MOVERS AND SHAKERS

A PHARMA MATTERS REPORT.

APRIL – JUNE 2009

The Thomson Reuters quarterly report on the US generics industry using strategic intelligence and competitive analysis information from *Newport Premium*™, the critical product targeting and global business development system from the industry authority on the global generics market.

In this quarterly report, we look at a few of the companies beginning to make their marks on the US generics market either with their finished dose products or active ingredients, and analyze trends and statistics relating to the market as a whole.

For more information on Thomson Reuters API Intelligence solutions, including *Newport Premium*, visit **go.thomsonreuters.com/globalgenerics**

SECTION I: INTRODUCTION

Is the generic industry sustainable? That was the question posed at the 15th EGA Annual Conference in Barcelona this June.

Indeed, we see an industry under threat from declining prices, increasing regulatory requirements, and lack of market share in some countries. In both the UK and US, the generic market is actually experiencing negative growth, while brand drugs are still growing, if only slowly. In other countries the generic industry is doing better, though overall its growth has dropped from double-digit rates a few years ago to just 3.7% in 2008.

One of the problems is, of course, the economic crisis, which is impacting the entire pharmaceutical industry and does not seem to have either favored or greatly supported the generics sector. Assuming the crisis is temporary, we might predict an upturn in fortunes in the near future, but changing pricing policies, increasing development and production costs, industry consolidation and unfavorable reimbursement policies will all have a continuing negative impact on the industry.

Relying solely on commodity generics may no longer be seen as a viable option, leaving companies no choice but to target niche products, among them biologics, or by picking up for development those drugs dropped by innovators for clinical or commercial reasons.

Of special concern in Europe is the tendering system, which creates short-term gains to payers but is a major contributor to the spiral of downward pricing, risking significant long-term losses to the industry and patients alike. The companies that don't win the tender may be forced to discontinue certain product lines, endangering the availability of these medicines to the patients that depend on them.

Despite these worries, *Movers & Shakers* continues to show significant activity throughout the US generics industry. First, let's take an in-depth look at this quarter's ANDA approvals and Paragraph IV challenges.

WHAT IS AN ANDA?

An Abbreviated New Drug Application (ANDA) is the first step for a generic drug in the US. It is submitted to the FDA to prove that the generic version is bioequivalent to the innovator drug in question. On approval, the generic version is added to the Approved Drug Products List ("Orange Book") and the company may manufacture and market it. An ANDA may be submitted before the patent on the innovator drug expires. However, in that case, the ANDA must include a certification indicating that the filer does not seek to market the product before the expiry of the Orange Book-listed patents ("paragraph III certification") or that the filer believes that its product does not infringe the Orange Book-listed patents or that the Orange Book-listed patents are invalid ("paragraph IV certification").

WHAT ARE "A" RATED DRUGS?

"A" rated drugs are considered therapeutically equivalent and can be substituted for each other. "A" rated drugs are designated as AA, AB, AN, AO, AP, and AT in the Orange Book.

WHAT IS A US DMF?

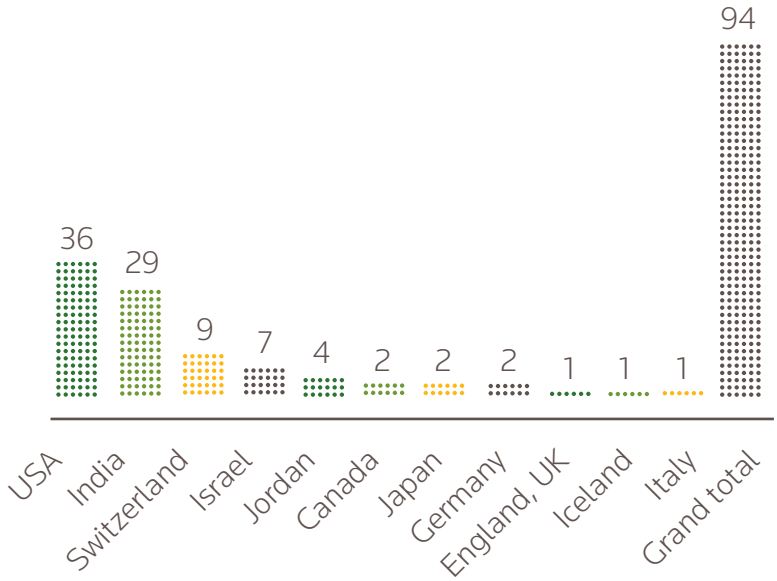
A DMF (Drug Master File) is a confidential document covering a specific manufacturing facility, process or article used in the manufacturing, processing, packaging or storing of a bulk drug. A DMF is reviewed by the FDA only if an ANDA or NDA referencing that particular DMF is filed. An ANDA or NDA will not be approved until any issues with the DMF are resolved.

