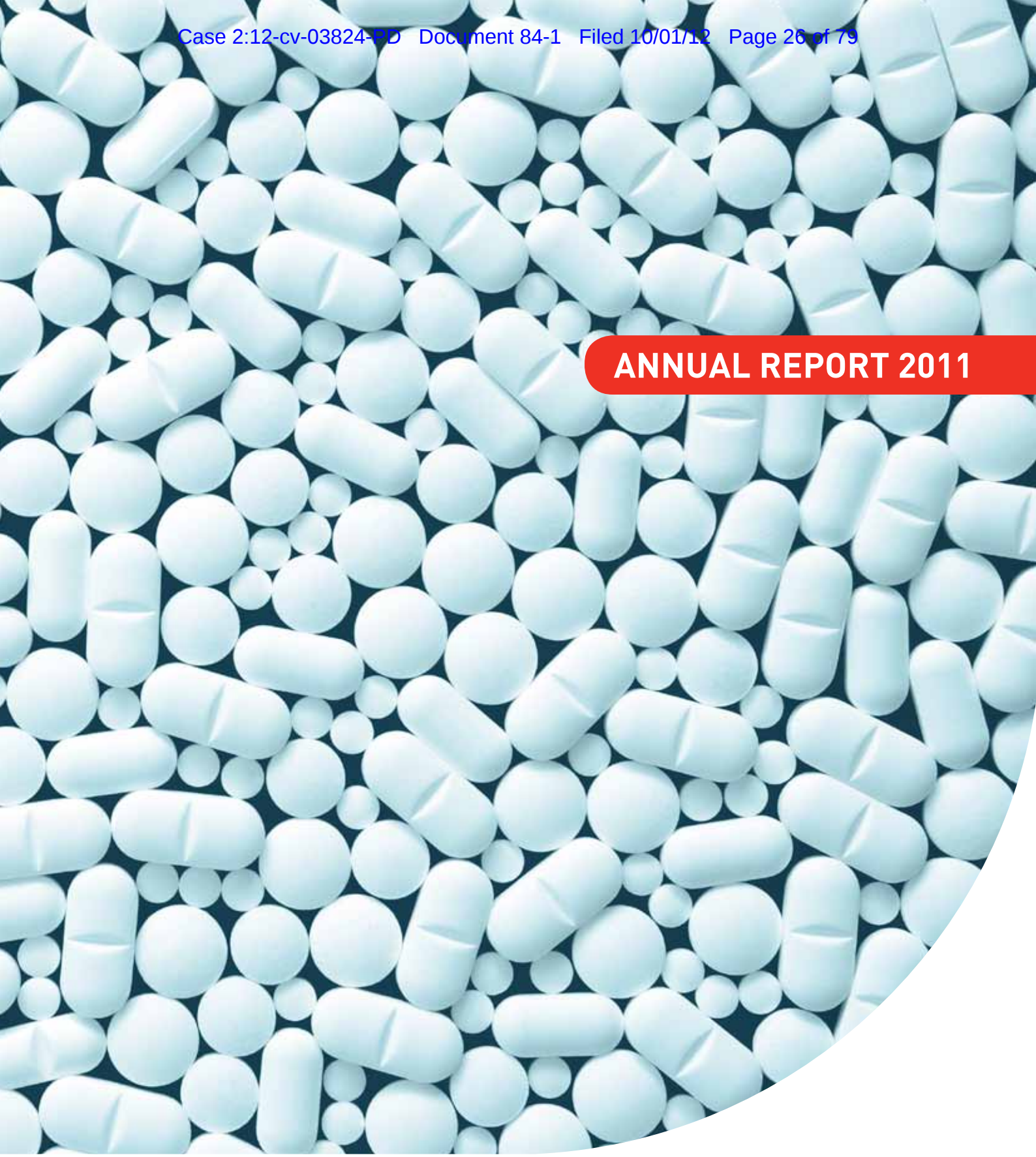
	Quarter Ended June 30, 2012	Quarter Ended June 30, 2011	Six Months Ended June 30, 2012	Six Months Ended June 30, 2011
Revenue breakdown by product:				
ASACOL	$ 187	$ 188	$ 398	$ 375
ACTONEL[1]	150	193	296	425
LOESTRIN 24 FE	97	102	205	221
ESTRACE Cream	46	38	98	73
ENABLEX	41	40	85	85
LO LOESTRIN FE	34	11	62	19
DORYX	23	32	53	98
ATELVIA	16	8	32	9
Other Women's Healthcare	14	19	29	35
Other Hormone Therapy	7	11	21	25
Other Oral Contraceptives	4	2	10	12
Other products	12	16	23	33
Contract manufacturing product sales	4	7	6	10
Other revenue	3	3	5	7
Total revenue	$ 638	$ 670	$ 1,323	$ 1,427

(1) "Other revenue" related to ACTONEL is combined with product net sales for purposes of presenting revenue by product.

The following tables present additional segment information for the quarters and six months ended June 30, 2012 and 2011:

	North America	ROW	Total Company
Quarter Ended June 30, 2012			
Capital expenditures	$ 6	$ 5	$ 11
Amortization of intangible assets	123	1	124
Impairment of intangible assets	106	—	106
Depreciation expense	6	4	10
Quarter Ended June 30, 2011			
Capital expenditures	$ 8	$ 8	$ 16
Amortization of intangible assets	146	1	147
Depreciation expense	5	4	9
Write-down of property, plant and equipment	2	—	2
Six Months Ended June 30, 2012			
Capital expenditures	$ 11	$ 6	$ 17
Amortization of intangible assets	252	2	254
Impairment of intangible assets	106	—	106
Depreciation expense	13	6	19
Six Months Ended June 30, 2011			
Capital expenditures	$ 16	$ 12	$ 28
Amortization of intangible assets	292	3	295
Depreciation expense	12	7	19
Write-down of property, plant and equipment	23	—	23

Exhibit 6



ANNUAL REPORT 2011

mayne pharma

Mayne Pharma at a Glance

Mayne Pharma Group Limited (Mayne Pharma) is an Australian specialist pharmaceutical company with an intellectual property portfolio built around the optimisation and delivery of oral dosage form drugs.

Mayne Pharma has a long and successful history of developing and commercialising improved pharmaceuticals and has launched and marketed numerous products through partnerships with licensees in various countries around the world. Mayne Pharma focuses on delivering to patients improved versions of existing drugs (Improved Chemical Entities) in order to advance safety and efficacy.

Drug delivery systems

Mayne Pharma has three Core Proprietary Technology Platforms:

CONTROLLED RELEASE DELIVERY SYSTEMS	**SUSTAINED RELEASE**	Steady levels of drug concentrations over 12-24 hours following a single dose.
	MODIFIED RELEASE	Immediate release of a small portion of drug followed by the delayed release of the balance.
	PULSED RELEASE	Pulse release of drug over 12-24 hours following a single dose.
	DELAYED RELEASE	Targets the drug to a specific site in intestinal tract, particularly avoiding release in the stomach.
SUBA®	**IMPROVED BIOAVAILABILITY**	Particularly for poorly soluble drugs.
CLEANTASTE®	**TASTE MASKED**	Allows drugs to be more palatable and chewable or easier to swallow.

Proprietary Products

Astrix®

THERAPEUTIC CLASS:
Cardiovascular

DESCRIPTION:
Delayed-release, low-dose aspirin indicated for chronic use in the treatment of cardiovascular or cerebrovascular disease. Astrix® capsules are the only enteric-coated pelletised form of low-dose aspirin in the market. The pellets are specially designed to release in the intestine therefore minimising the possibility of gastric irritation. Astrix® is sold in Australia, Hong Kong, Korea, Mauritius, Singapore and Sri Lanka.

Doryx®

THERAPEUTIC CLASS:
Anti-infective

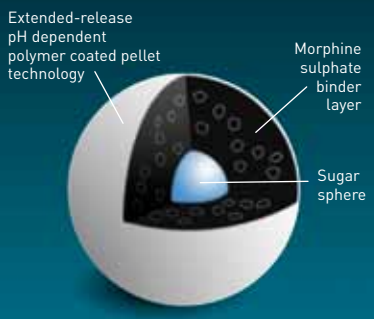
DESCRIPTION:
Delayed-release doxycycline is used for the treatment of severe acne, certain bacterial infections or as an anti-malarial. Doryx® capsules and tablets contain enteric-coated pellets of doxycycline hyclate designed to minimise nausea whilst still providing therapeutic blood levels of doxycycline. Doryx® is sold in Australia, Singapore and the US.

Eryc®

THERAPEUTIC CLASS:
Anti-infective

DESCRIPTION:
Delayed-release erythromycin used in the treatment of a wide variety of bacterial infections. Eryc® is currently sold in Australia, Canada, Norway, Sweden and the UK.

Kadian® / Kapanol®



THERAPEUTIC CLASS:
Analgesia

DESCRIPTION:
Sustained-release oral formulation of morphine used in the management of moderate to severe chronic pain. The product is sold under one of two brands - Kadian® in Canada and Japan or Kapanol® in Australia and various European countries.

Magnoplasm®

THERAPEUTIC CLASS:
First Aid

DESCRIPTION:
Magnoplasm® paste exerts a powerful osmotic action on living cells. It is indicated as an initial treatment for abscesses, boils, blind pimples and carbuncles. It is commonly known as a 'drawing ointment' and can also be used to remove splinters and other foreign bodies. It has been available in Australia for over 60 years.

SUBACAP®

THERAPEUTIC CLASS:
Anti-infective

DESCRIPTION:
Super-bioavailable itraconazole being developed to treat fungal infections. The improved absorption profile means that only about half the drug will be required by patients for the same therapeutic benefit as the originator product, Sporanox®, and will not need to be taken with food, providing more convenience for patients.

