MOVERS AND SHAKERS

A PHARMA MATTERS REPORT.

OCTOBER – DECEMBER 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.

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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

Despite a struggling economic climate worldwide, 2009 proved to be a productive year for the generic pharmaceutical industry. Companies from 15 countries received a total of 448 ANDA approvals, down only slightly from the 463 approvals received the previous year. U.S. companies received 151 approvals, more than any other country, followed closely by Indian companies that secured 139 nods.

Just as ANDA approvals were on the increase, so were patent challenges on the rise. No less than 61 molecules or combinations endured Paragraph IV patent challenges, nearly double the 33 such challenges mounted in 2008 and far above the 39 recorded in 2007. Products facing challenges in 2009 included such blockbusters as:

- Docetaxel anhydrous, Sanofi-Aventis' antineoplastic product marketed in the U.S. as Taxotere®
- Efavirenz, the anti-HIV product marketed in the U.S. by Bristol-Myers as Sustiva®
- Pregabalin, marketed in the U.S. by Pfizer under the Lyrica® name

Companies can expect the barrage of challenges to continue now that many generic companies are beginning to screen intellectual property (IP) on potential Paragraph IV target products well before those drugs are approved and patents are listed in the Orange Book.

As expected, healthcare reform held center stage on the U.S. legislative agenda throughout 2009. However, despite this, Congress failed to finalize a pathway for biosimilar products during the year, a key goal for the U.S. generic industry. Provisions in both the House and Senate versions of the bill provide a framework for follow-on biologics products to enter the U.S. market, but leaders in the generic industry are not pleased with several aspects of the proposed legislation. In particular, the 12-year data exclusivity period for reference products, that is present in both House and Senate versions of the bill, faces huge opposition from the generic industry. As lawmakers work toward combining the House and Senate bills, the debate over years of exclusivity remains unresolved due to continued pressure from the White House urging congressional leadership to instead consider a seven-year period. Topics such as data exclusivity, product interchangeability, evergreening, and FDA scrutiny, threaten to further prolong the establishment of the pathway for biosimilar drugs in 2010.

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.

The desire to gain access to biologics capabilities prompted several major acquisitions in 2009. At the end of June, Mylan and Biocon announced an exclusive collaboration on the development, manufacture, supply, and commercialization of a number of high-value generic biologic compounds. The deal gives manufacturer Biocon access to the global footprint Mylan has built through acquisitions of Merck Generics and Matrix. In return, Mylan gains exclusive commercialization rights in a number of countries, including the U.S.

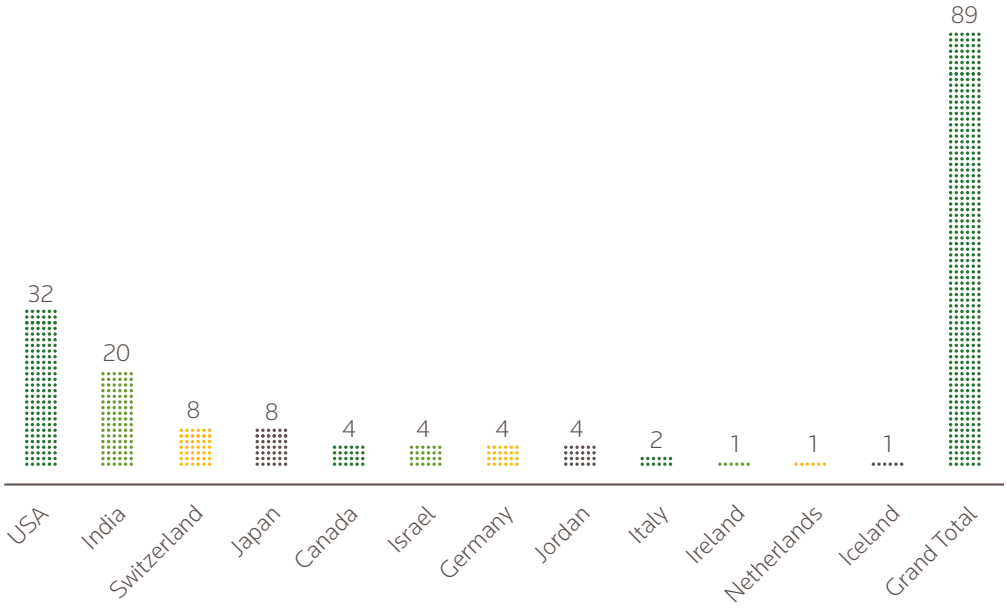
The year's most significant acquisition in the generic space was Watson Pharmaceuticals' purchase of Arrow Group for $1.75 billion. Arrow's presence in more than 20 countries will dramatically boost Watson's international showing, plus Watson may be able to leverage Arrow's biologics capabilities, since the latter held a 36 percent stake in Eden Biodesign. Watson has since extended its interest in Eden to full ownership in a recent $15M deal.