WHAT IS THE 180-DAY EXCLUSIVITY?

In order to encourage generic companies to develop non-infringing products and challenge invalid patents, the Hatch-Waxman act provides the incentive of 180 days of market exclusivity for the first company to file an ANDA with paragraph IV certification for a product. The FDA may not approve additional ANDAs for a period of 180 days commencing from the first commercial marketing of the first-to-file product. In cases where more than one ANDA with Paragraph IV certification is filed on the same day, the period of exclusivity may be shared.

SECTION II: ANDA APPROVALS

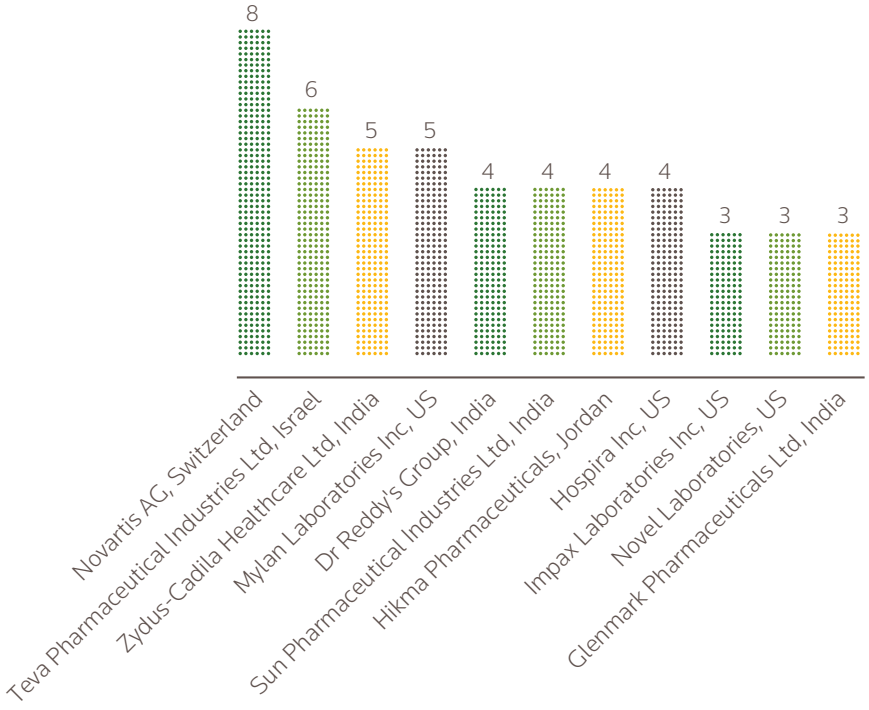
TOTAL 'A'-RATED ANDAS BY COUNTRY OF ORIGIN OF APPLICANT FOR APRIL TO JUNE 2009



During the second quarter of 2009, US-based companies were in first place in terms of final ANDA approvals, with 22 groups receiving a total of 36 approvals. Thirteen Indian companies received a total of 29 final ANDA approvals in the second quarter of 2009. Swiss groups, with nine approvals going to two groups, were in third place.

During the first quarter of 2009, Indian companies were in first place in terms of final ANDA approvals, with 17 groups receiving a total of 56 approvals, followed by the US (23 companies with 42 final ANDA approvals), and Israel (15 approvals going to two groups).