Financial Summary

Financial Summary

	2011	2010[2]	2009
	$m	$m	$m
Sales and profit			
Revenue	50.1	36.7	0.4
Gross profit	23.2	18.5	0.4
EBITDA	9.2[1]	8.5	(3.8)
EBITA	7.4[1]	7.2	(3.8)
NPAT	2.7[1]	3.3	(3.8)
Reported EBITDA	7.9	8.5	(3.8)
Reported NPAT	1.7	3.3	(3.8)
Balance sheet extract			
Cash	5.8	19.7	7.9
Inventory & receivables	12.8	12.5	-
PP&E	21.5	21.0	-
Intangibles	8.2	14.2	-
Total assets	53.7	71.2	8.0
Interest-bearing debt	2.3	8.6	-
Other financial liabilites	15.1	21.0	-
Total liabilities	29.5	45.6	0.3
Equity	24.2	25.5	7.7
Ratios			
EBITDA margin (%)	18.4[1]	23.1	n/m
EPS (cents)	1.1	2.6	n/m
Dividends per share (cents)	1.0	2.0	-
Debt/equity (%)	8.8	25.2	n/m

Notes to financial summary table:

1. After adjustments. Adjustments comprise $1.1m provision for the value of Doryx® inventory that is yet to be approved by the FDA, $0.8m non-cash reduction in earn-out liability and one-off redundancy costs of $1.0m for the restructure of the Salisbury production site to improve efficiencies and increase capacity utilisation.

2. Includes only 8 months contribution from MPI.

Revenue

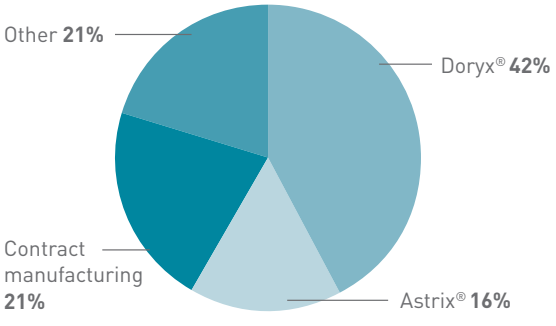
DORYX®

Sales of Doryx®, the key proprietary product representing $20.9 million or 42% of sales, were down 46% on the full 12 month FY10 result. This was driven by the continued and unprecedented strength of the Australian dollar and a contraction in pipeline inventories in the US as stocks of the current product were run down in preparation for the launch of a new Doryx® dosage form by the Company's US marketing and distribution partner, Warner Chilcott. Furthermore, US sales of Doryx® were also significantly affected as the distributor implemented changes to its Doryx® customer loyalty card program which has materially reduced prescription volumes to date in calendar year 2011.

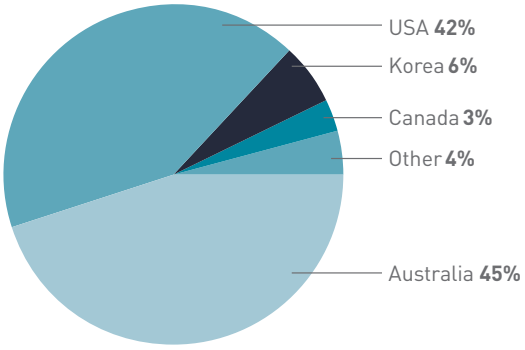
ASTRIX®

Astrix® remains the number one prescribed low-dose aspirin in Australia and contributed 16% of revenue in FY11 ($8.1 million). Global sales of Astrix® were up 27% on the full 12 month FY10 result following the implementation of new marketing programs that included the launch of a consumer website and the appointment of HealthOne to promote the brand in pharmacies. The Company also initiated marketing to GPs for the first time in many years. In Korea, Astrix® is the second largest low-dose aspirin product and sales continue to grow through our marketing partner, Boryung. New formulations of Astrix® are under development to expand the product offering to patients.

Sales Breakdown



Product sales



Regional sales

Exhibit 7

A
CBO
STUDY

HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY

JULY 1998

The Congress of the United States
Congressional Budget Office

Summary

The pharmaceutical market has become increasingly competitive since the early 1980s, in part because of the dramatic growth of the generic drug industry. In 1996, 43 percent of the prescription drugs sold in the United States (as measured in total countable units, such as tablets and capsules) were generic. Twelve years earlier, the figure was just 19 percent. Generic drugs cost less than their brand-name, or "innovator," counterparts. Thus, they have played an important role in holding down national spending on prescription drugs from what it would otherwise have been. Considering only sales through pharmacies, the Congressional Budget Office (CBO) estimates that by substituting generic for brand-name drugs, purchasers saved roughly $8 billion to $10 billion in 1994 (at retail prices).

Three factors are behind the dramatic rise in sales of generic drugs that has made those savings possible. First, the Drug Price Competition and Patent Term Restoration Act of 1984—commonly known as the Hatch-Waxman Act—made it easier and less costly for manufacturers to enter the market for generic, nonantibiotic drugs. Second, by 1980, most states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even when the prescription called for a brand-name drug. And third, some government health programs, such as Medicaid, and many private health insurance plans have actively promoted such generic substitution.

Greater sales of generic drugs reduce the returns that pharmaceutical companies earn from developing brand-name drugs. The Hatch-Waxman Act aimed to limit that effect by extending the length of time that a new drug is under patent—and thus protected from generic competitors. Those extensions compensate for the fact that part of the time a drug is under patent it is being reviewed by the Food and Drug Administration (FDA) rather than being sold. The act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentive to invest in developing innovative drugs. It fell somewhat short of achieving that balance, however, in part because the act shortened the average time between the expiration of a brand-name drug's patent and the arrival of generic copies on the market (so-called generic entry) from more than three years to less than three months. More important, it also greatly increased the number of drugs that experience generic competition and, thus, contributed to an increase in the supply of generic drugs. In the end, the cost to producers of brand-name drugs from faster generic entry has roughly offset the benefit they receive from extended patent terms. Meanwhile, the greater competition from generic drugs has somewhat eroded their expected returns from research and development.

CBO estimates that those factors have lowered the average returns from marketing a new drug by roughly 12 percent (or $27 million in 1990 dollars). In this study, "returns from marketing a new drug" refers to the present discounted value of the total stream of future profits expected from an average brand-name drug. Previous studies estimate that those profits had an average present discounted value of $210 million to $230 million (in 1990 dollars) for drugs introduced in the early 1980s. Those returns are

Exhibit 8

Drugs

Facts about Generic Drugs

Today, nearly 8 in 10 prescriptions filled in the United States are for generic drugs. The use of generic drugs is expected to grow over the next few years as a number of popular drugs come off patent through 2015. Here are some facts about generic drugs:

Click image to view larger graphic.

1

FACT: FDA requires generic drugs to have the same quality and performance as brand name drugs.

- When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency. However, some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass-produced, very small variations in purity, size, strength, and other parameters are permitted. FDA limits how much variability is acceptable.
- Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name product. Generic drugs do not need to contain the same inactive ingredients as the brand name product.
- The generic drug manufacturer must prove its drug is the same as (bioequivalent) the brand name drug. For example, after the patient takes the generic drug, the amount of drug in the bloodstream is measured. If the levels of the drug in the bloodstream are the same as the levels found when the brand name product is used, the generic drug will work the same.
- Through review of bioequivalence data, FDA ensures that the generic product performs the same as its respective brand name product. This standard applies to all generic drugs, whether immediate or controlled release.
- All generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs, and the generic products must meet the same exacting specifications as any brand name product. In fact, many generic drugs are made in the same manufacturing plants as brand name drug products.

FACT: Research shows that generics work just as well as brand name drugs.

- A study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand name counterparts. There was no evidence that brand name heart drugs worked any better than generic heart drugs.[1]

FACT: FDA does not allow a 45 percent difference in the effectiveness of the generic drug product.

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was 3.5 percent[2]. Some generics were absorbed slightly more, some slightly less. This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name drug. In fact, there have been studies in which brand name drugs were compared with themselves as well as with a generic. As a rule, the difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- Any generic drug modeled after a single, brand name drug must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability – just as there is for one batch of brand name drug compared to the next batch of brand name product.

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.

- In 2010 alone, the use of FDA-approved generics saved $158 billion, an average of $3 billion every week.[3]

FACT: Cheaper does not mean lower quality.

- Generic manufacturers are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of new drugs and generally do not pay for costly advertising, marketing, and promotion. In addition, multiple generic companies are often approved to market a single product; this creates competition in the market place, often resulting in lower prices.

FACT: FDA monitors adverse events reports for generic drugs.

- The monitoring of adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. Many times, reports of adverse events describe a known reaction to the active drug ingredient.
- Reports are monitored and investigated, when appropriate. The investigations may lead to changes in how a product (brand name and generic counterparts) is used or manufactured.

FACT: FDA is actively engaged in making all regulated products – including generic drugs – safer.

- FDA is aware that there are reports noting that some people may experience an undesired effect when switching from brand name drug to a generic formulation or from one generic drug to another generic drug. FDA wants to understand what may cause problems with certain formulations if, in fact, they are linked to specific generic products.
- FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

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[1] Kesselheim et al. Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526

[2] Davit et al. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. Ann Pharmacother. 2009;43(10):1583-97.

[3] SAVINGS An Economic Analysis of Generic Drug Usage in the U.S., GPhA, September 2011, page 1.

Exhibit 9

WARNER CHILCOTT

Izumi Hara
Senior Vice President
General Counsel

Tel. +1.973.442.3385
ihara@wcrx.com

5098 11 SEP 23 P2:10

September 23, 2011

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

The undersigned submits this petition on behalf of Warner Chilcott (U.S.), LLC (Warner Chilcott) and Mayne Pharmaceuticals International Pty Ltd. in accordance with section 505(q) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) and 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs take the actions described below. Warner Chilcott is the U.S. agent for Mayne Pharmaceuticals International Pty. Ltd., the sponsor of the Doryx (doxycycline hyclate delayed-release tablets, USP) new drug application (NDA) 50-795 that was originally approved on May 6, 2005.

I. Actions Requested

Warner Chilcott respectfully requests that the Food and Drug Administration (FDA):

1. Refrain from granting final approval to any abbreviated new drug application (ANDA) for a 150 mg doxycycline hyclate delayed-release tablet product citing Doryx as the reference listed drug unless and until the ANDA applicant adopts a dual-scored 150 mg tablet configuration; and

2. Require an ANDA for a 150 mg doxycycline hyclate delayed-release tablet product citing Doryx as the reference listed drug to have the same labeling as Doryx and not apply section 505(j)(10) of the FDCA to permit final ANDA approval.

