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MOVERS AND SHAKERS

A PHARMA MATTERS REPORT.

JANUARY – MARCH 2009

The Thomson Reuters quarterly report on the US generics industry using strategic intelligence and competitive analysis information from *Newport Horizon 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 Horizon Premium*, visit go.thomsonreuters.com/generics

SECTION I: INTRODUCTION

It is 25 years since the Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman” Act, created the US generic industry as we know it. Today two thirds of all prescriptions dispensed in the US are for generic equivalents.

Newport Horizon Premium was there to join the celebrations at the Generic Pharmaceutical Association (GPhA) 2009 Annual Meeting in Naples, Florida. Via a taped message, the Act’s sponsor, Congressman Henry Waxman, expressed his belief that the Hatch-Waxman model still achieves a strong balance between fostering innovation and making affordable medicines available to consumers.

The biggest issue facing the US generics industry this year is the passage of favorable biogeneric legislation. Even though biologic medicines were nonexistent when the Act was enacted, Waxman sees no reason why biogenerics cannot achieve the same balance as the rest of the industry.

Among generics’ other challenges are the relative lack of funding for foreign inspections conducted by the FDA, and the limited budget of the Office of Generic Drugs (OGD). Currently the OGD is facing a backlog of work amounting to as much as three years, with approximately 1600 ANDAs still waiting to be reviewed (most are paragraph III and IV applications) and receipts continuing at a high rate — around 800 ANDAs are submitted per year, on top of which the OGD received approximately 1400 letters last year.

It is feared that the OGD may not have sufficient resources to review citizen petitions, develop bioequivalence recommendations for complex products, develop policies, procedures and guidance for an ever-changing regulatory landscape, and ensure that all its decisions are supported scientifically. The median approval time of ANDAs has increased from 18.9 months in 2007 to 21.1 months in 2008.

One point of debate at GPhA concerned the increasing number of notable patent settlements between big pharma and generic companies. According to Mylan’s VP of the Board and CEO Robert Coury, settlements should not expand the scope or duration of the patent. Mr Coury explained that big pharma likes settlements because they bring about a level of certainty for them. Additionally, expenditures on research and development have shrunk, and big pharma now has fewer funds available to actively litigate patent challenges.

Former Chairman and CEO of Barr Pharmaceuticals Bruce Downey argued that banning patent settlements is a bad idea, since it is patents that keep generics off the market, not the settlement — if the patent is valid, a settlement is necessary to bring the generic to the market sooner. Moreover, Mr Downey indicated that patent settlements have a benefit in favor of the consumer.

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.

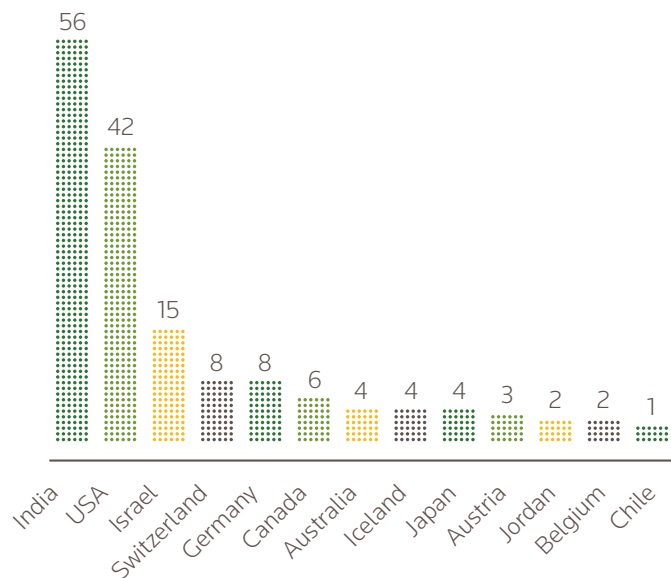
WHAT IS THE 180-DAY EXCLUSIVITY?

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.

In this edition of *Movers & Shakers* we introduce a new section on notable mergers and acquisitions, partnerships and other deals activity in the US market. But first, let's take an in-depth look at this quarter's ANDA approvals and Paragraph IV challenges.