Big Pharma, among them Sanofi-Aventis, GlaxoSmithKline , and Pfizer, also continued to show a strong interest in the generic space in the U.S. and emerging markets.

That's a brief recap of happenings on the generic stage in 2009. Now, let's take a closer look at the fourth quarter's ANDA approvals, Paragraph IV challenges, and noteworthy deals.

SECTION II: ANDA APPROVALS

TOTAL 'A'-RATED ANDAS BY COUNTRY OF ORIGIN OF APPLICANT FOR OCTOBER TO DECEMBER 2009

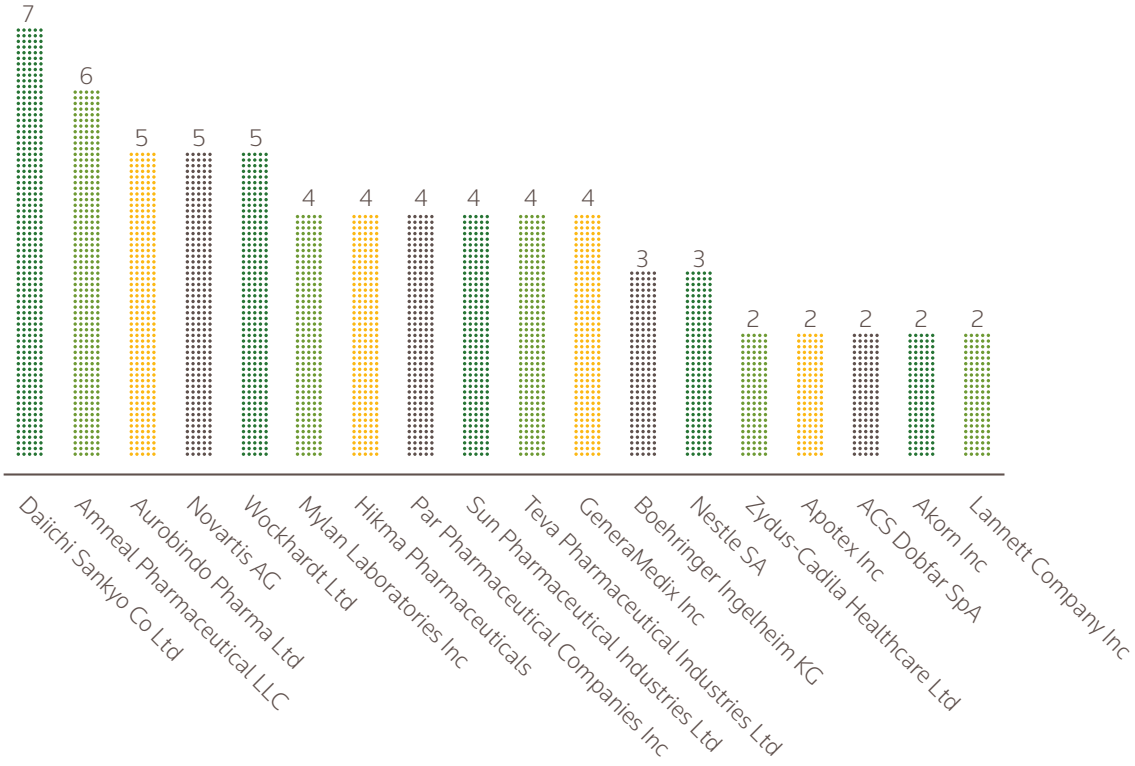


During fourth quarter 2009, U.S.-based companies again earned top standing in terms of final approvals, with 32 approvals going to 16 different groups, down from 44 approvals going to 24 groups in the third quarter.