GROUPS WITH THE MOST 'A'-RATED ANDA APPROVALS FOR APRIL TO JUNE 2009



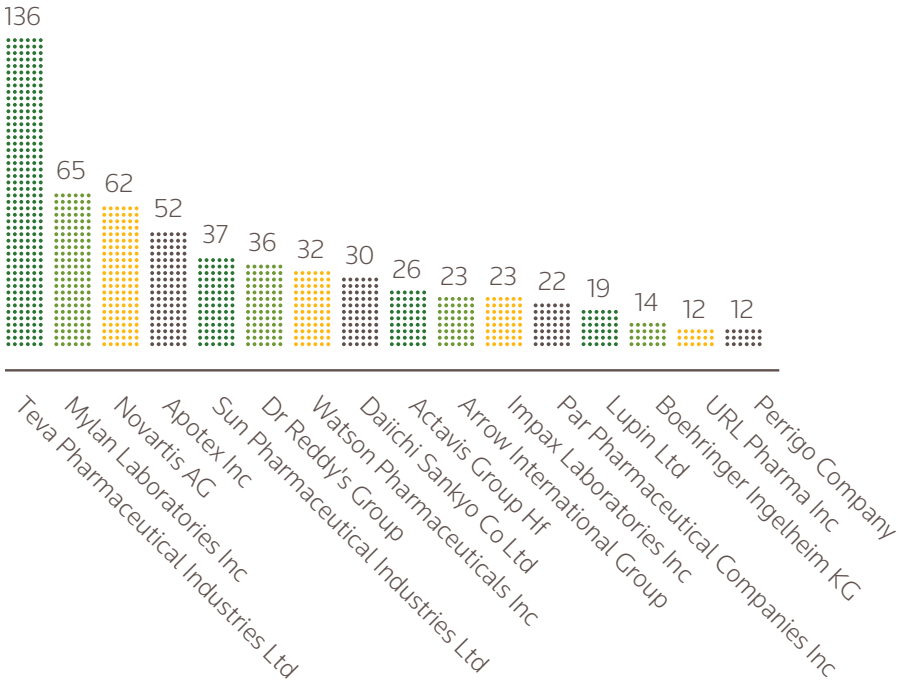
During the second quarter of 2009, Novartis of Switzerland (through its Sandoz subsidiary) received eight ANDA approvals, putting the company on top of the list. Teva of Israel (six approvals) was in second place, followed by Zydus-Cadila of India and Mylan of the US, each with five approvals.

In comparison, during the first quarter of 2009, Teva and Mylan both received 11 ANDA approvals, which put the companies on top of the list.

SECTION III: PARAGRAPH IV CHALLENGES

In the second quarter of 2009, we learned of first Paragraph IV patent challenges on 14 new active ingredients or combinations, down from 21 during the previous quarter.

GROUPS WITH THE MOST PATENT CHALLENGES ON RECORD AS OF JUNE 2009



At the time of the writing of this report, Teva continued to be by far the most prolific filer of ANDAs with patent challenges. We are currently linking them to challenges on 136 products, up from 124 the quarter before.

Mylan has stayed in second place with links to patent challenges on 65 different products, up from 61 the quarter before, with Novartis closely behind with challenges on 62 products.

WHAT IS CORPORATE API RATING?

Corporate API Rating is a proprietary analytic by Thomson Reuters designed to indicate how capable a corporate group is of supplying bulk materials to regulated markets, such as North America and Europe.

The rating values are:

ESTABLISHED
An experienced source with a history of supplying APIs to regulated markets.

LESS ESTABLISHED
A moderate track record in supplying APIs to regulated markets, either in terms of the number of years, or the number of products supplied. They are still considered capable of supplying regulated markets.

POTENTIAL FUTURE
The group has an interest in supplying regulated markets, but so far has no known performance.

LOCAL
Locally focused only (non-regulated markets).

BIG PHARMA
Large innovator company.

WHAT IS A PARAGRAPH IV CHALLENGE?

Bioequivalent generic versions of drugs that are not protected by patents can be produced and marketed in the US by any company, subject to FDA approval. However, a generic company may obtain FDA approval before patent expiry if it certifies its product does not infringe the listed patents or the patents are invalid (paragraph IV certification). Patent holders may then sue the ANDA filer for patent infringement. If the patent holder sues the ANDA filer within 45 days of notification, the FDA may not approve the ANDA for 30 months from the date of notification. If no suit is filed within 45 days, the FDA may approve the ANDA at any time.

PRODUCTS FIRST EXPOSED TO PARAGRAPH IV CHALLENGES, AS REPORTED BY THE FDA BETWEEN APRIL AND JUNE 2009

ACTIVE INGREDIENT: abacavir sulfate

POSTED BY FDA: 19 MAY 2009

BRAND NAME: ZIAGEN™

NDA HOLDER: GlaxoSmithKline

- At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Ziagen (abacavir sulfate) tablets. We do not know the identity of the ANDA filer at this time. ANDAs without Paragraph IV certification for generic versions of Ziagen tablets have received tentative approval under the expedited review provisions of the President's Emergency Plan for AIDS Relief (PEPFAR).
- The Orange Book lists three patents covering Ziagen tablets.