SECTION II: ANDA APPROVALS

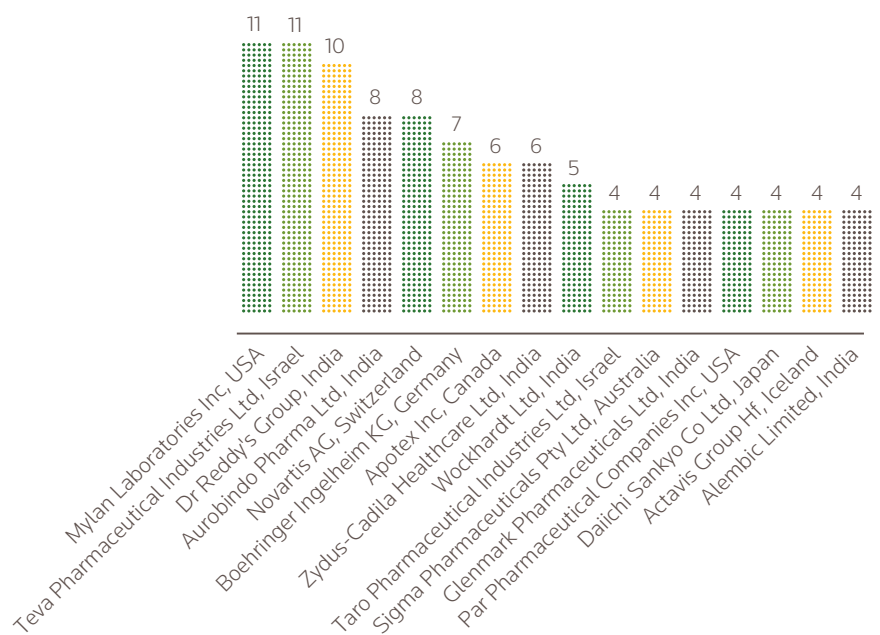
TOTAL 'A'-RATED ANDAS BY COUNTRY OF ORIGIN OF APPLICANT FOR JANUARY TO MARCH 2009



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. During the previous quarter, Indian groups, with 37 approvals going to 13 groups, were in the second place after US companies.

23 US companies received a total of 42 final ANDA approvals in the first quarter of 2009. Israeli groups, with 15 approvals going to two groups, were in the third place.

GROUPS WITH THE MOST 'A'-RATED ANDA APPROVALS FOR JANUARY TO MARCH 2009



During the first quarter of 2009, Teva of Israel and Mylan of USA both received 11 ANDA approvals, putting the companies on top of the list. Teva also received the most ANDA approvals (10) during the last quarter of 2008.

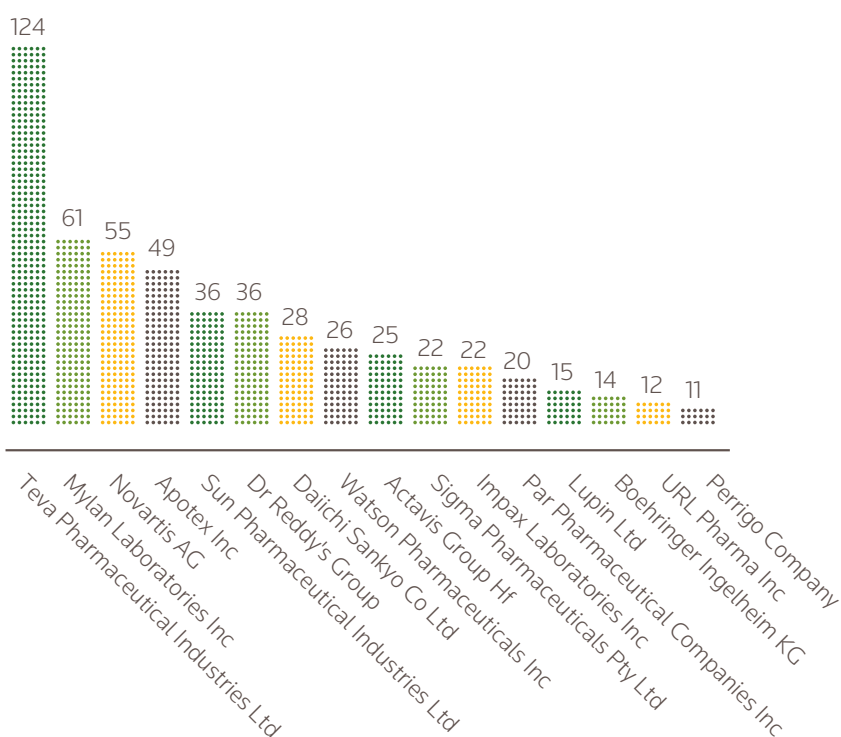
Dr Reddy's of India (10 approvals), Aurobindo of India (8 approvals) and Novartis (8 approvals) were also in the top five in terms of final approvals during the first quarter of 2009.