II. Statement of Grounds

A. Factual Background

On September 13, 2011, FDA approved a supplemental NDA for Doryx (S-014), a tetracycline-class antimicrobial.[1] The supplement supported, among other things, a manufacturing change to the

[1] Doryx is indicated for rickettsial infections; sexually transmitted infections; respiratory tract infections; specific bacterial infections; ophthalmic infections; anthrax, including inhalational anthrax (post-exposure); alternative treatment

FDA-2011-P-0702

CP

scoring of Doryx 150 mg tablets.[2] FDA approved a change from a single score configuration to a dual-scored configuration. The dual-scored tablets are designed to be broken into doses of 100 mg or 50 mg, whereas the single-scored tablets were designed to be broken into 75 mg doses. The dual-scored configuration is intended to facilitate tablet splitting to ease administration and promote patient compliance.[3] It enables patients to split the 150 mg tablet into doses of 100 mg or 50 mg, doses recommended in Doryx's prescribing information.[4]

The supplement also supported related changes to the Doryx prescribing information and patient labeling. Specifically, FDA approved the addition of a new "Patient Counseling Information" subsection of the prescribing information that provides written and graphic instructions for breaking the 150 mg dual-scored tablet,[5] as well as the addition of a description of the 150 mg tablets as "dual-scored" in the "Dosage Forms and Strengths" and "How Supplied/Storage and Handling" sections of the prescribing information.[6] The agency also approved the addition of written and graphic instructions for breaking the 150 mg dual-scored tablet in the FDA-approved patient labeling.

Warner Chilcott has committed to the Division of Anti-Infective Products to mitigate the risk of confusion caused by the transition to the new dual-scored tablets by substantially limiting the amount of time the dual-scored and single-scored products will be in the market at the same time. Warner Chilcott introduced the new dual-scored 150 mg tablet product into the market on September 21, 2011. Warner Chilcott has asked its major customers to return inventory of the single-scored product as they receive shipments of the dual-scored product. In addition, Warner Chilcott has sent letters to physicians and pharmacists to inform them of the scoring change to the Doryx 150 mg tablet and related labeling. Warner Chilcott is taking these steps to educate healthcare providers so they can

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for selected infections when penicillin is contraindicated; adjunctive therapy in acute intestinal amebiasis and severe acne; and prophylaxis of malaria. *See* Doryx prescribing information (Sept. 2011) at Highlights and § 1.

[2] A score is "a debossed line that runs across the planar surface of the tablet...." FDA, "Draft Guidance for Industry: Tablet Scoring: Nomenclature, Labeling, and Data For Evaluation" (Aug. 2011) (Draft Scoring Guidance) at 1, fn. 2.

[3] *See generally id.* at 2 ("scor[ing] can be used to facilitate the splitting of the tablet into fractions when less than a full tablet is desired for a dose"); CDER, FDA, "Scoring Configuration of Generic Drug Products," Manual of Policies and Procedures § 5223.2 (Nov. 1, 1995) (Scoring MAPP) at 1 (scoring "is useful because the score can be used to facilitate the splitting of the tablet into fractions when less than a full tablet is desired for a dose"); Green, G., et al., "Pharmacopeial Standards for the Subdivision Characteristics of Scored Tablets," Pharmacopeial Forum 35(6):1598, 1598 (Nov.-Dec. 2009) (USP Pharmacopeial Forum Article) ("Patients split tablets for a variety of reasons, including to adjust the dose, to ease swallowing, and to save money. ... Therefore, scored tablets play an important role in providing dose flexibility, among other benefits."); Letter from Janet Woodcock, M.D., Director, CDER, FDA, to Alan H. Kaplan and Bonnie B. Anderson, Kleinfeld, Kaplan and Becker, re: Docket Nos. 95P-0262/CP1 and 96P-0317/CP1 (Dec. 1, 2000) at 5 & 7 (noting that scorability, among other characteristics of tablets, is a "special property" that may be "significant to patients and healthcare practitioner" and "have particular significance for children and the elderly").

[4] *See* Doryx prescribing information at § 2.1 (the usual adult dose is 100 mg every 12 hours on the first day of treatment followed by a maintenance dose of 100 mg daily (which may be administered as a single dose or as 50 mg every 12 hours), and in the management of "more severe infections (particularly chronic infections of the urinary tract)" a dose of 100 mg every 12 hours is recommended).

[5] Doryx prescribing information at § 17.1.

[6] Doryx prescribing information at §§ 3 & 16.

properly inform patients about the new scoring configuration and provide appropriate dosing instructions.

B. Arguments

1. FDA Should Refrain From Approving an ANDA For a Generic 150 mg Doxycycline Hyclate Delayed-Release Tablet Product that Lacks a Dual-Score Configuration, Consistent With FDA Policy and the Public Health.

Approving an ANDA for a generic single-scored 150 mg doxycycline hyclate delayed-release product that relies on Doryx would be contrary to FDA's policy on scored tablets and would raise public health concerns.

The FDCA requires a generic product to be the "same as" its reference product (with certain limited exceptions).[7] By regulation, FDA has defined "same as" to mean "identical" in active ingredient(s), dosage form, strength, route of administration, and conditions of use (except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted).[8] Although FDA views scored and unscored tablets generally as not being different dosage forms,[9] the agency has repeatedly emphasized the importance of ensuring scoring consistency between generic drugs and their reference products. In its Manual of Policies and Procedures and in a recent draft guidance, FDA has explained that the agency "recognizes the need for consistent scoring between a generic product and its [reference product]."[10] As the draft guidance explains, "[c]onsistent scoring ensures that the patient is able to adjust the dose, by splitting the tablet, in the same manner as the [reference product]. This enables the patient to switch between products made by different manufacturers without encountering problems related to the dose."[11] The scoring configuration of generics therefore "should be the same as the [reference product]."[12]

FDA has also been clear that an ANDA applicant should not market its product until it is scored consistent with the reference product. FDA's Manual of Policies and Procedures provides that "[i]f the scoring configuration of the exhibit batch does not match that of the listed drug, the generic firm will be requested to provide a commitment, prior to the application's approval, not to market the product until it is correctly scored."[13]

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[7] 21 U.S.C. §§ 355(j)(2)(A)(i)-(iii).

[8] 21 C.F.R. § 314.92(a)(1).

[9] *See generally Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) (2011), Introduction, at vi-vii (pharmaceutical equivalents may "differ in characteristics such as shape, scoring, [and] release mechanism....").

[10] Draft Scoring Guidance at 2. *See also* Scoring MAPP at 1 ("For many years [the Office of Generic Drugs] has recognized the importance of having the scoring configuration of generic tablets be the 'same as' that of the reference listed drug.").

[11] Draft Scoring Guidance at 2. *See also* Scoring MAPP at 1.

[12] Draft Scoring Guidance at 5. *See also* Scoring MAPP at 2 (if the reference product is scored, the generic tablet should be scored "to produce partial doses equivalent to that of the listed drug" and "if the listed drug adds a score, the generic product generally should follow the same configuration").

[13] Scoring MAPP at 2.

FDA's position on consistent scoring[14] promotes patient care. If the agency were to approve an ANDA for 150 mg doxycycline hyclate delayed-release tablets and permit the applicant to market a single-scored tablet pending a postmarket transition to the dual-scored tablets, substantial quantities of dual-scored Doryx 150 mg tablets and single-scored generic 150 mg tablets could be sold simultaneously. This would pose public health concerns. For example, a physician could prescribe 150 mg doxycycline hyclate with instructions for a patient to take 100 mg or 50 mg, consistent with sections 2.1 and 17.1 of the Doryx prescribing information, but a patient receiving the generic product at the pharmacy would not be able to split a generic tablet along its single score to produce either dose.

This could lead to patient confusion and sub-optimal dosing. Patient attempts to split a generic single-scored tablet into 100 mg or 50 mg doses could produce widely variable doses. As FDA has concluded based on its studies of tablet splitting, "in some cases, there are possible safety issues, especially when tablets are not scored or evaluated for splitting."[15] FDA's concerns with splitting include "variations in the tablet content, weight, disintegration, or dissolution, which can affect how much drug is present in a split tablet and available for absorption," as well as stability issues.[16] Underdosing of doxycycline hyclate has the potential to pose efficacy concerns, and exceeding the recommended dosage of doxycycline "MAY RESULT IN AN INCREASED INCIDENCE OF SIDE EFFECTS."[17]

In addition, requiring a generic doxycycline hyclate 150 mg delayed-release tablet product to be dual-scored is consistent with FDA's approach to scoring in the past. In a 2002 response to a Citizen Petition concerning generic tramadol, for example, FDA stated that because tablets are scored "to permit dosing of the drug in accordance with the Dosage and Administration section of the approved labeling, it is appropriate to use the approved labeling of the innovator product as the reference point for considering whether the generic product must also be scored."[18] In that case, FDA determined that because generic tramadol products did not need to include an exclusivity-protected and patent-protected 25 mg titration schedule in their labeling, generic 50 mg tramadol tablets did not need to be scored to permit 25 mg dosing.[19] In contrast, the Dosage and Administration section of the Doryx prescribing information recommends doses of 100 mg and 50 mg — doses that can be readily achieved with a dual-scored 150 mg tablet but not a single-scored 150 mg tablet.

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[14] *See* Draft Scoring Guidance at 2 & 5; Scoring MAPP at 1 & 2.

[15] Draft Scoring Guidance at 2.

[16] *Id.* In recognition of concerns like these, the United States Pharmacopeia published an article in the Pharmacopeial Forum in 2009 proposing standards for the accuracy of subdivision and for loss of mass upon subdivision. *See* USP Pharmacopeial Forum Article, *supra* note 3. The European Pharmacopeia has already adopted standards for the accuracy of subdivision of scored tablets. *Id.*

[17] Doryx prescribing information at § 2.1 (emphasis in original).

[18] Letter from Janet Woodcock, M.D., Director, CDER, FDA, to Marcy Macdonald, Associate Director, Regulatory Affairs, Apotex Corp., Deborah A. Jaskot, Executive Director, Regulatory Affairs, Teva Pharmaceuticals USA, and James F. Hurst, Esq., Winston & Strawn, re: Docket Nos. 01P-0495/CP1, 02P-0191/CP1, & 02P-0252/CP1 (June 11, 2002), at 11 (footnote omitted).

[19] *Id. See also id.* at 11-12 ("Because the unscored 50 mg tablet will permit the patient to use the product in accordance with the approved labeling, the lack of scoring is not a bar to approval of the ANDA.").