  US Patent 5,034,394 claims the cis isomer of abacavir specifically and has been granted a 905 day extension with respect to Ziagen. The pediatric exclusivity associated with that patent will expire on June 18, 2012.

  US Patent 5,089,500 claims the use of abacavir to treat viral infections. The pediatric exclusivity associated with that patent will expire on December 26, 2009.

  US Patent 6,294,540 includes substance and use claims directed to hemisulfate salt of abacavir. The pediatric exclusivity associated with that patent will expire on November 14, 2018.
- At the time the first ANDA with Paragraph IV certification for a generic version of Ziagen tablets was submitted, Aurobindo, Hetero, Matrix, and Solmag held active DMFs for abacavir sulfate.

ACTIVE INGREDIENT: benzoyl peroxide, clindamycin phosphate

POSTED BY FDA: 8 APRIL 2009

BRAND NAME: Duac®

NDA HOLDER: Stiefel Laboratories

- At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Duac (clindamycin phosphate/benzoyl peroxide) gel: KV Pharmaceutical Company.
- The Orange Book lists only one patent covering Duac gel. US Patent 5,466,446 concerns topical compositions containing benzoyl peroxide and clindamycin and methods of their use. It will expire on February 16, 2014.

ACTIVE INGREDIENT: bimatoprost POSTED BY FDA: 8 APRIL 2009 BRAND NAME: Lumigan® NDA HOLDER: Allergan	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Lumigan (bimatoprost) ophthalmic solution: Barr (Teva). • The Orange Book lists two patents covering Lumigan ophthalmic solution. US Patent 6,403,649 claims bimatoprost specifically as well as its use in the treatment of ocular hypertension and glaucoma. It will expire on September 21, 2012. US Patent 5,688,819 claims, among other things, the use of bimatoprost in the treatment of ocular hypertension and glaucoma. The term of US Patent 5,688,819 has been extended by 698 days with regard to Lumigan. The Orange Book now lists the date of expiration as August 19, 2014. • When the first ANDA with Paragraph IV certification was submitted for a generic version of Lumigan, Chirogate International, Daiichi Fine Chemical Co., and Everlight Chemical Industrial Corporation held active DMFs for bimatoprost.
ACTIVE INGREDIENT: cevimeline hydrochloride POSTED BY FDA: 19 MAY 2009 BRAND NAME: Evoxa® NDA HOLDER: Daiichi Sankyo	• At least one company has submitted an ANDA for a generic version of Evoxac (cevimeline hydrochloride) capsules: Apotex. • In its suit against Apotex, Daiichi alleged infringement of US Patent 5,340,821. That patent is directed to a method of treatment for Sjogren Syndrome Disease and will expire on July 7, 2013. • When the first ANDA with Paragraph IV certification for a generic version of Evoxac capsules was submitted, Excella and Apotex held the only active DMFs for cevimeline HCl likely to be referenced in an ANDA.
ACTIVE INGREDIENT: dextromethorphan polistirex POSTED BY FDA: 19 MAY 2009 BRAND NAME: Delsym® NDA HOLDER: Reckitt Benckiser	• At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Delsym (dextromethorphan polistirex) extended-release suspension: Tris Pharma. • The Orange Book lists only one patent covering Delsym extended-release suspension. US Patent 5,980,882 is a formulation patent expiring on April 16, 2017 • Cambrex Charles City submitted a DMF for dextromethorphan polistirex on December 19, 2008. Coating Place, Inc. also holds an active DMF for dextromethorphan polistirex, which was submitted in 2005.