Sun Pharmaceutical of India, which was in the second place with eight approvals during the previous quarter, received only three final approvals during this quarter.

SECTION III: PARAGRAPH IV CHALLENGES

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

GROUPS WITH THE MOST PATENT CHALLENGES ON RECORD AS OF MARCH 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 124 products, up from 114 the quarter before.

Mylan has remained in second place with links to patent challenges on 61 different products, up from 51 the quarter before, with Novartis and Apotex closely behind with challenges on 55 and 49 different products respectively.

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.

NEW PRODUCTS FIRST EXPOSED TO PARAGRAPH IV CHALLENGES, AS REPORTED BY THE FDA BETWEEN JANUARY AND MARCH 2009

ACTIVE INGREDIENT: aprepitant	<ul style="list-style-type: none">At least one company has filed an ANDA with Paragraph IV certification for a generic version of Emend (aprepitant) capsules: Sandoz.
POSTED BY FDA: 21 JANUARY 2009	<ul style="list-style-type: none">The Orange Book lists seven patents covering Emend capsules, expiring between January 25, 2011 and July 1, 2018. In its complaint against Sandoz, Merck has alleged infringement of US Patent 5,719,147, US Patent 6,048,859, US Patent 6,096,742, and US Patent 6,235,735.
BRAND NAME: Emend®	
NDA HOLDER: Merck	
<hr/>	
ACTIVE INGREDIENT: bortezomib	<ul style="list-style-type: none">At least one company has filed an ANDA with Paragraph IV certification for a generic version of Velcade (bortezomib) for injection: Teva.
POSTED BY FDA: 21 JANUARY 2009	<ul style="list-style-type: none">The Orange Book lists several patents covering Velcade, expiring between October 28, 2014 and January 25, 2022. In its suit against Teva, Millennium has alleged infringement of US Patent 6,713,446 and US Patent 6,958,319.
BRAND NAME: Velcade®	
NDA HOLDER: Millennium	
<hr/>	
ACTIVE INGREDIENT: brimonidine tartrate and timolol maleate	<ul style="list-style-type: none">At least one company has filed an ANDA with Paragraph IV certification for a generic version of Combigan (brimonidine tartrate/timolol maleate) ophthalmic solution: Sandoz.
POSTED BY FDA: 3 MARCH 2009	<ul style="list-style-type: none">In its suit against Sandoz, Allergan has alleged infringement of both Orange Book patents covering Combigan ophthalmic solution: US Patent 7,030,149 and US Patent 7,320,976.
BRAND NAME: Combigan®	
NDA HOLDER: Allergan	
<hr/>	
ACTIVE INGREDIENT: capecitabine	<ul style="list-style-type: none">At least one company has filed an ANDA with Paragraph IV certification for a generic version of Xeloda (capecitabine) tablets: Mylan.
POSTED BY FDA: 3 MARCH 2009	<ul style="list-style-type: none">The Orange Book lists two patents covering Xeloda tablets: US Patent 4,966,891 and US Patent 5,472,949. In its suit against Mylan, Roche has alleged infringement of US Patent 5,472,949.
BRAND NAME: Xeloda®	
NDA HOLDER: Roche	
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ACTIVE INGREDIENT: clindamycin phosphate	<ul style="list-style-type: none">An ANDA with Paragraph IV certification for a generic version of Evoclin (clindamycin phosphate) foam 1% has been submitted by Cobrek and its partner Perrigo.
POSTED BY FDA: 17 FEBRUARY 2009	<ul style="list-style-type: none">In its suit against Cobrek and Perrigo, Stiefel alleged infringement of both patents listed in the Orange Book: US Patent 7,141,237 and US Patent 7,374,747.
BRAND NAME: Evoclin®	
NDA HOLDER: Stiefel Laboratories	

ACTIVE INGREDIENT: daptomycin

- At least one company has filed an ANDA with Paragraph IV certification for a generic version of Cubicin (daptomycin) for injection: Teva.

