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DOJ: Former BMS Exec Lied to Government About Generic Plavix

Andrew Bodnar, a former Bristol-Myers Squibb (BMS) senior vice president, has been indicted for lying to the federal government about a patent deal involving the blood-thinner Plavix.

The Justice Department said it is charging Bodnar with violating the Federal False Statements Act, which carries a maximum sentence of five years and a fine of \$250,000.

In its indictment filed Wednesday in the U.S. District Court for the District of Columbia, Justice charges that Bodnar lied to the FTC about assurances he gave to Canadian drugmaker Apotex regarding the launch of generic Plavix (clopidogrel bisulfate). BMS markets Plavix with sanofi-aventis.

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Controversial Patent Reform Bill Hits Roadblock in Senate

A controversial patent reform bill has stalled in the Senate because of a disagreement over the bill's damages provision.

Sen. Patrick Leahy (D-Vt.), chairman of the Senate Judiciary Committee, delayed the introduction of the Patent Reform Act, S. 1145 because of disagreements with Sen. Arlen Specter (R-Pa.), the committee's ranking member, about language in the bill's damages provision, a Judiciary Committee aide said.

Earlier this year, the Commerce Department notified the Judiciary Committee that the damages section, which would establish a codified system for courts to use when calculating reasonable royalty awards in patent litigation, would seriously harm the U.S. intellectual property system (*Generic Line*, Feb. 20). In a Feb. 4 letter to Leahy and other committee members, Commerce said the bill's damages provision "will create more problems than it solves."

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In 2006, sanofi, BMS and Apotex had been negotiating to settle litigation over the validity of the '265 patent covering Plavix. The FDA granted final approval to Apotex's application to market a generic version of the drug earlier that year (*Generic Line*, Feb. 8, 2006).

At the time, BMS was subject to a consent decree for unrelated conduct that required it to submit any proposed patent settlements for review and advisory approval to the FTC. The commission had warned the company that it would not approve a settlement if BMS agreed not to launch its own generic version of Plavix.

At a 2006 meeting, Bodnar assured Apotex that BMS would not launch a generic version of Plavix if Apotex agreed not to launch its generic version until 2011 when the '265 patent expires, according to the indictment. Justice alleges that Bodnar lied to the FTC by not telling it of his assurance to Apotex.

In June 2006, the three companies submitted a modified settlement to the FTC, a move that halted the patent case brought by sanofi and BMS against Apotex. But states' attorneys general, who must approve of such patent settlements, rejected the agreement the following month.

Despite the decision by the attorneys general, Apotex launched its generic Plavix that August, prompting sanofi to move to enjoin Apotex's marketing as an infringement. A preliminary injunction, which still stands, was entered. Last June, the U.S. District Court for the Southern District of New York upheld the validity and enforceability of the '265 patent. The case is now before the U.S. Court of Appeals for the Federal Circuit.

Separately, Apotex has brought a suit against HHS Secretary Michael Leavitt, FDA Commissioner Andrew von Eschenbach and the FDA in the U.S. District Court for the District of Columbia. The company is asking the court to set aside the FDA's refusal to stay the effectiveness of an ANDA for a generic version of Plavix filed by Indian drugmaker Dr. Reddy's Laboratories.

Absent a stay, Dr. Reddy's, whose ANDA for clopidogrel bisulfate tablets was approved last January, will be allowed to distribute its generic Plavix during the remainder of the 180 days during which Apotex is entitled to be the sole generic manufacturer.

Apotex is seeking to protect its remaining 156 days of exclusivity and has asked the court to enjoin the FDA from approving further clopidogrel bisulfate ANDAs until the company's period of exclusivity is over or the '265 patent expires. — Elizabeth Jones

MHRA Gives Green Light To Study of Insmed FOB

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has given permission to Virginia-based Insmed to start its first clinical study with a follow-on biologic.

The product, INS-19, is a recombinant form of human granulocyte colony-stimulating factor, which selectively stimulates production of certain white blood cells in patients undergoing chemotherapy or bone marrow transplants. It is a follow-on of Amgen's Neupogen (filgrastim), whose patent expires in 2013.