As in the third quarter, Indian groups came in second, with 20 approvals going to eight groups, down from 39 approvals going to 13 groups the previous quarter. Switzerland and Japan, each with eight approvals going to two groups, were in the third and fourth places.

Groups based in Canada, Israel, Germany, Jordan, Italy, Ireland, Netherlands, and Iceland also received final approvals this quarter.

GROUPS WITH THE MOST 'A'-RATED ANDA APPROVALS FOR OCTOBER TO DECEMBER 2009



During fourth quarter 2009, Japan's Daiichi Sankyo, which owns Ranbaxy (India), received seven ANDA approvals, earning it top ranking. U.S.-based Amneal Pharmaceuticals with six approvals and India's Aurobindo with five approvals were in second and third place respectively.

In comparison, the third quarter saw Israel's Teva Pharmaceutical on top of the list with nine ANDA approvals, while India's Aurobindo and Sun Pharmaceutical Industries with eight and six ANDAs respectively ranked second and third.

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.

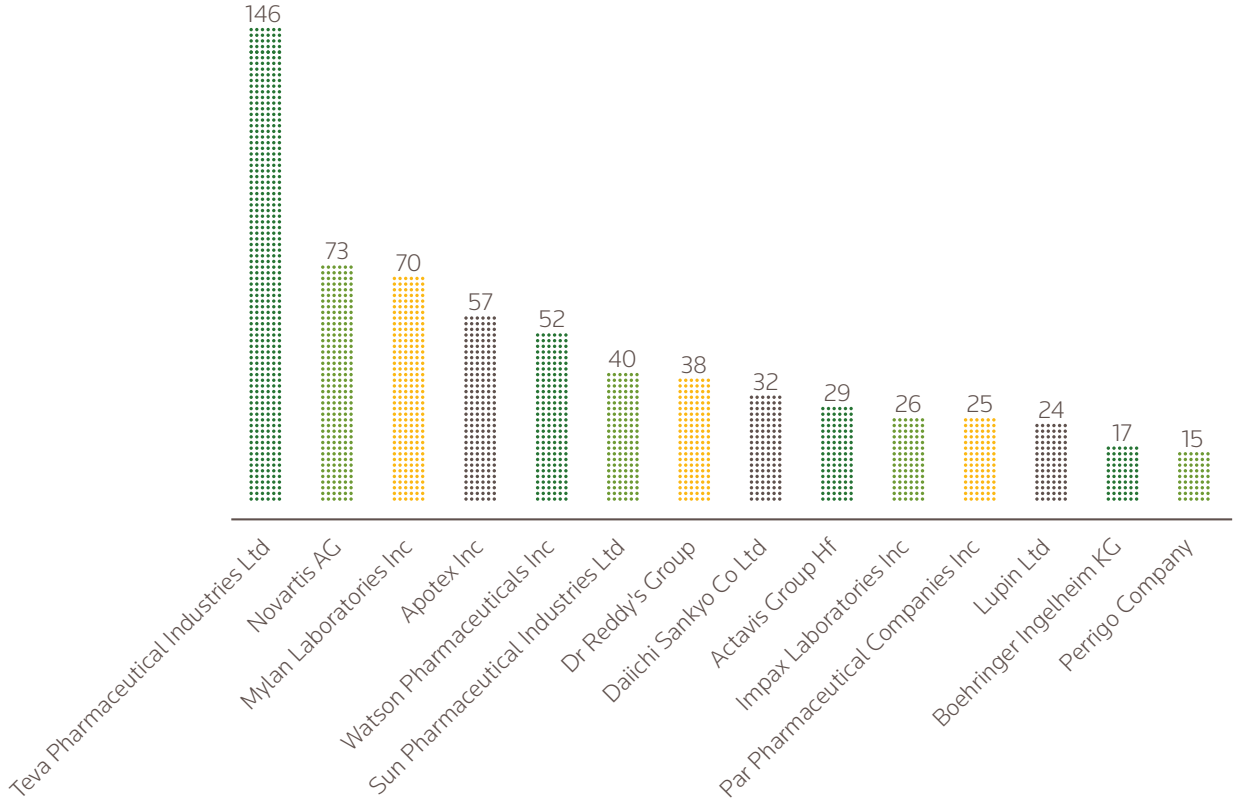
WHAT IS A PARAGRAPH IV CHALLENGE?