POSTED BY FDA: 17 FEBRUARY 2009

- In its suit against Teva, Cubist has alleged infringement of all three patents covering Cubicin: US Patent RE39,071, US Patent 6,468,967 and US Patent 6,852,689.

BRAND NAME: Cubicin®

NDA HOLDER: Cubist Pharmaceuticals

ACTIVE INGREDIENT: darifenacin hydrobromide

- At least three companies have filed ANDAs with Paragraph IV certification for generic versions of Enablex (darifenacin hydrobromide) extended-release tablets: Anchen, Teva, and Watson.

POSTED BY FDA: 16 MARCH 2009

- In its suit against Teva, Novartis alleged infringement of both US Patent 5,096,890 and US Patent 6,106,864. In its suits against Anchen and Watson, Novartis alleged infringement of only US Patent 6,106,864.

BRAND NAME: Enablex®

NDA HOLDER: Novartis

ACTIVE INGREDIENT: diclofenac sodium and misoprostol

- At least one company has filed an ANDA with Paragraph IV certification for a generic version of Arthrotec (diclofenac sodium/misoprostol) delayed-release tablets, 75mg/0.2mg: Teva.

POSTED BY FDA: 3 MARCH 2009

- The Orange Book lists two patents covering Arthrotec delayed-release tablets: US Patent 5,601,843 and US Patent 5,698,225. In its suit against Teva, Pfizer alleged infringement of US Patent 5,601,843.

BRAND NAME: Arthrotec®

NDA HOLDER: Pfizer

ACTIVE INGREDIENT: doxycycline hyclate

- At least five companies have submitted ANDAs with Paragraph IV certification for generic versions of Doryx (doxycycline hyclate) delayed-release tablets, 75mg and 100mg: Actavis, Impax, Mutual, Mylan, and Sandoz. Impax and Mylan have also submitted ANDAs with Paragraph IV certification for the 150mg strength.

POSTED BY FDA: 21 JANUARY 2009

- The Orange Book lists only one patent covering Doryx delayed-release tablets. US Patent 6,958,161 will expire on February 19, 2018.

BRAND NAME: Doryx®

NDA HOLDER: Mayne

<p>ACTIVE INGREDIENT: epinastine hydrochloride</p> <p>POSTED BY FDA: 21 JANUARY 2009</p> <p>BRAND NAME: Elestat®</p> <p>NDA HOLDER: Allergan</p>	<ul style="list-style-type: none"> At least three companies have filed ANDAs with Paragraph IV certification for generic versions of Elestat (epinastine hydrochloride) ophthalmic solution, 0.05%: Cypress Pharmaceutical, Paddock Laboratories, and Sandoz. The Orange Book lists only one patent covering Elestat ophthalmic solution. US Patent 7,429,602 will expire on November 29, 2020.
<p>ACTIVE INGREDIENT: eptifibatide</p> <p>POSTED BY FDA: 21 JANUARY 2009</p> <p>BRAND NAME: Integrilin®</p> <p>NDA HOLDER: Schering</p>	<ul style="list-style-type: none"> At least one company has filed an ANDA with Paragraph IV certification for a generic version of Integrilin (eptifibatide) injection: Teva. The Orange Book lists five patents covering Integrilin, expiring between November 11, 2014 and September 15, 2015. Millennium and Schering have alleged infringement of US Patent 5,807,825, US Patent 5,747,447 and US Patent 5,968,902.
<p>ACTIVE INGREDIENT: erlotinib hydrochloride</p> <p>POSTED BY FDA: 17 FEBRUARY 2009</p> <p>BRAND NAME: Tarceva®</p> <p>NDA HOLDER: OSI Pharmaceuticals</p>	<ul style="list-style-type: none"> At least two companies have filed ANDAs with Paragraph IV certification for generic versions of Tarceva (erlotinib hydrochloride) tablets: Teva and Mylan. The Orange Book lists three patent covering Tarceva tablets: US Patent 5,747,498, US Patent 6,900,221, and US Patent 7,087,613. OSI, Pfizer, and Genentech have alleged that Teva and Mylan have infringed all three patents.
<p>ACTIVE INGREDIENT: estrogens, conjugated synthetic A</p> <p>POSTED BY FDA: 21 JANUARY 2009</p> <p>BRAND NAME: Cenestin®</p> <p>NDA HOLDER: Duramed</p>	<ul style="list-style-type: none"> At least one company has filed an ANDA with Paragraph IV certification for a generic version of Cenestin (synthetic conjugated estrogens, A) tablets in the 1.25mg strength: Paddock Laboratories. The Orange Book lists only one patent covering Cenestin tablets. US Patent 5,908,638 will expire on July 26, 2015.
<p>ACTIVE INGREDIENT: eszopiclone</p> <p>POSTED BY FDA: 17 FEBRUARY 2009</p> <p>BRAND NAME: Lunesta®</p> <p>NDA HOLDER: Sepracor</p>	<ul style="list-style-type: none"> Several companies have filed ANDAs with Paragraph IV certification for generic versions of Lunesta (eszopiclone) tablets. Among the filers are Cobalt, Dr. Reddy's Laboratories, Glenmark, Lupin, Mylan, Orchid, Roxane, Sun, Teva, and Wockhardt. The Orange Book lists four patent covering Lunesta tablets: US Patent 6,319,926, US Patent 6,444,673, US Patent 7,381,724, and US Patent 6,864,257. Sepracor has alleged infringement of all four patents.