Results from the Phase I study, which will compare the safety and bioequivalence of INS-19 with Neupogen, are expected in the second half of this year. Geoffrey Allan, Insmed's CEO, said the company will use data generated from the trial and results from preclinical studies in discussions with the FDA to establish a Phase III trial protocol. The study is one of two planned this year as part of Insmed's follow-on biologic program.

In February, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted positive opinions for biosimilar versions of Neupogen made by ratiopharm, CT Arzneimittel and Teva Pharmaceutical Industries. Neupogen had worldwide sales of approximately \$1.3 billion in 2007, according to Amgen. — Elizabeth Jones

FDA Clears Generic Wellbutrin, Consumer Advocates Skeptical

The FDA has concluded that Teva's bupropion XL 300 mg, a generic version of Wellbutrin XL, is a safe and effective choice for patients with depression.

Questions about the safety and efficacy of Teva's bupropion XL arose after the agency received 85 postmarketing reports of patients experiencing side effects after switching from Glaxo-SmithKline's Wellbutrin (bupropion HCl) to the generic version. The reports were documented between Jan. 1 and June 30, 2007.

In 78 of the cases, there was a reported loss of antidepressant effect following the switch. In addition, a number of patients experienced the onset or worsening of side effects, which included headache, gastrointestinal disorders, fatigue and anxiety. More than half of the patients who switched back to Wellbutrin XL 300 mg reported improvement of depression or abatement of side effects.

After evaluating the adverse event reports and other data, the FDA has decided Teva's bupropion is bioequivalent to, and interchangeable with, Wellbutrin XL. "The recurrent nature of MDD [major depressive disorder] offers a scientifically reasonable explanation for the reports of lack of efficacy following a switch to a generic product," the FDA report says.

Not everyone agrees with the agency's conclusions. ConsumerLab.com, which evaluates health and nutrition products, and *The People's Pharmacy*, a syndicated newspaper column, expressed disappointment with the FDA's report, which it considered to be inadequate.

"No safety or efficacy testing of this novel 300-milligram formulation appears to have been conducted nor reviewed by the FDA. In fact, the FDA does not have bioequivalence data for this product," Tod Cooperman, ConsumerLab.com's president, said.

"The FDA is misleading the public by publishing a positive review, which actually provides no data for the 300-milligram product — the strength about which people are complaining," Joe Graedon of *The People's Pharmacy* said.

Last year, people posting to www.people.spharmacy.com indicated they experienced a return of depressive symptoms after switching from brand Wellbutrin to generic. After switching back to the brand drug, patients said their symptoms were brought under control.

ConsumerLab.com subsequently conducted tests with brand and generic Wellbutrin. The group said data showed the generic product released the active ingredient at a different rate than Wellbutrin XL. The tests also indicated that two generic Wellbutrin sustained-release products released the drug at different rates, according to ConsumerLab.com.

"Generic drugs can significantly reduce pharmaceutical costs, but consumers and healthcare providers need to be aware of the potential differences among products," Cooperman said at the time. "Even if the active ingredient is the same, generics that release the ingredient at a different rate may act differently in the body. Generics are not clinically tested for safety and efficacy, so the consumer will be the first to find out if there is a problem."

GPhA scoffed at the report, urging consumers to side with the FDA and the U.S. Pharmacopeia over a company "that contracts out testing for headlines."

"The FDA reviews all generics to ensure that they are the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use," GPhA said. "The inadequate testing done by ConsumerLab.com was based on information that is simply not relevant to the testing of generics." (*Generic Line*, Oct. 17, 2007).

The FDA's report is available at www.fda.gov/cder/drug/infopage/bupropion/TE_review.htm. ConsumerLab.com's full report is available to subscribers at www.consumerlab.com/results/wellbutrin-bupropion.asp. — Elizabeth Jones

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The provision aims “to give judges and juries better guidance on the proper way to calculate a reasonable royalty,” according to a Jan. 24 Judiciary Committee report on the bill. Rather than leaving juries to calculate royalties using various factors, the Patent Reform Act would require judges to tell juries which factors to consider. The judge also would decide whether royalties are to be calculated based on the entire market value of the invention or on the specific patent’s contribution over prior art.