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.

SECTION III: PARAGRAPH IV CHALLENGES

Fourth quarter 2009 brought first Paragraph IV patent challenges on 16 new active ingredients or combinations. The previous quarter, 10 such challenges were recorded.

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



Teva remains by far the most prolific filer of ANDAs that include patent challenges. At the time of this report, we linked the company to challenges on 146 products, up from 140 the quarter before.

Novartis (Sandoz) replaced Mylan in second place with links to patent challenges on 73 products, up from 66 the previous quarter. Mylan ranked third this quarter with links to patent challenges on 70 products, up from 68 the preceding quarter.

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

ACTIVE INGREDIENT: adapalene POSTED BY FDA: 7 December 2009 BRAND NAME: Differin® NDA HOLDER: Galderma	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Differin (adapalene) topical gel, 0.30%: Tolmar. • The Orange Book lists three patents covering Differin topical gel, 0.30%: U.S. Patent 4,717,720 includes both drug substance and drug product claims concerning Differin topical gel. It expires May 31, 2010. U.S. Patent RE34,440 covers a process for treating dermatological, rheumatismal, respiratory, or ophthalmological disease with compounds such as adapalene. This patent also expires May 31, 2010. U.S. Patent 7,579,377 concerns the use of adapalene for the treatment of dermatological disorders. This patent expires on February 23, 2025. In a suit against Tolmar, Galderma alleges infringement of this patent.
ACTIVE INGREDIENTS: amoxicillin, clavulanate potassium POSTED BY FDA: 5 November 2009 BRAND NAME: Augmentin XR® NDA HOLDER: GlaxoSmithKline	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Augmentin XR (amoxicillin/clavulanate potassium) extended-release tablets. We do not know the identity of the filer at this time. • When the reported ANDA for a generic version of Augmentin XR extended-release tablets was submitted, the Orange Book listed five patents for that product, all expiring on April 4, 2020. Augmentin XR has been discontinued and no longer appears in the Orange Book. • A number of other generic amoxicillin/clavulanate potassium products have been on the market for years.
ACTIVE INGREDIENT: arformoterol tartrate POSTED BY FDA: 22 December 2009 BRAND NAME: Brovana® NDA HOLDER: Sepracor	• A least one company has filed an ANDA with Paragraph IV certification for a generic version of Brovana (arformoterol tartrate) inhalation solution: Teva. • The eight patents listed for Brovana inhalation solution in the Orange Book will expire between April 3, 2012 and November 9, 2021. In its suit against Teva, Sepracor alleges infringement of U.S. Patent 6,472,563, U.S. Patent 6,720,453, and U.S. Patent 7,145,036. Those patents will expire on November 9, 2021. • Cipla submitted a DMF for arformoterol tartrate in August 2009.