ACTIVE INGREDIENT: doxycycline POSTED BY FDA: 19 MAY 2009 BRAND NAME: Oracea® NDA HOLDER: Galderma	• At least two companies have submitted ANDAs with Paragraph IV certification for generic versions of Oracea (doxycycline) delayed-release capsules: Mylan and Lupin. Other generic doxycycline products have been approved for years. • The Orange Book lists four patents covering Oracea delayed-release capsules. US Patent 5,789,395 and US Patent 5,919,775 will expire on August 30, 2016. US Patent 7,211,267 and US Patent 7,232,572 will expire on April 5, 2022.
ACTIVE INGREDIENT: efavirenz, emtricitabine, tenofovir disoproxil fumarate POSTED BY FDA: 8 APRIL 2009 BRAND NAME: Atripla® NDA HOLDER: Gilead	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate) tablets: Teva. • The Orange Book lists fifteen patents covering Atripla tablets. In its suit against Teva, Gilead alleged infringement of US Patent 6,642,245 and US Patent 6,703,396. Those patents are owned by Emory University and licensed exclusively to Gilead. They are the same patents challenged by Teva in its ANDA for a generic version of Truvada (emtricitabine/tenofovir disoproxil fumarate) tablets. US Patent 6,642,245 claims the use of emtricitabine for treating HIV infection. It has been granted a pediatric exclusivity expiring on May 4, 2021. US Patent 6,703,396 claims the (-)-enantiomer of emtricitabine that is 95% free of the (+)-enantiomer. It has been granted a pediatric exclusivity expiring on September 9, 2021. • When the first ANDA with Paragraph IV certification for a generic version of Atripla was submitted, Aurobindo, Cipla, Hetero, and Matrix held active DMFs for each of the compounds in the combination. Ranbaxy held DMFs for emtricitabine and tenofovir disoproxil fumarate. Aptuit Laurus, Emcure, Macleods Pharmaceuticals, and Sibra Pharmaceuticals held active DMFs for efavirenz at that time.
ACTIVE INGREDIENT: formoterol fumarate POSTED BY FDA: 19 MAY 2009 BRAND NAME: PERFOROMIST™ NDA HOLDER: Dey	• At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Perforomist (formoterol fumarate) inhalation solution: Teva. • The Orange Book lists four patents covering Perforomist inhalation solution. They are all formulation patents that will expire on June 22, 2021. In its suit against Teva, Dey alleged infringement of all four patents. • At the time the first ANDA with Paragraph IV certification for a generic version of Perforomist was submitted, several companies held active DMFs for formoterol fumarate, including Cipla, Industriale Chimica, Inke, and Sicor (Teva).

ACTIVE INGREDIENT: guaifenesin + pseudoephedrine hydrochloride POSTED BY FDA: 4 MAY 2009 BRAND NAME: Mucinex D® NDA HOLDER: Reckitt Benckiser	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Mucinex D (guaifenesin/pseudoephedrine hydrochloride) extended-release tablets: Watson. • In its suit against Watson, Reckitt alleged infringement of both patents listed for Mucinex D in the Orange Book. US Patent 6,372,252 and US Patent 6,955,821 are both formulation patents expiring on April 28, 2020.
ACTIVE INGREDIENT: mycophenolic acid POSTED BY FDA: 1 JUNE 2009 BRAND NAME: Myfortic® NDA HOLDER: Novartis	• At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Myfortic (mycophenolic acid) delayed release tablets. We do not know the identity of the ANDA filer at this time. • The Orange Book lists three patents covering Myfortic delayed-release tablets. US Patent 6,025,391, US Patent 6,172,107, and US Patent 6,306,900 are directed to enteric-coated pharmaceutical compositions and will expire on April 10, 2017. • At the time the first ANDA with Paragraph IV certification for a generic version of Myfortic delayed-release tablets was submitted, Antibioticos SpA, Chongqing Daxin, Formosa Laboratories, and Sandoz were among the holders of mycophenolic acid DMFs.
ACTIVE INGREDIENT: telmisartan, hydrochlorothiazide POSTED BY FDA: 1 JUNE 2009 BRAND NAME: Micardis HCT® NDA HOLDER: Boehringer Ingelheim	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Micardis HCT (telmisartan and hydrochlorothiazide) tablets, 80mg/12.5mg and 80mg/25mg. We do not know the identity of the filer at this time. • The Orange Book lists only one patent covering Micardis HCT in the 80mg/25mg strength. US Patent 5,591,762 is the product patent for telmisartan and expires on January 7, 2014. • For Micardis HCT in 80mg/12.5mg and 40mg/12.5mg strengths, the Orange Book also lists US Patent 6,358,986. That patent concerns polymorphic forms of telmisartan and will expire on January 10, 2020.