The proposed method for calculating damages is too narrow and would discourage innovation, according to Commerce. Judges should be required to identify all possible factors to use when calculating reasonable royalties, and juries should be required to apply all factors.

Specter, who has voiced concerns with the bill, raised issues with the damages language earlier this month. The window for considering the bill at that time closed, and the language is still in dispute, the Judiciary Committee aide said. No date has been set for further consideration of the bill. “It’s difficult to schedule floor time for anything these days,” the aide added.

Last year, a version of the bill, H.R. 1908, passed the House of Representatives. A Judiciary Committee staff member said lawmakers are committed to passing the legislation before the end of the 110th Congress (*Generic Line*, Nov. 28, 2007).

Industry also has spoken out against the bill. It would make the pharmaceutical marketplace “much more friendly for [patent] infringers,” Biotechnology Industry Organization (BIO) President and CEO Jim Greenwood has said.

However, BIO supports some of the bill’s provisions. The House committee adopted an amendment that would revoke the ability of defendants to use best mode as a defense in patent infringement cases, which BIO praised. Specter had proposed a similar amendment in the Senate version, but it was not included.

The Generic Pharmaceutical Association (GPhA) has “significant concerns” over the House bill, GPhA President and CEO Kathleen Jaeger said. The group opposes a provision in the bill that would codify the inequitable conduct defense.

Earlier this month, PhRMA said the bill would need more work before it is ready for floor consideration. Echoing Commerce’s concerns, the group said the legislation as written would reduce incentives for innovation. — April Astor

Merck, J&J Lose in Pepsid Patent Case

Merck, Johnson & Johnson (J&J) and J&J’s operating unit, McNeil, lost their latest battle to prevent Perrigo from marketing a generic version of the heartburn drug Pepsid.

The U.S. Court of Appeals for the Federal Circuit affirmed a lower court’s decision that invalidated as obvious the ’340 patent related to the formulation of Pepsid Complete (famotidine/calcium carbonate/magnesium hydroxide). In the case, *McNeil-PPC, Inc., Merck, Inc. and Johnson & Johnson – Merck Consumer Pharmaceuticals Company v. Perrigo*, the three plaintiff companies sued Perrigo for infringing on the patent.

Last June, the U.S. District Court for the Southern District of New York ruled the patent invalid (*Generic Line*, June 27, 2007). The court noted issues with the patent existed from the beginning and “the Patent Office repeatedly rejected McNeil’s original claims, primarily on the ground of obviousness,” even though it issued the patent in October 1998.

Perrigo now may sell a generic version of the OTC drug, which the company said has annual retail sales of approximately \$90 million. The company recently secured FDA approval of a generic version of Pepsid Complete, the chewable formulation of the OTC Pepsid heartburn franchise. Perrigo has been waiting for the appeal to be resolved before launching the drug with 180-day market exclusivity in the third quarter of the year. — Yuliya Melnyk

AstraZeneca, Ranbaxy Settle Nexium Suit, Ink Agreements

AstraZeneca and Indian drugmaker Ranbaxy Laboratories have filed a consent judgment that will settle a patent infringement lawsuit over Nexium. The companies also signed agreements covering the manufacture of Nexium and the distribution of authorized generic versions of Prilosec and Plendil.

AstraZeneca originally filed the case November 2005 in the U.S. District Court for the District of New Jersey. It claimed Ranbaxy had infringed on six patents — '504, '192, '872, '810, '085 and '789 patents — with the submission of an ANDA for generic Nexium (esomeprazole magnesium) 20 mg and 40 mg, a treatment for gastroesophageal reflux disease. AstraZeneca asked the court to declare the effective date for any approval of Ranbaxy's ANDA to be later than May 3, 2020, the expiration of the last patent involved in the suit.

Under the settlement agreement, Ranbaxy conceded that all six patents are valid and enforceable and accepted that four of the patents would be

infringed by the unlicensed sale of the proposed generic product. However, it will be allowed to sell its generic Nexium when the '192 and '872 patents expire in May 2014, AstraZeneca said. AstraZeneca's Nexium patent infringement litigations against Teva/Ivax and Dr. Reddy's Laboratories are ongoing.