ACTIVE INGREDIENT: armodafinil POSTED BY FDA: 5 November 2009 BRAND NAME: Nuvigil® NDA HOLDER: Cephalon	• At least five companies have filed ANDAs with Paragraph IV certification for generic versions of Nuvigil (armodafinil) tablets: Actavis, Mylan, Sandoz, Teva, and Watson. • The Orange Book lists four patents covering Nuvigil tablets: U.S. Patent 4,927,855 claims the stereospecific form of modafinil. The pediatric exclusivity associated with the patent will expire on October 22, 2010. U.S. Patent 7,132,570 concerns crystalline forms of optical enantiomers of modafinil. The pediatric exclusivity associated with this patent expires on June 18, 2024. U.S. Patent 7,297,346 concerns formulations of modafinil, including diluents, disintegrants, binders, and lubricants. The pediatric exclusivity associated with this patent expires on May 29, 2024. U.S. Patent RE37,516 claims modafinil of a defined particle size. Pediatric exclusivity associated with this patent expires on April 6, 2015. • The FDA reports that at the time of the first ANDA submission for a generic version of Nuvigil tablets, Actavis, Teva, and Matrix held active DMFs for armodafinil. In addition, Lupin has claimed to hold a U.S. DMF for armodafinil as early as 2008. Amino Chemicals submitted a DMF for armodafinil in October 2009.
ACTIVE INGREDIENT: atazanavir sulfate POSTED BY FDA: 5 November 2009 BRAND NAME: Reyataz® NDA HOLDER: Bristol-Myers Squibb	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Reyataz (atazanavir sulfate) capsules: Teva. • The are two Orange Book patents covering Reyataz capsules and Teva's ANDA includes Paragraph IV certification to both: U.S. Patent 5,849,911 covers atazanavir and salts and will expire on June 20, 2017. U.S. Patent 6,087,383 claims atazanavir bisulfate specifically and expires on December 21, 2018. • At the time Teva submitted its ANDA for a generic version of Reyataz capsules, Cipla, Emcure, Matrix, and Solmag held active DMFs for atazanavir sulfate.
ACTIVE INGREDIENT: caspofungin acetate POSTED BY FDA: 5 November 2009 BRAND NAME: Cancidas® NDA HOLDER: Merck	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Cancidas (caspofungin acetate) for injection: Teva. • In its suit against Teva, Merck alleges infringement of three of the five Orange Book patents covering Cancidas for injection: U.S. Patent 5,378,804 claims caspofungin specifically. The pediatric exclusivity associated with this patent expires on September 16, 2013. U.S. Patent 5,514,650 includes composition and method of use claims. The patent's pediatric exclusivity expires on July 26, 2015. U.S. Patent 5,952,300 claims formulations of caspofungin. Pediatric exclusivity associated with this patent expires September 28, 2017. • Teva submitted a DMF for caspofungin acetate in May 2009.

ACTIVE INGREDIENT: cisatracurium besylate POSTED BY FDA: 5 November 2009 BRAND NAME: Nimbex® NDA HOLDER: Abbott	• At least one company has filed ANDAs with Paragraph IV certification for generic versions of Nimbex (cisatracurium besylate) injection products: Sandoz. • The Orange Book lists just one patent covering Nimbex injection: U.S. Patent 5,453,510 concerns a method of producing neuromuscular blockade and will expire on September 26, 2012. • Gland Pharma holds the only reported DMF for cisatracurium besylate filed before the submission of the first reported ANDA for a generic version of Nimbex in August 2009. Teva submitted a DMF for cisatracurium besylate in September 2009.
ACTIVE INGREDIENT: colesevelam HCl POSTED BY FDA: 7 December 2009 BRAND NAME: Welchol® NDA HOLDER: Daiichi Sankyo	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Welchol (colesevelam HCl) tablets: Impax Laboratories. • The Orange Book lists ten patents covering Welchol tablets, which have been granted pediatric exclusivities that expire between October 29, 2014 and October 17, 2022. In their suit against Impax, Daiichi and Genzyme allege infringement of U.S. Patent 5,607,669 and U.S. Patent 5,693,675. Genzyme is the owner of these patents and Daiichi Sankyo is an exclusive licensee in the United States. • At the time of the first ANDA submission for a generic version of Welchol tablets, Formosa Laboratories held the only DMF for colesevelam HCl reported by the FDA.
ACTIVE INGREDIENTS: ezetimibe, simvasatin POSTED BY FDA: 5 November 2009 BRAND NAME: Vytorin® NDA HOLDER: Merck/Schering-Plough	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Vytorin (ezetimibe/simvastatin) tablets: Mylan. • The Orange Book lists two patents for Vytorin, both of which Schering alleges are infringed by Mylan: U.S. Patent 5,486,966 includes drug product claims and method of use claims for the reduction of plasma cholesterol in a mammal and for the treatment of primary hypercholesterolemia, mixed hyperlipidemia, and/or homozygous familial hypercholesterolemia. The pediatric exclusivity associated that patent will expire on March 21, 2014. U.S. Patent RE37, 721 includes both drug substance and drug product claims along with a use claim for the reduction of plasma cholesterol in a mammal. Pediatric exclusivity associated with this patent expires on April 25, 2017.