ACTIVE INGREDIENT: travoprost POSTED BY FDA: 8 APRIL 2009 BRAND NAME: Travatan® NDA HOLDER: Alcon	• At least two companies have filed ANDAs with Paragraph IV certification for generic versions of Travatan (travoprost) and Travatan Z (travoprost) ophthalmic solutions: Barr (Teva) and Par. • For Travatan ophthalmic solution, the Orange Book lists five patents: US Patent 5,510,383, US Patent 5,631,287, US Patent 5,849,792, US Patent 5,889,052, and US Patent 6,011,062. For Travatan Z ophthalmic solution, the Orange Book lists four patents: US Patent 5,510,383, US Patent 5,889,052, US Patent 6,503,497, and US Patent 6,849,253. The patents for both travoprost ophthalmic solution products expire between August 3, 2013 and December 22, 2014. In its suits against Barr and Par, Alcon alleged infringement of all the patents listed for Travatan and Travatan Z in the Orange Book. • When the first ANDA with Paragraph IV certification was submitted for a generic version of Travatan in November 2008, FineTech and Johnson Matthey held the only two DMFs for travoprost that were likely to be referenced in an ANDA. On December 8, 2008, Cayman Pharma also submitted a DMF for travoprost.
ACTIVE INGREDIENT: trospium chloride POSTED BY FDA: 19 MAY 2009 BRAND NAME: Sanctura XR™ NDA HOLDER: Allergan	• At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Sanctura XR (trospium chloride) extended-release capsules: Watson. • The Orange Book lists only one patent covering Sanctura XR extended-release capsules. US Patent 7,410,978 concerns once-daily dosage forms of trospium and will expire on February 1, 2025. Supernus Pharmaceuticals is the owner of US Patent 7,410,978. Allergan and Endo hold certain exclusive rights to the patent and co-market Sanctura XR in the United States. • At the time of the ANDA submission in early March 2009, BASF Orgamol, Enaltec Labs, Interpharma Praha, and Procos were among the holders of DMFs most likely to be referenced in ANDAs for trospium chloride products. On March 30, 2009, Glenmark Generics also submitted a DMF for trospium chloride.
ACTIVE INGREDIENT: vardenafil hydrochloride POSTED BY FDA: 1 JUNE 2009 BRAND NAME: Levitra® NDA HOLDER: Bayer	• At least one company has submitted an ANDA with Paragraph IV certification for a generic version of Levitra (vardenafil hydrochloride) tablets: Teva. • The Orange Book lists only one patent covering Levitra tablets. US Patent 6,362,178 will expire on October 31, 2018. • At the time the first ANDA with Paragraph IV certification for a generic version of Levitra tablets was submitted, Dr. Reddy's Laboratories held an active DMF for vardenafil hydrochloride trihydrate.

SECTION IV: NOTABLE DEALS

The biggest acquisition of the quarter was Watson Pharmaceutical's purchase of Arrow Group for $1.75 billion. This is expected to increase Watson's international showing appreciably—Arrow sells drugs in more than 20 countries worldwide, including UK, France and Canada, with 2008 revenues of $647 million. As seen in the previous section of the report, both companies are significant players in the paragraph IV patent challenge space. Watson may also be able to leverage Arrow's biogenerics capabilities, due to the latter's 36% stake in Eden Biodesign, and it will benefit from Arrow's deal with Pfizer to produce an authorized generic version of its blockbuster cholesterol treatment Lipitor®.

Just shy of this in monetary terms at $1.2 billion was Novartis's acquisition of the specialty generic injectables business of EBEWE Pharma. EBEWE's separate injectable neurological products business is excluded from the transaction.

Deal-making between big pharma and global generic companies continues. Most notably, Pfizer shows no sign of slowing down its impressive deals activity. Last quarter we detailed its licensing agreement with Aurobindo.

This quarter, Pfizer struck a deal with Ahmedabad-based Claris Lifesciences Limited to commercialize generic versions of sterile injectable drugs, including anti-infectives and antibiotics, in the US, Europe, Canada, Australia and New Zealand.

GlaxoSmithKline also signed two significant deals this quarter. Firstly, a 16% stake in Aspen Pharmacare gives Aspen the right to distribute GSK's drugs in South Africa. Aspen will in addition have the global distribution rights to eight medicines manufactured in one of GSK's German factories. And secondly, GSK has entered into partnership with Dr Reddy's Laboratories to develop and sell selected products across emerging markets, excluding India.