ACTIVE INGREDIENT: • At least one company has filed an ANDA with Paragraph IV certification for a generic version of Mucinex DM (guaifenesin/dextromethorphan) extended-release tablets: Watson.

POSTED BY FDA: • The Orange Book lists two patents covering Mucinex DM extended-release tablets. US Patent 6,372,252 and US Patent 6,955,821 are both formulation patents expiring on April 28, 3 MARCH 2009

BRAND NAME: Mucinex®DM

NDA HOLDER: Reckitt Benckiser

ACTIVE INGREDIENT: • At least three companies have submitted ANDAs with Paragraph IV certification for generic versions of Fosrenol (lanthanum carbonate) chewable tablets: Barr, Mylan, and Natco.

POSTED BY FDA: • The Orange Book lists three patents covering Fosrenol chewable tablets. Shire's suit against Barr alleges infringement of all three patents. Shire's suit against Mylan alleges infringement of US Patent 5,968,976. Shire's suit against Natco alleges infringement of US Patent 5,968,976 and US Patent 21 JANUARY 2009

BRAND NAME: Fosrenol®

NDA HOLDER: Shire

ACTIVE INGREDIENT: • At least one company has filed an ANDA with Paragraph IV certification for a generic version of Kaletra (lopinavir/ritonavir) tablets: Matrix Laboratories, a subsidiary of Mylan.

POSTED BY FDA: • The Orange Book lists eleven patents covering Kaletra tablets, with associated pediatric exclusivities expiring between January 21 JANUARY 2009

BRAND NAME: Kaletra

NDA HOLDER: Abbott

ACTIVE INGREDIENT: • At least four companies have submitted ANDAs with Paragraph IV certification for generic versions of Solodyn (minocycline HCl) extended-release tablets: Barr (Teva), Impax, Matrix (Mylan), and Sandoz.

POSTED BY FDA: • The Orange Book currently lists only one patent covering Solodyn extended-release tablets. In its suit against Barr, Mylan, and Sandoz, Medicis alleged infringement of claims 3, 21 JANUARY 2009

BRAND NAME: Solodyn®

NDA HOLDER: Medicis

ACTIVE INGREDIENT: • At least three companies have filed ANDAs with Paragraph IV certification for a generic version of Lovaza (omega-3-acid ethyl esters) capsules: Apotex, Par, and Teva.

POSTED BY FDA: • At the time of the first ANDA submission for a generic version of Lovaza capsules, the Orange Book listed three unexpired patents covering that product. The Apotex, Par, and Teva ANDAs included Paragraph IV certification to US Patent 16 MARCH 2009

BRAND NAME: Lovaza®

NDA HOLDER: GlaxoSmithKline

ACTIVE INGREDIENT: pregabalin

POSTED BY FDA:
16 MARCH 2009

BRAND NAME:
Lyrica®

NDA HOLDER:
CP Pharmaceuticals

- Several companies have filed ANDAs with Paragraph IV certification for generic versions of Lyrica (pregabalin) capsules. Among the filers are Actavis, Alphapharm (Mylan) Cobalt, Lupin, Sandoz, Sun, Teva, and Wockhardt.
- The Orange Book lists three patents covering Lyrica capsules. The suits against Actavis, Lupin, and Sandoz alleged infringement of all three patents. The suits against Teva, Cobalt, Sun, Wockhardt, and Alphapharm/Mylan alleged infringement of only some of the patents.