ACTIVE INGREDIENT: fulvestrant POSTED BY FDA: 7 December 2009 BRAND NAME: Faslodex® NDA HOLDER: AstraZeneca	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Faslodex (fulvestrant) injection: Teva. • The Orange Book lists two patents covering Faslodex injection, both of which AstraZeneca alleges are infringed by Teva. U.S. Patent 6,774,122 and U.S. Patent 7,456,160 are both directed to a sustained release formulation of fulvestrant and its use in the treatment of hormone receptor positive metastatic breast cancer in postmenopausal women. Both patents expire on January 9, 2021. AstraZeneca indicates that Teva's notice letter included allegations of invalidity with respect to the patents, but did not argue non-infringement. • Teva and ScinoPharm held the only DMFs for fulvestrant at the time of the first ANDA submission for a generic version of Faslodex injection.
ACTIVE INGREDIENT: glycopyrrolate POSTED BY FDA: 16 October 2009 BRAND NAME: Robinul® Forte NDA HOLDER: Sciele Pharma	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Robinul Forte (glycopyrrolate) tablets, 1.5 mg. Robinul Forte tablets have not been approved in that strength. We do not know the identity of the ANDA filer at this time. • The Orange Book lists only one patent covering Robinul Forte tablets: U.S. Patent 7,091,236 concerns methods of increasing the bioavailability of drug products containing glycopyrrolate. The patent expires on April 24, 2024.
ACTIVE INGREDIENTS: niacin, simvastatin POSTED BY FDA: 22 December 2009 BRAND NAME: Simcor® NDA HOLDER: Abbott	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Simcor (niacin/simvastatin): Teva. • The Orange Book lists eight patents for Simcor extended-release tablets. They will expire between September 20, 2013 and March 15, 2018. Abbott alleges infringement of all eight patents in its suit against Teva.
ACTIVE INGREDIENT: ramelteon POSTED BY FDA: 5 November 2009 BRAND NAME: Rozerem® NDA HOLDER: Takeda	• At least two companies have filed ANDAs with Paragraph IV certification for generic versions of Rozerem (ramelteon) tablets: Teva and Watson. • The Orange Book lists only one patent covering Rozerem tablets: U.S. Patent 6,034,239 claims ramelteon specifically and will expire on March 6, 2017. The USPTO issued an ex parte reexamination certificate for this patent on May 20, 2008. • Teva submitted a DMF for ramelteon on July 22, 2009, which was the same day it submitted its ANDA for a generic version of Rozerem tablets.

ACTIVE INGREDIENT: sibutramine HCl POSTED BY FDA: 5 November 2009 BRAND NAME: Meridia® NDA HOLDER: Abbott	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Meridia (sibutramine HCl) capsules: Apotex. • The Orange Book lists only one patent covering Meridia capsules: U.S. Patent 5,436,272 is directed to the treatment of obesity. The pediatric exclusivity associated with the patent will expire on January 25, 2013. • At the time the first ANDA with Paragraph IV certification for a generic version of Meridia capsules was submitted, Cipla, Divi's Laboratories, Matrix, SMS Pharmaceuticals, Solmag, and Symed Laboratories held active DMFs for sibutramine HCl.
ACTIVE INGREDIENT: tigecycline POSTED BY FDA: 5 November 2009 BRAND NAME: Tygacil® NDA HOLDER: Wyeth	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of Tygacil (tigecycline) for injection: Sandoz. • The Orange Book lists two patents covering Tygacil for injection: U.S. Patent RE40,183 includes both drug substance and drug product claims for Tygacil. The patent's term was extended by 1,335 days and will expire on April 9, 2016. U.S. Patent RE40,086 claims a method of treating bacterial infections with tigecycline. It expires on June 25, 2013. Wyeth alleges infringement of U.S. Patent RE40,183 in its suit against Sandoz. • At the time of the first ANDA submission for a generic version of Tygacil, Sandoz, Teva, and Unimark held active DMFs for tigecycline.
ACTIVE INGREDIENT: tobramycin POSTED BY FDA: 5 November 2009 BRAND NAME: Tobi® NDA HOLDER: Novartis	• At least one company has filed an ANDA with Paragraph IV certification for a generic version of TOBI (tobramycin) inhalation solution: Teva. • The Orange Book lists only one patent covering TOBI inhalation solution: U.S. Patent 5,508,269 claims aerosol formulations containing an aminoglycoside, including tobramycin, and the use of these formulations to treat cystic fibrosis patients with pseudomonas aeruginosa. The patent expires on October 19, 2014. • Teva holds an active DMF for tobramycin. Other holders of active DMFs for tobramycin at the time of the reported ANDA submission for a generic version of TOBI inhalation solution include Chongqing Daxin Pharmaceutical Company and Livzon New North River Pharmaceutical Company.