As another example, FDA changed the approval requirements for proposed generic doxycycline hyclate 75 mg and 100 mg products subject to a pending ANDA "when [Doryx] was approved for a scored tablet configuration."[20] The ANDA applicant "was required to change to a scored tablet and conduct additional dissolution testing."[21] An ANDA applicant for a generic 150 mg doxycycline hyclate delayed-release tablet product similarly should be required to match the scoring configuration recently approved for the Doryx 150 mg tablet.

2. FDA Should Require an ANDA For a 150 mg Tablet Product Citing Doryx as the Reference Listed Drug to Have the Same Labeling as Doryx and Cannot Apply FDCA § 505(j)(10) to Permit ANDA Approval.

Generic drugs must have the "same" labeling as the "currently approved" labeling of their reference products (with limited exceptions).[22] There is no basis under FDA regulations or section 505(j)(10) of the Act to deviate from that requirement. Although a generic drug's labeling may differ from that of its reference listed drug because the drugs are "produced or distributed by different manufacturers,"[23] this narrow exception would not permit a generic single-scored 150 mg tablet to be sold with the former Doryx labeling. The change here goes to basic information about the product's form and recommended use, and thus goes well beyond what could reasonably be considered within the "different manufacturers" exception.[24]

Further, section 505(j)(10) of the FDCA does not permit approval of an ANDA for a 150 mg tablet product that relies on Doryx. Section 505(j)(10) of the Act allows an ANDA that relies on a reference product for which a labeling change has been approved within 60 days of expiration of the

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[20] *See* Letter from Keith Webber, PhD, Deputy Director, Office of Pharmaceutical Science, CDER, to Impax Laboratories, Inc. (Dec. 28, 2010), at 3, fn. 3.

[21] *Id.*

[22] 21 U.S.C. §§ 355(j)(2)(A)(v) & (4)(G); 21 C.F.R. § 314.94(a)(8)(i).

[23] *Id. See also* 21 C.F.R. § 314.127(a)(7) (FDA may refuse to approve an ANDA if "[i]nformation submitted in the abbreviated new drug application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the abbreviated new drug application except for changes required ... because the drug product and the reference listed drug are produced or distributed by different manufacturers....").

[24] Neither could a generic single-scored 150 mg tablet product use the revised Doryx labeling. Doing so would confuse patients and be false and misleading, misbranding the product under section 502(a) of the Act. And FDA has repeatedly recognized that tablets should be split only in accordance with a product's approved labeling. *See, e.g.*, Draft Scoring Guidance at 2, fn. 5 ("[U]nless the tablet splitting is conducted pursuant to the drug product's approved labeling, the resultant split drugs are considered new drugs under the FD&C Act and, therefore, require an approved new drug application before they may be introduced into interstate commerce."); *id.* at 4 ("The scored tablet should be tested using the indicated patient population to ensure patients can split the tablet correctly, as labeled."); FDA, "Tablet Splitting: A Risky Practice," Consumer Updates (posted July 21, 2009), at www.fda.gov/ForConsumers/ConsumerUpdates/ucm171492.htm ("'If the tablet is approved for splitting, the information will be provided in the drug's professional prescribing information,' says Mansoor Khan, Ph.D., director of the Division of Product Quality Research in FDA's Office of Pharmaceutical Science. 'FDA does not encourage the practice of tablet splitting unless it's specified in the drug's professional prescribing information.'").

reference product sponsor's 30-month stay (or other specified event) to be eligible for approval despite that labeling change, provided certain criteria are met.[25] The section provides:

> (A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if—
>
> > (i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;
> >
> > (ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;
> >
> > (iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and
> >
> > (iv) such application otherwise meets the applicable requirements for approval under this subsection.
>
> (B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.[26]

For several reasons, FDA cannot rely on section 505(j)(10) to permit the approval of a generic doxycycline hyclate 150 mg delayed-release tablet with a single score. As a threshold matter, section 505(j)(10) provides an exception to the statutory requirement that a generic drug generally must have the same labeling as its reference product.[27] The change to a dual-scored tablet is a change to the *product* itself (regardless of any accompanying changes to the Doryx labeling). Section 505(j)(10) does not give FDA authority to approve an ANDA that does not otherwise meet requirements for approval under section 505(j).[28] As described above, consistent with FDA policy and precedents, an

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[25] Section 505(j)(10) was added to the statute under section 10609 of the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010).

[26] 21 U.S.C. § 355(j)(10).

[27] 21 U.S.C. §§ 355(j)(2)(A)(v) & (4)(G).

[28] *See* 21 U.S.C. § 355(j)(10)(A)(iv) (to be eligible for approval, an ANDA must "otherwise meet[] the applicable requirements for approval under [section 505(j)]").

ANDA for a doxycycline hyclate 150 mg delayed-release tablet product that relies on Doryx is not eligible for approval or marketing until the product has a dual-scored tablet configuration.

Even if labeling inconsistencies were the sole issue preventing approval of an otherwise-eligible ANDA, generic approval could not be granted pursuant to section 505(j)(10). First, a generic product's continued use of the former Doryx labeling would "adversely impact[] the safe use of the [generic] drug," contravening section 505(j)(10)(B). Marketing a generic single-scored product under the former Doryx labeling could lead to patient confusion if a patient is switched between products with single and dual score and to sub-optimal dosing where a physician prescribes the tablet with instructions to split the tablet into 100 mg or 50 mg doses.

Second, even under section 505(j)(10), the ANDA sponsor likely would be required to submit revised labeling within 60 days after notification of labeling changes required by the Secretary.[29] It is doubtful that an ANDA applicant could change its manufacturing processes and conduct the studies necessary to transition to a dual-scored tablet within 60 days, and an applicant could not revise its labeling without transitioning to a dual-scored tablet. Marketing a single-scored tablet under the revised labeling would prompt patient confusion and be misleading in violation of section 502(a), as discussed above. Although section 505(j)(10) provides conditions under which a generic drug will not be considered misbranded under section 502, the exception should apply only during the 60-day period after notification by the Secretary.

C. Conclusion

The new dual-scored tablet configuration of Doryx 150 mg is designed to facilitate patient compliance with dosing instructions by enabling patients to split the tablets easily into 100 mg and 50 mg doses, consistent with doses recommended in the Doryx prescribing information. In accordance with the governing legal and regulatory requirements, FDA policy, agency precedents, and the interests of patient care, FDA should: (1) decline to approve any ANDA for doxycycline hyclate delayed-release 150 mg tablets that cites Doryx as its reference product until the applicant adopts a dual-scored configuration; and (2) require an ANDA for a doxycycline hyclate 150 mg delayed-release tablet product citing Doryx as the reference listed drug to have the same labeling as Doryx and not apply section 505(j)(10) of the FDCA to permit ANDA approval.

III. Environmental Impact

This petition is categorically exempt from the requirement for an environmental assessment or an environmental impact statement pursuant to 21 C.F.R. § 25.31.

IV. Economic Impact

Information on the economic impact of the petition will be provided upon request.

[29] 21 U.S.C. § 355(j)(10)(A)(iii).

V. Certifications

Pursuant to 21 C.F.R. § 10.30(b), the undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Pursuant to 21 U.S.C. § 355(q)(l)(H), I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: September 13, 2011, the date that FDA approved Warner Chilcott's sNDA for a change to the Doryx 150 mg tablet from a single score configuration to a dual score configuration. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: I am making these representations on behalf of Warner Chilcott and Mayne Pharmaceuticals International Pty. Ltd. as part of my responsibilities as an employee and officer of Warner Chilcott; I am not being separately compensated for submitting this petition. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Respectfully Submitted,

Izumi Hara
Senior Vice President and General Counsel
Warner Chilcott (US), LLC

Exhibit 10

Therapeutic Equivalents

Drug Name(s)	**DORYX**
FDA Application No.	**(NDA) 050795**
Active Ingredient(s)	**DOXYCYCLINE HYCLATE**
Company	**MAYNE PHARMA**

TABLET, DELAYED RELEASE; ORAL; EQ 75MG BASE
TE Code = AB

Download data

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application Number	Company
DORYX	**DOXYCYCLINE HYCLATE**	**EQ 75MG BASE**	**TABLET, DELAYED RELEASE; ORAL**	**Prescription**	**No**	**AB**	**050795**	**MAYNE PHARMA**
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 75MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	090134	ACTAVIS ELIZABETH
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 75MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	090505	IMPAX LABS INC
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 75MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	090431	MYLAN

TABLET, DELAYED RELEASE; ORAL; EQ 100MG BASE
TE Code = AB

Download data

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application Number	Company
DORYX	**DOXYCYCLINE HYCLATE**	**EQ 100MG BASE**	**TABLET, DELAYED RELEASE; ORAL**	**Prescription**	**No**	**AB**	**050795**	**MAYNE PHARMA**
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 100MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	090134	ACTAVIS ELIZABETH
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 100MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	090505	IMPAX LABS INC
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 100MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	090431	MYLAN

TABLET, DELAYED RELEASE; ORAL; EQ 150MG BASE
TE Code = AB

Download data

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application Number	Company
DORYX	**DOXYCYCLINE HYCLATE**	**EQ 150MG BASE**	**TABLET, DELAYED RELEASE; ORAL**	**Prescription**	**Yes**	**AB**	**050795**	**MAYNE PHARMA**
DOXYCYCLINE HYCLATE	DOXYCYCLINE HYCLATE	EQ 150MG BASE	TABLET, DELAYED RELEASE; ORAL	Prescription	No	AB	091052	MYLAN PHARMS INC

Label Information | Approval History, Letters, Reviews, and Related Documents

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Exhibit 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Walgreen Co., et al., Plaintiffs, v. AstraZeneca Pharmaceuticals L.P, et al. Defendants.	:	**Civil Case Number:** **1:06-cv-02084-RWR**
Rite Aid Corporation, et al. Plaintiffs, v. AstraZeneca Pharmaceuticals L.P., et. al, Defendants.	:	**Civil Case Number:** **1:06-cv-02089-RWR**
Louisiana Wholesale Drug Co., Inc., Plaintiff, v. AstraZeneca Pharmaceuticals L.P., et al., Defendants	:	**Civil Case Number:** **1:06-cv-02157-RWR**
Burlington Drug Company, Inc., et al., Plaintiffs, v. AstraZeneca Pharmaceuticals L.P., et al., Defendants	:	**Civil Case Number:** **1:07-cv-00041-RWR**
Meijer, Inc., et al., Plaintiffs, v. AstraZeneca Pharmaceuticals L.P., et al., Defendants	:	**Civil Case Number:** **1:06-cv-02155-RWR**

PLAINTIFFS' STATEMENT OF POINTS OF AUTHORITY
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Dated: May 21, 2007

equivalent but far less expensive drug. The prescription drug market is very different from other markets because the consumer does not choose which product to buy - a doctor does. Therefore, "[t]he basic problem is that the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay." Drug Product Selection, Staff Report to the FTC (Jan. 1979) at 2-3. As detailed below, AstraZeneca's design change, and its massive campaign of blanketing doctors' offices with free samples of Nexium and deceptive claims of clinical superiority of Nexium over Prilosec, were intended to exploit this basic problem in the market and substantially impair "free consumer choice."