ACTIVE INGREDIENT: sevelamer carbonate

POSTED BY FDA:
3 MARCH 2009

BRAND NAME:
Renvela™

NDA HOLDER:
Genzyme

- At least two companies have filed ANDAs with Paragraph IV certification for generic versions of Renvela (sevelamer carbonate) tablets: Impax and Lupin.
- The Orange Book lists six patents covering Renvela tablets, expiring between August 11, 2013 and September 16, 2014. In its suit against Impax, Genzyme alleged infringement of only US Patent 5,667,775. In its suit against Lupin, Genzyme alleged infringement of all the patents.

SECTION IV: NOTABLE DEALS

By far the most active acquirer this quarter was Sanofi-Aventis, purchasing Zentiva of the Czech Republic for \$2.56 billion and Medley of Brazil for approximately \$680 million. It is worth noting that in 2006, Zentiva had acquired the leading Turkish generic Eczacibasi for \$675 million.

As this edition of Movers & Shakers goes to press, Sanofi-Aventis has also announced its acquisition of Laboratorios Kendrick, one of Mexico's leading generic companies. Meanwhile, Mylan plans to purchase the remaining shares in Matrix Laboratories Ltd, of which it already owns 71.2%.

Actavis of Iceland and ASKA of Japan have formally signed an agreement to establish a joint company, called Actavis ASKA K.K., which was poised to enter the Japanese generic market as we went to press.

A number of product-related deals were concluded this quarter. The most notable of these is Pfizer's expansion of its generic medicines portfolio in the US and Europe through licensing agreements with Aurobindo. These agreements include the rights to 39 of Aurobindo's generic solid oral dose products in the US and 20 in Europe, plus an additional 11 in France and 12 sterile injectible products in the US and Europe.

Two deals involving biologics are of special interest. In a joint venture, Teva and Lonza have declared that they will cooperate to develop, manufacture and market a number of generic equivalents of a selected portfolio of biologic pharmaceuticals. Intas and Apotex have announced an extension of their May 2008 agreement to co-develop and market a biosimilar version of pegfilgrastim, originally marketed by Amgen as Neulasta®.

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.

BEIJING DOUBLE-CRANE PHARMACEUTICAL CO LTD

In 2008, unnoticed by many, Beijing Double-Crane Pharmaceutical Co Ltd became the first Chinese company to hold a final ANDA approval in the US, when it acquired Ranbaxy's ANDA 78039 for meloxicam 7.5mg and 15mg tablets. The ANDA was originally approved on December 14, 2006. A supplemental filing was approved on July 15, 2008.

The parent company Beijing Pharmaceutical Group was founded in 1939 as a small military clinic, and is now one of China's largest pharmaceutical companies, boasting 10,000 employees and annual sales of approximately US \$600 million by the end of 2006. It is based in the Chaoyang district of Beijing.

Double-Crane was formed in 1997. As an innovator and manufacturer, its products include nutritional and therapeutic IV solutions (for which it is the market leader in China), synthetic antibodies, antibacterials, and branded natural remedies (such as Beijing Royal Jelly). It also manufactures pharmaceutical equipment.

We believe that Ranbaxy's ANDA specified manufacturing at its Ohm Laboratories facility in North Brunswick, New Jersey. Since it looks like Double-Crane's dose facilities have not yet been inspected by the FDA, we assume it will continue to use Ranbaxy's facility and transfer manufacturing to China later.

Newport Horizon Premium gives Beijing Pharmaceutical Group a rating of Potential Future.

THEPHARMANETWORK, LLC

Based in Montvale, New Jersey, with offices in Hyderabad, India, and Beijing and Shanghai, China, ThePharmaNetwork (TPN) has two ANDA approvals under its own name, for benzonatate capsules in 100mg and 200mg strengths.