SECTION IV: NOTABLE DEALS

With many deals in the making, the generic space was anything but quiet during Q4 2009. One of the most active players was Hospira. In October 2009, Hospira entered into an agreement with Celltrion to manufacture, market, and distribute eight of Celltrion's biogeneric products in the United States, Europe, Australia, New Zealand, and Canada.

In December, Hospira agreed to acquire Orchid Chemicals and Pharmaceuticals' generic injectable pharmaceutical business for approximately $400 million. The company signed a long-term, exclusive agreement for Orchid to supply the active pharmaceutical ingredients (API) for the acquired generic business, building on an existing product development and commercialization relationship between the two companies.

Other notable deals were also underway. In December 2009, Watson Pharmaceuticals, Inc. acquired the Arrow Group through an exchange of cash and stock. The result is a combined company with more than $3 billion in annual revenue, operations in 20 countries, and a strong product franchise and pipeline. As a result of this acquisition, IMPAX Laboratories acquired rights to two ANDAs: Watson's ANDA for cabergoline (Dostinex®) and Cobalt's (an Arrow subsidiary) pending ANDA for dronabinol (Marinol®).

Big Pharma also made inroads into the generic arena through a number of partnerships and acquisitions. In December, GlaxoSmithKline took a 19 percent stake in Aspen Pharmacare, the largest generic drug maker in Africa. This move is in keeping with Glaxo's strategy to sell branded generic drugs in emerging markets and rely less heavily on blockbuster medicines in Western countries. Glaxo also has arranged deals with companies in China and with Dr. Reddy's in India.

Also in December, Pfizer announced its plans to expand its generic business in Japan. The company could use its Japanese plants to make generic products for the local market or source them from partners to lower costs. For more information about the opportunities and challenges facing foreign companies interested in pursuing the generic market in Japan, read go.thomsonreuters.com/japanese_whitepaper.

SECTION V: OPENING MOVES

Based on our research of ANDA filings and Paragraph IV challenges, this section highlights a few of the organizations making game-changing plays in the U.S. generics industry.

HISAMITSU PHARMACEUTICAL CO., INC.

Hisamitsu Pharmaceutical Co, headquartered in Tosu, Japan, specializes in transdermal delivery methods. The company is committed to increasing its presence in the United States and, as part of that strategy, acquired all the outstanding shares of Noven Pharmaceuticals, making the Miami-headquartered company its wholly-owned subsidiary. Hisamitsu plans to leverage Noven's expertise in transdermal drug development, clinical and regulatory affairs, manufacturing, and marketing to solidify its position in the U.S. market.

In October 2009, Hisamitsu announced the FDA approval of its first ANDA, notably for a fentanyl transdermal system of chronic pain management. This drug joins five other generic versions of the patch in the marketplace. It is worth noting that a number of fentanyl patches, including those by Janssen, Watson, and Actavis, have gone through recalls. Hisamitsu's matrix type transdermal patch is distributed in the United States by Apotex, under an exclusive agreement between the two companies. The drug is manufactured in Hisamitsu's factory in Carlsbad, California.