A recent decision held that the *Microsoft II* rule of reason analysis governs pharmaceutical product design changes because "the nature of the pharmaceutical drug market, as described in Plaintiffs' allegations" - including the fact that doctors, rather than consumers, select which product to purchase - undermines free consumer choice. *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006). The leading academic authority on intellectual property and antitrust issues has reached exactly the same conclusion. H. Hovenkamp, et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW, at § 12.5 at 12-45 - 12-48 (Supp. 2007) ("IP AND ANTITRUST").

Antitrust scrutiny is particularly appropriate here, not only because of the "nature of the pharmaceutical drug market," but also because of AstraZeneca's own conduct that magnified the anticompetitive effect of its product redesign scheme. It began switching Prilosec prescriptions to Nexium 18 months before generic Prilosec even entered the market. By the time the generics entered, AstraZeneca had already switched over 10 million unit sales from Prilosec to Nexium, putting these units beyond effective generic competition. Both before and after generic Prilosec entered, AstraZeneca's army of nearly 8,000 detailers made deceptive and misleading statements

to doctors regarding the supposed superiority of Nexium over Prilosec. And its introduction of non-prescription Prilosec ("Prilosec OTC") had the intended effect of causing managed care organizations to stop providing insurance coverage for generic Prilosec - even though generic prescription Prilosec cost less than half of Prilosec OTC and a fraction of prescription Nexium.

Moreover, the Complaints here also allege that AstraZeneca's conduct is exclusionary under the far more forgiving (of the monopolist) "profit sacrifice" test. AstraZeneca's multi-billion dollar investment in its product redesign scheme was profitable to AstraZeneca *solely* because the scheme had the effect of impairing generic competition. AstraZeneca made no new sales or profits from Nexium except those that it made by impairing generic competition. No court has ever held that a product design change that is alleged to fail the profit sacrifice test is nevertheless lawful under Section 2.

AstraZeneca makes a last effort to avoid antitrust scrutiny by invoking the FDA's regulatory authority to approve new drugs. But the FDA approves New Drug Applications based on whether the drug is *safe* and *effective,* not whether it is an improvement or whether its introduction will have anticompetitive consequences. Thus, courts have unanimously rejected the argument that the FDA's limited regulatory authority can preclude antitrust scrutiny.

Finally, Plaintiffs' allegations regarding AstraZeneca's representations to doctors and consumers that Nexium was superior to Prilosec are not subject to Federal Rule of Civil Procedure 9(b) because the representations are not alleged as a stand-alone fraud claim, but as part of an overall anti-competitive product-redesign scheme. Even if Rule 9(b) did apply, the allegations satisfy the Rule by quoting the statements and identifying by, when, and to whom they were made. Nor were the misrepresentations supported by the studies in the FDA-approved Nexium label - those studies showed definitively that Nexium is *not* superior to Prilosec, and

Exhibit 12

1 OVERVIEW

The Doryx® Tablet is a new delayed-release formulation of doxycycline hyclate. Doxycycline hyclate pellets were coated with a pH-dependent polymer coating and then blended with excipients and compressed into tablets. Doryx Tablets were designed to delay the release of doxycycline hyclate until the pellets reach the higher pH environment of the small intestine.

The following 2 studies have been conducted to characterize doxycycline bioavailability following oral administration of a Doryx (doxycycline hyclate) Delayed-Release Tablet, 100 mg which has been sprinkled over applesauce: 1) Study PR-10904 (Research Report RR-05305): "*A Study to Characterize Doxycycline Bioavailability Following Oral Administration of Doryx Tablets Pellets Sprinkled over Applesauce [with Water] Versus a Doryx Tablet Intact in Healthy Volunteers*" and 2) Study PR-03605 (Research Report RR-08505): "*A Study to Characterize Doxycycline Bioavailability Following Oral Administration of Doryx Delayed Release Tablets Sprinkled over Applesauce [without Water] Versus a Doryx Delayed Release Tablet Intact in Healthy Volunteers*"

In both studies, a Doryx Tablet was broken up and sprinkled over 15 mL applesauce in a tablespoon; the reference treatment was a Doryx Tablet swallowed intact. In one study (PR-10904), the applesauce was taken with 240 mL of water; in the other study (PR-03605) the applesauce was taken without water.

Table 1 contains a summary of the studies, Table 2 contains a summary of the pharmacokinetic data, and Table 3 contains a summary of the statistical evaluation. Study synopses are found in sections 2.1 and 2.2; complete study reports are contained in sections 3.1 and 3.2. Study results indicated that when Doryx Tablets are sprinkled over applesauce and taken with or without water, extent of doxycycline absorption is equivalent, but absorption rate is increased slightly.

These data support the following addition to the labeling:

CLINICAL PHARMACOLOGY

When Doryx Tablets are sprinkled over applesauce and taken with or without water, extent of doxycycline absorption is equivalent, but absorption rate is increased slightly.

DOSAGE AND ADMINISTRATION

Sprinkling the Tablet on Applesauce

Doryx Tablets may also be administered by carefully breaking up the tablet and sprinkling the tablet contents on a spoonful of applesauce. However, any loss of pellets in the transfer would prevent using the dose. The applesauce should be swallowed immediately without chewing; the applesauce may be taken with or without water. The applesauce should not be hot, and it should be soft enough to be swallowed without chewing. In the event that a prepared dose of applesauce/Doryx tablet cannot be taken immediately, the mixture should be discarded and not stored for later use.

Table 1. Summary of Human Pharmacokinetic and Bioavailability Studies of Doryx Tablets 100 mg

Study Description (Location)	Study No (Report No)	Study Design	Number Enrolled/ Completed	Study Objective	Dose / Regimen / Lot Number	Conclusions
Doryx Tablet sprinkled over Applesauce with water Bioavailability Study (US)	PR-10904 (RR-05305)	Single-center, randomized, balanced, single-dose, non-blinded, 2-treatment, 2-period, 2-sequence, crossover study in healthy male volunteers	26 / 25	To characterize doxycycline bioavailability following oral administration of a Doryx Tablet broken up and sprinkled over applesauce versus a Doryx Tablet administered intact [with water] in healthy volunteers	Doryx Tablet, 100 mg Single-dose Lot 228429A	When Doryx Tablets, 100 mg are sprinkled over applesauce and taken with water, doxycycline absorption rate is increased slightly, but extent of absorption is equivalent. Doryx Tablets were generally well tolerated.
Doryx Tablet sprinkled over Applesauce without water Bioavailability Study (US)	PR-03605 (RR-08505)	Single-center, randomized, balanced, single-dose, non-blinded, 2-treatment, 2-period, 2-sequence, crossover study in healthy male volunteers	24 / 24	To characterize doxycycline bioavailability following oral administration of a Doryx Tablet broken up and sprinkled over applesauce versus a Doryx Tablet administered intact [without water] in healthy volunteers	Doryx Tablet, 100 mg Single-dose Lot 301938	Doryx (Doxycycline Hyclate) Delayed Release tablets, 100 mg either swallowed whole or broken-up and sprinkled on a spoonful of applesauce were generally well tolerated. When Doryx tablets were broken-up, sprinkled on a spoonful of applesauce and administered without water the extent of doxycycline absorption was equivalent, but rate of doxycycline absorption was slightly increased.

Note that the above studies were conducted under IND 66,553.

Table 2. Summary of Pharmacokinetic Data Following Oral Administration of Doryx Tablets

Study No (Report No)	Dose × Duration	Treatment	n	Arithmetic Mean (%CV) by Pharmacokinetic Parameter				
				Cmax	Tmax	AUC(0–tldc)	AUCinf	t½
PR-10904 (RR-05305)	100-mg Single Dose	Doryx Tablet, 100 mg (applesauce with water)	25	1710.8 (18.5)	2.0 (1.5-4.0)	26485.6 (20.8)	28528.5 (19.8)	16.3
		Doryx Tablet, 100 mg (fasted)	25	1530.8 (31.2)	2.0 (1.0-4.0)	23785.5 (34.0)	26016.3 (30.4)	17.6
PR-03605 (RR-08505)	100-mg Single Dose	Doryx Tablet, 100 mg (applesauce without water)	24	2057.1 (23.2)	2.5 (2.0-4.0)	36557.0 (22.6)	38841.6 (20.9)	18.7
		Doryx Tablet, 100 mg (fasted)	24	1810.7 (30.4)	2.5 (1.0-8.0)	33103.4 (27.2)	35403.2 (26.3)	19.2

Cmax = Maximum plasma concentration, ng/mL; tmax = Time of Cmax, h (median (range)); AUC(0–tldc) = Area under plasma concentration-time curve from 0 to time t, the time of last determinable concentration, ng·mL/h; AUCinf = Area under plasma concentration-time curve from 0 to time infinity, ng·mL/h
t½ = Apparent terminal elimination half-life, h (harmonic mean)

Table 3. Summary of Pharmacokinetic Data Following Oral Administration of Doryx Tablets

Study No (Report No)	Test Treatment	Parameter	Geometric Mean		Ratio	90% Confidence Interval
			Test	Reference		
PR-10904 (RR-05305)	Doryx Tablet, 100 mg (applesauce with water)	Cmax	1684.4	1461.7	115.24	104.24 – 127.40
		AUC(0-tldc)	25947.5	22450.7	115.58	103.96 – 128.49
		AUCinf	28005.4	24882.1	112.55	102.68 – 123.38
PR-03605 (RR-08505)	Doryx Tablet, 100 mg (applesauce without water)	Cmax	2001.9	1719.5	116.43	104.17 – 130.13
		AUC(0-tldc)	35649.4	31696.6	112.47	101.78 – 124.29
		AUCinf	38011.9	33999.1	111.80	101.54 – 123.11

Geometric Mean = antilog of mean of log-transformed value

2 STUDY SYNOPSES

2.1 Study PR-10904 (Research Report RR-05305) Synopsis:

"*A Study to Characterize Doxycycline Bioavailability Following Oral Administration of Doryx Tablets Pellets Sprinkled over Applesauce [with Water] Versus a Doryx Tablet Intact in Healthy Volunteers*"

2.1.1 Clinical Investigator(s)/Center(s):

James D Carlson, Pharm D, PRACS Institute Ltd, 4801 Amber Valley Parkway, Fargo, ND 58104

2.1.2 Study Period:

November 28, 2004 to December 23, 2004

2.1.3 Objective:

To characterize doxycycline bioavailability following oral administration of a Doryx Tablet broken up and sprinkled over applesauce versus a Doryx Tablet intact in healthy volunteers

2.1.4 Study Design:

This single-center, randomized, balanced, single-dose, 2-treatment, 2-period, 2-sequence crossover study was conducted under medical supervision. All subjects received a single Doryx Tablet (100 mg doxycycline) with 240 mL of water in each of 2 treatment periods. In Period 1, half the subjects received the intact Doryx Tablet following an overnight fast of at least 10 hours and did not receive food for at least 4 hours post-dose (Reference). The remaining subjects received the Doryx Tablet broken up and sprinkled over applesauce following an overnight fast of at least 10 hours and did not receive anything further for at least 4 hours post-dose (Test). After a 21-day washout, each subject received the alternative treatment.