TPN was originally engaged in the business of pharmaceutical contract sales and marketing, but has since moved into the development of generic drugs. Of particular interest are hard and soft gelatin capsules, ophthalmic products and injectibles. The company had been marketing and distributing its products and services primarily to other generic companies. However, in order to increase profitability and market share, TPN set up its own sales and marketing organization through its wholly-owned subsidiary Ascend Laboratories, LLC.

NOVEL LABORATORIES

At the end of 2008, Novel Laboratories (based in Somerset, New Jersey) achieved approval for one ANDA in its own name — sodium polystyrene sulfonate rectal powder. Formed in 2006 from a strategic alliance between VGS Pharma LLC and Elite Pharmaceuticals, the company specializes in the development and manufacturing of orally-disintegrating and modified-release dosage forms.

The company is fast expanding. In February 2009, it opened a new 40,000 square foot packaging, warehousing and distribution facility in Somerset, doubling its total facility size. It has additional manufacturing capabilities through its allied company Novel Therapeutics, based in Chennai, India. Novel claims that it has more than 50 products in development and will launch as many as six of them this year. Some of these will be labeled under the name of its affiliate GAVIS Pharmaceuticals.

Newport Horizon Premium links the company to three patent challenges: in April 2008, for a generic version of Salix and Norgene's *MoviPrep*[®], in July 2008 for a generic version of Salix's *OsmoPrep*, and in October for CIMA and Azur Pharma's clozapine orally disintegrating tablets in 12.5mg, 25mg and 100mg strengths.

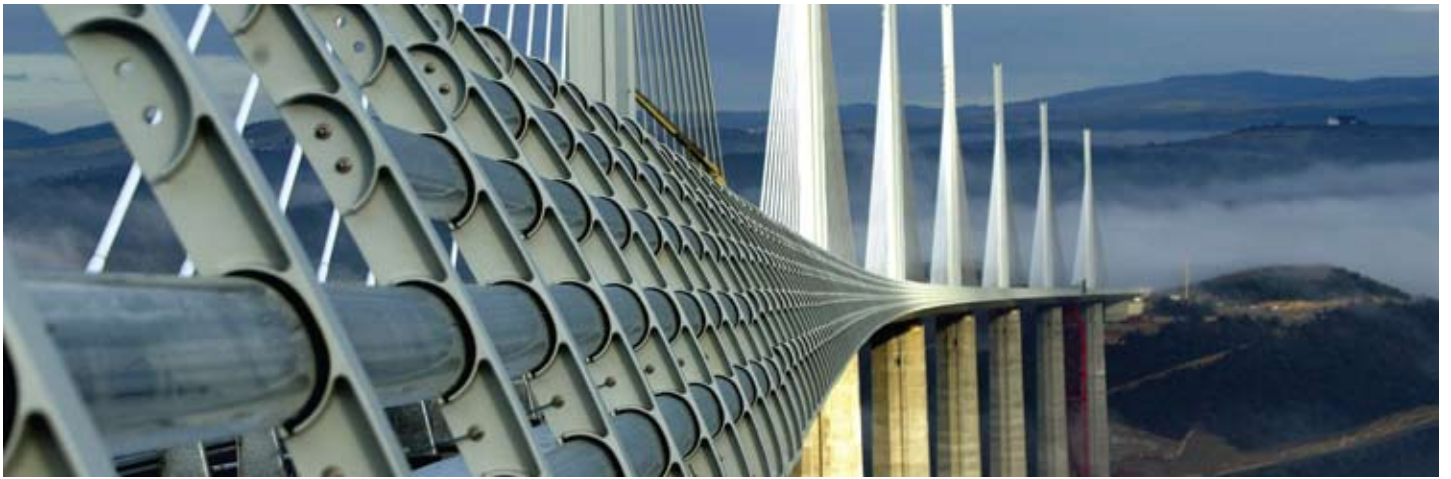


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PHASE III DRUGS – INTERESTED IN TARGETING EARLIER IN THE DEVELOPMENT LIFECYCLE?

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 *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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Focuses on the latest phase changes in the pharmaceutical pipeline.

MOVERS AND SHAKERS

Unravels the most significant game-play in the US generics market.

WHO IS MAKING THE BIGGEST SPLASH

Reviews the leading sources of information on medical research.

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Newport Horizon Premium is the critical product targeting and global business development system from Thomson Reuters, the industry authority on the global generics market.

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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