PHARMAFORCE, INC.

PharmaForce, Inc., based in Columbus, Ohio, was founded in 1999. Until recently, it was a privately held specialty pharmaceutical company specializing in sterile (injectable, ophthalmic, otic, and nasal) products. At the end of December 2009, Luitpold Pharmaceuticals, a New York-based subsidiary of Daiichi Sankyo, acquired PharmaForce. The deal included PharmaForce's dose facility, located in Hilliard, Ohio, where the company also handles cytotoxic and other highly potent compounds, along with an R&D site. The PharmaForce product line will be marketed by Luitpold's subsidiary, American Regent, Inc.

When announcing the acquisition, the representatives of Luitpold explained that the move allows them to diversify their product portfolio, expand their R&D pipeline, increase manufacturing capacity, and establish a base for taking advantage of the rapidly growing generic injectable market. In Q4 2009, PharmaForce received approvals for a number of its ANDAs, including those for nicardipine HCl injection, clonidine HCl injection, and dorzolamide drops.

In 2007, PharmaForce became embroiled in a lawsuit by Allergan against Exela regarding Exela's ANDA for brimonidine ophthalmic solution. Allergan alleged that PharmaForce performed formulation and development work for the proposed generic product. On November 23, 2009, the court entered judgments in favor of Allergan, finding that the Exela product would infringe the asserted claims of the patents-in-suit and declaring the patents to be valid and enforceable.

CLARIS LIFESCIENCES LIMITED

Ahmedabad, India-based Claris Lifesciences, a manufacturer and marketer of injectable products in approximately 80 countries, got its start in 2000. The company's products cover a range of therapeutic categories such as anti-infectives, clinical nutrition, dialysis, oncology, and cardiac care. Claris has aspirations to become a leading player in the global injectables market, including in the United States, Japan, and China. The company has filed at least 18 ANDAs in the United States and, so far, has received approval for four, covering injectable versions of ciprofloxacin, metronidazole, and ondansetron.

In May 2009, Claris entered into a partnership with Pfizer to commercialize off-patent sterile injectable drugs in the United States, Canada, Australia, New Zealand, and Europe. Through Pfizer, Claris hopes to enhance its presence in regulated markets, while remaining focused on sterile injectables.

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

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 400 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 have been 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.

HOW TO SUBSCRIBE

The *Newport Phase III Drugs Module* is an optional subscription module that may be added on a per-seat basis to *Newport Premium*™ and *Newport Global*™ product configurations for an additional annual charge. A subscription to a base system is required before purchasing this module.

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Do you have all the background facts at hand when making your next deal, choosing a partner, scouting the competition, or looking for your next acquisition?

The *Newport Generic Deals Module* covers many thousands of merger, acquisition, development, supply, manufacturing, joint venture, patent settlement and authorized generic deals involving generic companies worldwide since 1999.

For these deals, you will be able to view the parties involved, transaction date, dollar value, deal type and a short summary description. A new focused search enables comprehensive searching and analysis of global generic deal-making activity.

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THE JAPANESE GENERIC DRUG MARKET: OPPORTUNITIES AND STRATEGIES FOR SUCCESS

The Japanese generic drug industry may seem all but closed to your company — difficult to penetrate, harder still to achieve long-term market share. In an important new white paper, Thomson Reuters reveals the strategies that can guide your campaign and ensure you succeed.

In *The Japanese generic drug market: opportunities and strategies for success*, Thomson Reuters draws on the unique intelligence of *Newport Premium*™ and *Thomson Pharma*® to reveal exactly what's happening in the Japanese generic drug market, and predicts how the situation may change under the Democratic Party of Japan (DPJ) administration.

Written with the cooperation of generic industry experts in Japan, the white paper shows how the country is already embracing foreign drugs, active pharmaceutical ingredients (APIs) and generic companies. It explores the public perception of generic drugs in Japan, the attitude of Japanese physicians and pharmacies, the importance of quality and brand equivalence, and the drug reimbursement, approval, exclusivity, distribution, and other issues that foreign companies need to be aware of.

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Sue Besaw
Phone: + 1 215 823 1840
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