Subjects attended the clinic on the evening prior to dosing and were fasted over night. Subjects were randomly assigned to one of the two treatments. The treatments were administered after pre-dose clinical assessments and a blood sample (0 hours) was taken. The subjects remained at the clinic for the 24 hours after dosing, during which time blood samples were collected at 15, 30, 60, 90 minutes and 2, 2.5, 3, 4, 6, 8, 12, 16 and 24 hours post-treatment. Subjects then returned to the clinic for collection of further blood samples at 36, 48, 72 and 96 hours post-treatment.

2.1.5 Safety Assessments:

At screening medical, surgical and medication histories were obtained, physical examinations, vital signs assessments, clinical laboratory tests (hematology, biochemistry, urinalysis, serology, drug/alcohol screen) and ECGs were performed. The vital signs assessment was repeated prior to Period 1 dosing and at the end of the study and the drug/alcohol screen was repeated prior to

dosing in both Periods. The physical examination and clinical laboratory tests were also repeated at the end of the study. Concomitant medication use was recorded at all visits and adverse events were recorded at all visits except screening.

2.1.6 Trial Population:

Twenty-six (26) healthy, non-smoking, male volunteers, 18–45 years of age, within 15% of their ideal weight or with a body mass index (BMI) within 19 and 30 and with no concomitant medication use in the previous 14 days were enrolled into the study.

2.1.7 Test Drug(s):

A single Doryx Tablet was broken up and crumbled by hand into small pieces, the entire tablet contents were then sprinkled over the surface of 15 mL of applesauce in a tablespoon. The applesauce was swallowed immediately without chewing and followed with 240 mL (8 oz) of room temperature water. The Lot number for Doryx Tablets used for the Test and Reference treatments was 228429A; the date of manufacture was December 4, 2002.

2.1.8 Reference Drug(s):

A single Doryx Tablet was swallowed whole and followed with 240 mL (8 oz) of room temperature water.

2.1.9 Analytical Method(s)/ Center(s):

Doxycycline concentrations were determined in plasma using a validated HPLC/UV method; the analytical range was 50–5000 ng/mL. The bioanalytical work was performed by AAI Applied Analytical Industries.

2.1.10 Pharmacokinetic/Statistical Methods:

Doxycycline noncompartmental pharmacokinetic parameters were calculated following administration of the Test and Reference treatments. Analyses of variance (ANOVA) were performed on the log-transformed pharmacokinetic parameters AUC(0–tldc), AUCinf and Cmax.

The 90% confidence intervals for the difference between treatment least-squares means (LSM) were calculated for the parameters AUC(0–tldc), AUCinf and Cmax using log-transformed data. The confidence intervals were expressed as a percentage relative to the LSM of the Reference formulation. Individual subject data and descriptive statistics were inspected for trends likely to be of clinical relevance.

2.1.11 Pharmacokinetic Results and Discussion:

Twenty-five subjects completed the study; the pharmacokinetic data from all 25 subjects was evaluable. The 26 subjects enrolled in the study had a median (range) age of 23 (18–34) years, a median (range) weight of 83.2 (55.8–99.3) kg, and a median (range) height of 177.8 (165.1–185.4) cm. Twenty-five subjects were Caucasian and one was Hispanic.

Following administration of Doryx Tablets either swallowed whole or sprinkled on applesauce plasma doxycycline concentrations increased rapidly (median tmax = 2.0 hours for both treatments). Doxycycline concentrations then decreased in a log-linear fashion over the remainder of the 96-hour period.

Mean doxycycline Cmax, AUC(0-tldc), and AUCinf values following administration of Doryx Tablets are presented in Synopsis Table 1. The rate of doxycycline absorption was increased slightly when one Doryx Tablet was crumbled onto applesauce as compared to one tablet administered intact; mean Cmax values were 16% higher.

The assessment of extent of doxycycline absorption was based on AUCinf values. The extent of doxycycline absorption for Doryx Tablets sprinkled over applesauce was equivalent to that following Doryx Tablets intact; the 90% confidence intervals about the ratio of the test geometric mean to the reference geometric mean were within the 80.00% to 125.00% bioequivalence limits.

2.1.12 Safety Results and Discussion:

A total of four (4) treatment-emergent AEs were reported by 4 of the 26 subjects over the course of the study; none of the AEs were classified as severe, serious or unexpected. Three of the AEs (75%), limb injury, hoarseness and nausea, were reported following administration of the Reference treatment and one AE (25%), headache, was reported following administration of the Test treatment. The headache was reported as being moderate intensity and required therapy, the other 3 AEs were mild in intensity and did not require therapy. The limb injury and hoarseness were deemed unrelated to study treatment and the nausea and headache were deemed probably related to study treatment.

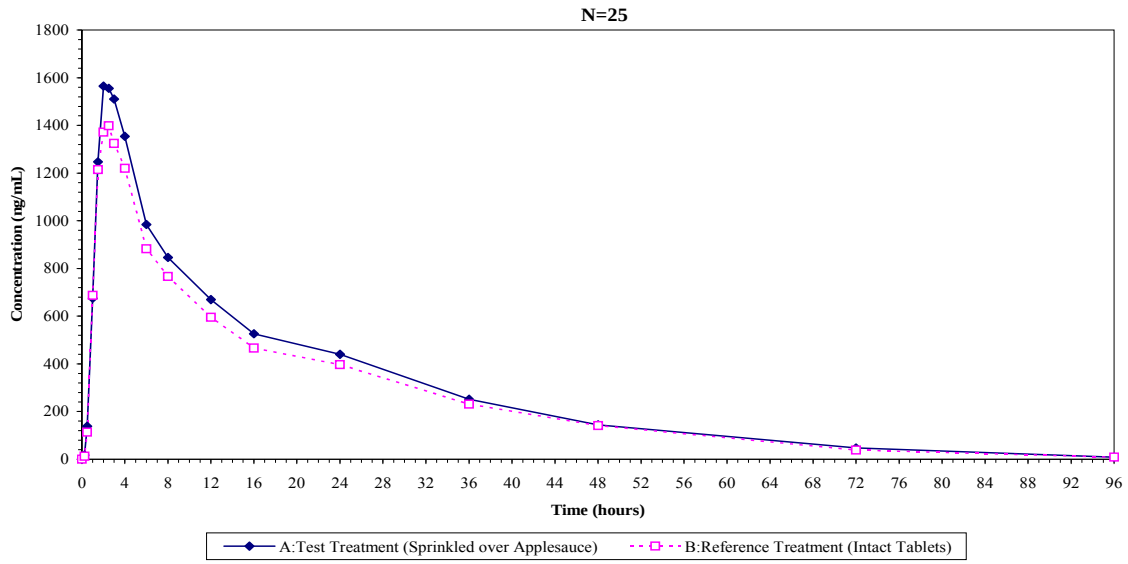
No clinically significant abnormalities in laboratory evaluations, vital signs, or physical exams were observed.

Table 4. Summary of Doxycycline Pharmacokinetic Parameter Values Following Oral Administration of One Doryx Tablet Swallowed Whole or Crumbled Over a Spoonful of Applesauce in Healthy Male Volunteers; PR-10904.0 (n=25)

Parameter	Geometric Mean		Ratio	90% Confidence
	Test (Applesauce Sprinkle)	Reference (Intact Tablet)	(Test : Ref)	Intervals
Cmax	1684.4	1461.7	115.24	104.24 – 127.40
AUC(0–tldc)	25947.5	22450.7	115.58	103.96 – 128.49
AUCinf	28005.4	24882.1	112.55	102.68 – 123.38
tmax [a]	2.3	2.1	--	--

Cmax = Maximum plasma concentration (pg/mL); tmax = time of Cmax (h)
AUC(0–tldc) = Area under the plasma concentration versus time curve from 0 to the tldc, time of last determinable concentration (ng/mL·h)
AUCinf = Area under the plasma concentration versus time curve from time 0 to infinity. AUCinf is calculated as the sum of AUC(0–tldc) plus the ratio of the last determinable plasma concentration to the elimination rate constant (ng/mL·h)
[a] the arithmetic mean is reported for tmax
Source Data: RR-05305.1; Table 14.2 and Section 16.1.9, Statistical Report

Figure 1. Mean Plasma Doxycycline Concentration Versus Time Curves Following Oral Administration of One Doryx Tablet Swallowed Whole or Crumbled Over a Spoonful of Applesauce in Healthy Male Volunteers; PR-10904.0 (n=25)



Source data: RR-05305.1; Figure 14.1

2.1.13 Conclusions:

When Doryx Tablets, 100 mg are sprinkled over applesauce and taken with water, doxycycline absorption rate is increased slightly, but extent of absorption is equivalent. Doryx Tablets were generally well tolerated.