Global generic companies are continuing to make deals in the follow-on biologics area. At the end of June, Mylan and Biocon announced an exclusive collaboration on the development, manufacturing, supply and commercialization of a number of high value generic biologic compounds. For manufacturer Biocon, the deal gives them access to the global footprint Mylan has built up through acquisitions of Merck Generics and Matrix. In return, Mylan will have exclusive commercialization rights in a number of countries, including the US.

SECTION V: OPENING MOVES

Based on our research of ANDA filings and Paragraph IV challenges, we highlight some of the companies making significant game play in the US generics industry.

NATCO PHARMA

Indian generics manufacturer Natco Pharma has been working under contract for the likes of Dr Reddy's and Ranbaxy since 1984—we note a deal with Dr Reddy's in April this year to develop, manufacture and supply a range of generic oncology drugs for the US and European market—but is now of note for its ambitions to become a 'complete' global pharmaceutical company in its own right.

In the last few years, Natco has garnered a great deal of attention for its acquisition of a clutch of drugstores in the US—Nick's Drugs, SaveMart Drugs and Newark Drugs.

Its success in replicating Teva's multiple sclerosis therapy Copaxone® (active ingredient glatiramer acetate) has led to a collaboration with Mylan in which Natco will supply pre-filled syringes of glatiramer acetate for Mylan to distribute exclusively in the US, Europe, Japan, Canada, and Australasia.

Also in April this year, a deal with Lupin saw the company challenging Shire Plc over its kidney disease treatment lanthanum carbonate (brand name Fosrenol®), Natco's first Paragraph IV filing. The company currently holds two ANDAs, for citalopram and ondansetron.

PIRAMAL GROUP

In the first quarter of 2009, Piramal Healthcare Ltd, part of the Piramal Group and ranked the fourth largest generics drug manufacturer in India, acquired Minrad International Inc., effecting its entrance into the US market.

The two companies had already collaborated in 2003 to manufacture and market the inhalation anesthetics isoflurane, enflurane, and sevoflurane. Minrad also has partnerships in place with Merck, Novartis, Baxter and others.

The latter agreement is presumably no longer in place, since Minrad has filed an ANDA with Paragraph IV certification for desflurane volatile liquid for inhalation (Baxter's Suprane®). Baxter responded with a patent infringement lawsuit in January 2009. The automatic 30-month stay of approval of Minrad's ANDA will expire in June 2011.

BEIJING YABAO BIPHARMACEUTICAL CO LTD

An affiliate of the Yabao Group, known domestically for more than 300 modern Chinese medicines, chemical medicines, and biological products, Beijing Yabao is only the second Chinese company to hold final ANDA approvals in the US. The company also exports to the rest of Asia, Europe and the Middle East.

The approved ANDAs are for galantamine hydrobromide tablets (4, 8, and 12mg) and meloxicam tablets (7.5 and 15mg), and have been achieved in partnership with US generics company Par Pharmaceutical Inc. Par's ANDA for galantamine was originally the subject of paragraph IV litigation before Par dropped the challenge.

PHASE III DRUGS – INTERESTED IN TARGETING EARLIER IN THE DEVELOPMENT LIFECYCLE?

Coming soon... will be the first of our new optional content modules:

Newport Phase III Drugs.

Targeting new opportunities reliably and as early as possible in the drug development lifecycle can mean the difference between success and failure in today's intensely competitive global generics market.

The *Newport Phase III Drugs Module* answers this need by seamlessly integrating information for more than 700 compounds currently in Phase III clinical research or later with an existing *Newport Global*™ or *Newport Premium*™ subscription.

Included for development-stage compounds is information concerning indications pursued, mechanisms of action, worldwide development status histories, patents and synthetic routes (if already known). Development histories will also be added to all existing (launched/approved) products.

Email alerts may be set on Phase III drugs, providing automatic notification of the latest changes as drugs progress through trials and regulatory review. A new Phase III Drugs Focused Search enables comprehensive searching of development-stage drug information, and Phase III drug data may be included or eliminated from the results of any existing Target or Focused searches.

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Created specifically for generic pharmaceutical companies and strategic API manufacturers, it can help you to identify and evaluate product opportunities worldwide, ensuring you'll be first to find the generic product and niche opportunity, first to make the deal, and first to get to market.

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