2.2 Study PR-03605 (Research Report RR-08505) Synopsis:

"*A Study to Characterize Doxycycline Bioavailability Following Oral Administration of Doryx Delayed-Release Tablets Sprinkled over Applesauce (without Water) Versus a Doryx Delayed-Release Tablet Intact in Healthy Volunteers*"

2.2.1 Clinical Investigator(s)/Center(s):

James D Carlson, Pharm D, PRACS Institute Ltd, 4801 Amber Valley Parkway, Fargo, ND 58104

2.2.2 Study Period:

August 14, 2005 to September 01, 2005

2.2.3 Objective:

To characterize doxycycline bioavailability following oral administration of a Doryx Delayed Release Tablet broken up and sprinkled over applesauce versus a Doryx Delayed Release Tablet intact with water in healthy volunteers.

2.2.4 Study Design:

This single-center, randomized, balanced, single-dose, 2-treatment, 2-period, 2-sequence crossover study was conducted under medical supervision. All subjects received a single Doryx Delayed Release Tablet in each of the 2 treatment periods. In Period 1, half the subjects received the intact tablet following an overnight fast of at least 10 hours and did not receive food for at least 4 hours post-dose (Reference). The remaining subjects received the tablet broken up and sprinkled over applesauce following an overnight fast of at least 10 hours and did not receive anything further for at least 4 hours post-dose (Test). Only the intact tablet was co-administered with 240 mL of water. After a 14-day washout, each subject received the alternative treatment.

Subjects attended the clinic on the evening prior to dosing and were fasted over night. Subjects were randomly assigned to one of the two treatments. The treatments were administered after pre-dose clinical assessments and a blood sample (0 hours) was taken. The subjects remained at the clinic for the 24 hours after dosing, during which time blood samples were collected at 15, 30, 60, 90 minutes and 2, 2.5, 3, 4, 6, 8, 12, 16 and 24 hours post-treatment. Subjects then returned to the clinic for collection of further blood samples at 36, 48, 72 and 96 hours post-treatment.

2.2.5 Safety Assessments:

At screening medical, surgical and medication histories were obtained, physical examinations, vital signs assessments, clinical laboratory tests (hematology, biochemistry, urinalysis, serology, drug/alcohol screen) and ECGs were performed. The vital signs assessment was repeated prior to Period 1 dosing and at the end of the study and the drug/alcohol screen was repeated prior to dosing in both Periods. The physical examination and clinical laboratory tests were also repeated at the end of the study. Concomitant medication use was recorded at all visits and adverse events were recorded at all visits except screening.

2.2.6 Trial Population:

Twenty-four (24) healthy, non-smoking, male volunteers, 18–45 years of age, within 15% of their ideal weight or with a body mass index (BMI) within 19 and 30 and with no concomitant medication use in the previous 14 days were enrolled into the study.

2.2.7 Test Drug(s):

A single Doryx Tablet was broken up and crumbled by hand into small pieces, the entire tablet contents were then sprinkled over the surface of 15 mL of applesauce in a tablespoon. The applesauce was swallowed immediately without chewing; no water was provided. The Lot number of the Doryx Tablets was 301938; the date of manufacture was March 29, 2005.

2.2.8 Reference Drug(s):

A single Doryx Tablet was swallowed whole and followed with 240 mL (8 oz) of room temperature water. The Lot number of the Doryx Tablets was 301938; the date of manufacture was March 29, 2005.

2.2.9 Analytical Method(s)/ Center(s):

Doxycycline concentrations were determined in plasma using a validated HPLC/UV method; the analytical range was 50–5000 ng/mL. The bioanalytical work was performed by AAI Applied Analytical Industries.

2.2.10 Pharmacokinetics/ Statistical Methods:

Doxycycline noncompartmental pharmacokinetic parameters were calculated following administration of the Test and Reference treatments. Analyses of variance (ANOVA) were performed on the log-transformed pharmacokinetic parameters AUC(0–tldc), AUCinf and Cmax.

The 90% confidence intervals for the difference between treatment least-squares means (LSM) were calculated for the parameters AUC(0–tldc), AUCinf and Cmax using log-transformed data. The confidence intervals were expressed as a percentage relative to the LSM of the Reference formulation. Individual subject data and descriptive statistics were inspected for trends likely to be of clinical relevance.

2.2.11 Pharmacokinetic Results and Discussion:

Twenty-four subjects completed the study; the pharmacokinetic data from all 24 subjects was evaluable. The 24 subjects enrolled in the study had a median (range) age of 23 (19–45) years, a median (range) weight of 80.3 (66.2–97.0) kg, and a median (range) height of 177.8 (167.6–190.5) cm. All 24 subjects were White.

Following administration of Doryx Tablets either swallowed whole or sprinkled on applesauce plasma doxycycline concentrations increased rapidly (median tmax = 2.5 hours for both treatments). Doxycycline concentrations then decreased in a log-linear fashion over the remainder of the 96-hour period. (Synopsis Figure 1)

Geometric mean doxycycline Cmax and AUC(0–tldc) values following administration of Doryx Tablets are presented in Synopsis Table 1. The rate of doxycycline absorption was increased slightly when a Doryx Tablet was crumbled into applesauce; the geometric mean doxycycline Cmax value following administration of one Doryx Tablet crumbled into applesauce and administered without water was 16% higher than when one tablet was administered intact. The extent of doxycycline absorpton was equivalent; the 90% confidence intervals about the ratio of the test geometric mean to the reference geometric mean were within the 80% and 125% bioequivalence limits for AUC(0-tldc) and AUC∞.

2.2.12 Safety Results and Discussion:

There were a total of 4 AEs reported by 4 subjects over the course of the study; none of the AEs were classified as severe, serious or unexpected. Three of the 4 AEs (nausea, headache and dizziness; all mild in severity) were reported after administration of Doryx tablets swallowed whole, the fourth AE (venipuncture site pain; moderate severity) was reported after administration of Doryx tablets broken up and sprinkled over applesauce. Headache and nausea were considered probably related to the study treatment, dizziness and venipuncture site pain were considered unrelated to study treatment. None of the AEs required the use of concomitant medication.

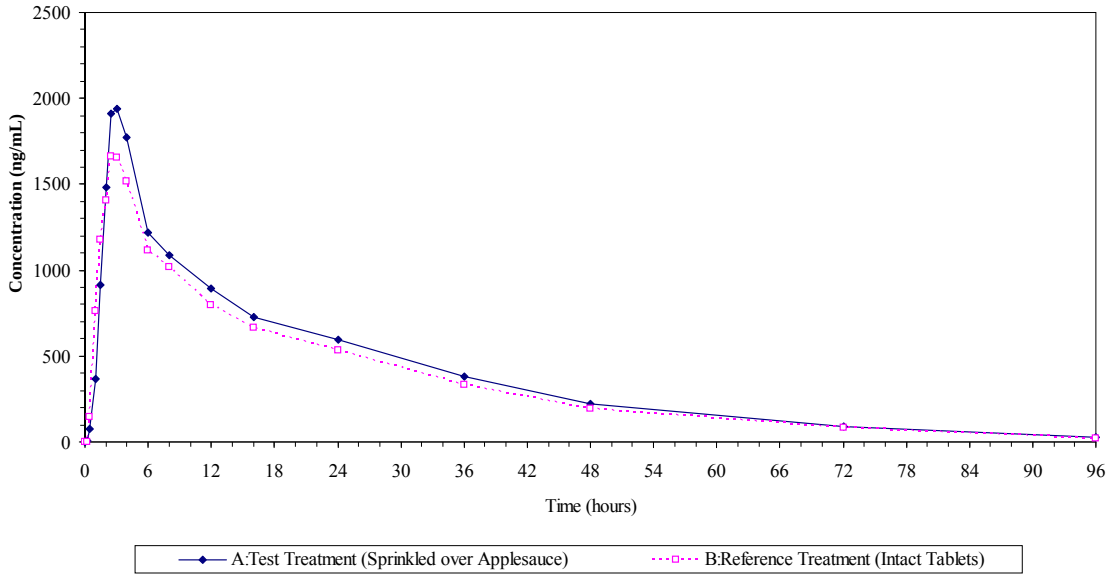
No clinically significant abnormalities in clinical laboratory evaluations, vital signs or physical exams were observed.

Table 5. Summary of Doxycycline Pharmacokinetic Parameter Values Following Oral Administration of One Doryx Tablet Swallowed Whole or Crumbled Over a Spoonful of Applesauce in Healthy Male Volunteers; PR-03605.0 (n=24)

Parameter	Geometric Mean		Ratio	90% Confidence
	Test (Applesauce Sprinkle)	Reference (Intact Tablet)	(Test : Ref)	Intervals
Cmax	2001.9	1719.5	116.43	104.17 – 130.13
AUC(0–tldc)	35649.4	31696.6	112.47	101.78 – 124.29
AUCinf	38011.9	33999.1	111.80	101.54 – 123.11
tmax [a]	2.7	2.7	--	--

Cmax = Maximum plasma concentration (pg/mL); tmax = time of Cmax (h)
AUC(0–tldc) = Area under the plasma concentration versus time curve from 0 to the tldc, time of last determinable concentration (ng/mL·h)
AUCinf = Area under the plasma concentration versus time curve from time 0 to infinity. AUCinf is calculated as the sum of AUC(0–tldc) plus the ratio of the last determinable plasma concentration to the elimination rate constant (ng/mL·h)
[a] the arithmetic mean is reported for tmax
Source Data: RR-08505; Table 14.2 and Section 16.1.9, Statistical Report

Figure 2. Mean Plasma Doxycycline Concentration Versus Time Curves Following Oral Administration of One Doryx Tablet Swallowed Whole or Crumbled Over a Spoonful of Applesauce in Healthy Male Volunteers; PR-03605.0 (n=24)



Source data: RR-08505.0; Figure 14.1

2.2.13 Conclusions:

Doryx (Doxycycline Hyclate) Delayed Release tablets, 100 mg either swallowed whole or broken-up and sprinkled on a spoonful of applesauce were generally well tolerated. When Doryx tablets were broken-up, sprinkled on a spoonful of applesauce and administered without water the extent of doxycycline absorption was equivalent, but rate of doxycycline absorption was slightly increased.

3 COMPLETE STUDY REPORTS

3.1 Complete Study Report –Study PR-10904 (Research Report RR-05305):

"*A Study to Characterize Doxycycline Bioavailability Following Oral Administration of Doryx Tablets Pellets Sprinkled over Applesauce [with Water] Versus a Doryx Tablet Intact in Healthy Volunteers*"

3.2 Complete Study Report – Study PR-03605 (Research Report RR-05305):

"*A Study to Characterize Doxycycline Bioavailability Following Oral Administration of Doryx Tablets Pellets Sprinkled over Applesauce [with Water] Versus a Doryx Tablet Intact in Healthy Volunteers*"

Exhibit 13

« Previous Release | Next Release »

April 30, 2012

Mylan Launches First Generic Version of Doryx® 150 mg

Court Rules in Favor of Mylan in Warner Chilcott's Patent Infringement Suit

PITTSBURGH, April 30, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has launched Doxycycline Hyclate Delayed-release (DR) Tablets USP, 150 mg, following a favorable decision by the U.S. District Court for the District of New Jersey in a patent infringement lawsuit brought by Warner Chilcott. The Court held, after trial, that Mylan's product does not infringe the subject patent. Mylan is shipping product immediately.

Doxycycline Hyclate Delayed-release (DR) Tablets USP, 150 mg is the generic version of Mayne Pharma's Doryx® 150 mg product (marketed by Warner Chilcott), and is a tetracycline-class antimicrobial.

Doxycycline Hyclate DR Tablets, 150 mg, had U.S. sales of approximately $264.1 million for the 12 months ending Dec. 31, 2011, according to IMS Health.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

SOURCE Mylan Inc.

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Exhibit 14

New Products

The following is a list of new products which have become available from Mylan in the last six months. Please check back often to stay informed of new product additions to the Mylan product line.

PRODUCT	STRENGTHS	AVAILABILITY DATE
Ibandronate Sodium Tabs	150mg	3/17/2012
Quetiapine Fumarate Tabs	25mg	3/27/2012
Fluvastatin Caps	20mg & 40mg	4/11/2012
Olanzapine Tabs	2.5mg, 5mg, 7.5mg, 10mg, 15mg & 20mg	4/23/2012
Doxycycline Hyclate DR Tabs	150mg	4/30/2012
Clopidogrel Tabs	75mg	5/17/2012
Nevirapine Tabs	200mg	5/22/2012
Atorvastatin Calcium Tabs	10mg, 20mg, 40mg & 80mg	5/29/2012
Doxycycline Caps	150mg	6/12/2012
Naratriptan Tabs	1mg & 2.5mg	6/13/2012
Abacavir Sulfate Tabs	300mg	6/19/2012
Desloratadine Tabs	5mg	7/2/2012
Lithium Carbonate ER Tabs (300mg)	300mg	7/2/2012
Itraconazole Caps	100mg	7/26/2012
Montelukast Sodium Chewable Tabs	4mg & 5mg	8/3/2012
Montelukast Sodium Tabs	10mg	8/3/2012
Lithium Carbonate ER Tabs (450mg)	450mg	8/9/2012
Modafinil Tabs (CIV)	100mg & 200mg	8/10/2012
Pioglitazone HCl Tabs	15mg, 30mg & 45mg	08/17/2012
Pioglitazone/Metformin HCl Tabs	15mg/500mg & 15mg/850mg	08/17/2012

Exhibit 15

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "202778."

Active Ingredient:	DOXYCYCLINE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	DOXYCYCLINE
Applicant:	MYLAN PHARMS INC
Strength:	EQ 150MG BASE
Application Number:	A202778
Product Number:	001
Approval Date:	Jun 8, 2012
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
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- Orange Book Data - **Monthly**
- Generic Drug Product Information & Patent Information - **Daily**
- Orange Book Data Updated Through August, 2012
- Patent and Generic Drug Product Data Last Updated: October 01, 2012

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Exhibit 16

Acne and Rosacea:
Epidemiology, Diagnosis and Treatment

David J. Goldberg, MD, JD

Clinical Professor of Dermatology & Director of Laser Research,
Mount Sinai School of Medicine,
New York, NY

Clinical Professor of Dermatology & Chief of Dermatologic Surgery
UMDNJ New Jersey Medical School,
Newark, NJ

Adjunct Professor of Law
Fordham Law School,
New York, NY

Director, Skin Laser & Surgery Specialists,
New York, NY

Alexander L. Berlin, MD

Clinical Assistant Professor of Dermatology,
UMDNJ New Jersey Medical School,
Newark, NJ

Director of Mohs & Cosmetic Surgery,
US Dermatology Medical Group - Mullanax Dermatology Associates
Arlington, TX.

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2 ACNE VULGARIS – CURRENT MEDICAL THERAPEUTICS

INTRODUCTION

NUMEROUS therapeutic agents have been developed over the years for the treatment of acne vulgaris (*Table 1*). Although the mechanism of action of some of these agents has not been completely elucidated, most affect one or more of the etiological factors in acne. As research into the pathophysiology of this common disorder continues, additional, more effective therapeutic modalities will likely become available in the years to come.

This chapter will present current information on the most commonly utilized medical treatments. Although additional therapeutic agents have been tried in this condition, sufficient data from randomized prospective studies are lacking or incomplete, and some agents are not yet available in the US; thus, these agents will be beyond the scope of this chapter.

TOPICAL AGENTS

Topical agents are the mainstay of acne therapy. They are frequently used alone in mild cases, but are frequently combined with the oral agents in moderate to severe acne or in resistant cases.

Although most topical agents are left on the surface of the skin, some, such as cleansers, washes, and masks, are removed after only a short contact, thus lessening their absorption and, possibly, adverse effects.

Benzoyl peroxide

Benzoyl peroxide has been available both by prescription and over-the-counter for over 50 years, making it one of the most commonly used medications in acne. It is also available in several commercially-available combinations with topical antibacterial agents, to be covered later in this chapter. Numerous formulations are now available, with concentrations ranging from 2.5% to 10%, and may be used once or twice daily, depending on tolerability and the use of other topical agents. Newer formulations include microspheres (currently only available in the US) to slow the delivery of the active ingredient and to reduce its irritant potential, and a micronized form thought to improve follicular penetration (Del Rosso 2008).

Benzoyl peroxide seems to have bactericidal, keratolytic, and comedolytic properties (Cunliffe *et al.* 1983; Waller *et al.* 2006). Its antibacterial properties are

Topical	Benzoyl peroxide
	Antibiotics
	Clindamycin
	Erythromycin
	Retinoids
	Adapalene
	Tretinoin
	Tazarotene
	Isotretinoin*
	Azelaic acid
	Sulfur
	Sodium sulfacetamide
Oral	Antibiotics
	Tetracyclines
	Azithromycin
	Trimethoprim +/- sulfamethoxazole
	Isotretinoin
	Hormonal agents
	Spironolactone
	Oral contraceptive agents

*not available in the US.

Table 1 Agents commonly used in the treatment of acne vulgaris

Exhibit 17

Mylan

Mylan Begins Marketing First Generic Version of BenzaClin(R) Acne Treatment

PITTSBURGH, Aug. 27 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has begun to market 1% Clindamycin and 5% Benzoyl Peroxide Gel based on an agreement with licensing partner Dow Pharmaceutical Sciences, a subsidiary of Valeant Pharmaceuticals International. The preparation is the first generic version of Sanofi Aventis' BenzaClin® to be approved by the U.S. Food and Drug Administration (FDA).

On Aug. 11, Dow received FDA approval for its Abbreviated New Drug Application (ANDA) for Clindamycin 1% and Benzoyl Peroxide 5% Gel, a prescription-strength topical antibiotic used to treat acne. According to IMS Health, BenzaClin had total U.S. sales of approximately $221 million for the 12 months ending June 30.

Mylan Inc., which provides products to customers in more than 140 countries and territories, ranks among the leading diversified generics and specialty pharmaceutical companies in the world. The company maintains one of the industry's broadest - and highest quality - product portfolios, supported by a robust product pipeline; operates a controlling interest in the world's third largest active pharmaceutical ingredient manufacturer; and runs a specialty business focused on respiratory and allergy therapies. For more information, please visit *www.mylan.com*.

SOURCE Mylan Inc.

Media, Michael Laffin, +1-724-514-1968, or Investors, Dan Crookshank, +1-724-514-1813, both of Mylan Inc.

Exhibit 18

« Previous Release | Next Release »

November 11, 2002

Mylan Laboratories Inc. Announces First ANDA Approval for Isotretinoin; Bertek Pharmaceuticals Inc. to Market Amnesteem

PITTSBURGH--(BUSINESS WIRE)--Nov. 11, 2002--Mylan Laboratories Inc. (NYSE: MYL) today announced that the Food and Drug Administration has granted the first Abbreviated New Drug Application (ANDA) approval for isotretinoin soft-gelatin capsules.

Mylan's branded subsidiary Bertek Pharmaceuticals Inc. will market isotretinoin under the trade name Amnesteem™ in 10 mg, 20 mg and 40 mg strengths.

Mylan acquired the exclusive U.S. marketing rights for isotretinoin through a three-way supply and distribution agreement with Genpharm Inc., Toronto, Canada, which submitted the ANDA, and the Oral Technologies business of Cardinal Health, Inc. (NYSE:CAH), which will manufacture and package the product.

Amnesteem is bioequivalent and thus therapeutically equivalent to Roche Laboratories' Accutane® capsules. Accutane, which is prescribed for the treatment of severe recalcitrant nodular acne, currently has annual sales in excess of one-half billion dollars in the U.S.

Bertek will market Amnesteem through its detail sales force and will provide a comprehensive education/risk management program to patients, pharmacists and doctors, with a focus on dermatologists.

Bertek will offer Amnesteem in both 30 capsule and 100 capsule packages containing either three or ten blister packs of 10 capsules each.

Bertek Pharmaceuticals Inc., based in Research Triangle Park, NC, develops and licenses proprietary pharmaceuticals, with a current focus on dermatology, neurology and cardiology. For more information, visit www.bertek.com.

Mylan Laboratories Inc. is a leading pharmaceutical company that develops, manufactures and markets generic and proprietary prescription products. Mylan has two operating segments that market an extensive line of generic and branded products through four business units: Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories, Inc. and Bertek Pharmaceuticals Inc. For more information about Mylan, visit www.mylan.com.

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. We refer you to the risk factors and other disclosures contained in our most recent Form 10-K and other periodic SEC filings.

We undertake no duty to update our forward-looking statements, even though our situation may change in the future.

--30--db/in*

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CONTACT: Mylan Laboratories Inc., Pittsburgh
Patricia Sunseri, 412/232-0100