Separately, AstraZeneca and Ranbaxy signed an agreement under which Ranbaxy will formulate a portion of AstraZeneca's U.S. supply of Nexium starting in May 2010. The agreement includes provisions allowing Ranbaxy to manufacture the active pharmaceutical ingredient in Nexium starting in May 2009. AstraZeneca also has designated Ranbaxy the U.S. distributor for authorized generic versions of Plendil (felodipine), a treatment for hypertension and angina, and Prilosec (omeprazole) 40 mg, a heartburn drug.

Nexium had sales of \$5.2 billion in 2007, down 2 percent from 2006. Prilosec had sales of \$1.1 billion, down from \$1.3 billion in 2006. Sales of Plendil fell 7 percent in 2007 from 2006 to \$271 million. — Elizabeth Jones

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Nu-Pharm Loses Appeal In Depakote Case

Canadian drugmaker Nu-Pharm has lost its latest bid to force the FDA to approve its ANDA for a generic version of Abbott's epilepsy drug Depakote.

In January, Nu-Pharm filed suit in the U.S. District Court for the District of Columbia, claiming it had satisfied all requirements for approval and that, by not approving its generic Depakote (divalproex sodium), the FDA violated the Federal Food, Drug and Cosmetic Act (*Generic Line, Jan. 23*). The drugmaker had submitted an ANDA with Paragraph IV certification to the '731 and '326 patents in March 2005. Although the patents expired Jan. 29, Abbott received pediatric exclusivity for Depakote, which may delay generic approval further.

The 30-month stay of approval triggered by Abbott Laboratories' patent infringement suit against Nu-Pharm expired in November 2007, the company said in its Jan. 14 complaint. Abbott had sued the generic drugmaker in the U.S. District Court for the Northern District of Illinois in 2005 in response to Nu-Pharm's Paragraph IV challenge.

However, the FDA said it would not approve Nu-Pharm's ANDA due to an injunction ordered in a different Depakote patent case involving Apotex. Nu-Pharm argued that the FDA couldn't refuse to approve its ANDA based on an injunction against a different company. But according to Abbott, which was added as a defendant, Nu-Pharm collaborated with Apotex and submitted its own ANDA for the same generic product that Apotex had developed. Abbott was successful in requesting that the Illinois district court extend the injunction against Apotex to include Nu-Pharm (*Generic Line, Feb. 6*).

The U.S. District Court for the District of Columbia found for the FDA and Abbott and denied Nu-Pharm's motion for a temporary restraining order and/or preliminary injunction as well as its request for emergency relief pending appeal. Nu-Pharm subsequently appealed the ruling, and the case went before the U.S. Court of Appeals for the District of Columbia Circuit.

A three-judge panel reviewed the case and found for the FDA and Abbott April 17. The judges said the district court had properly dismissed Nu-Pharm's complaint to avoid conflict with the injunction entered in *Abbott Labs. v. Apotex, Inc.* It further ordered that Nu-Pharm's motion to expedite be dismissed as moot. — Elizabeth Jones

Bayer Goes to Court to Stop Generic Versions of Yasmin

Watson and Sandoz face a patent infringement lawsuit after the drugmakers submitted ANDAs to market generic versions of Bayer Schering Pharma's oral contraceptive Yasmin.

Bayer filed the suit in the U.S. District Court for the Southern District of New York alleging Watson and Sandoz are infringing on its '652 patent, dihydrospirorenone as an antiandrogen, which covers certain uses of Yasmin (drospirenone/ethinylestradiol) tablets. The drugmaker wants the court to bar the companies from selling generic drug products containing drospirenone and ethinylestradiol before the expiration of the patent in October 2013.

Bayer has not been successful in previous attempts to keep generic Yasmin off the market. Last month, Barr won its case when a federal court ruled that the '531 patent, which covers a combination of micronized drospirenone and ethinylestradiol, was invalid due to obviousness. Barr had submitted an ANDA with a Paragraph IV certification for Yasmin in 2005.

Watson and Bayer also are involved in a patent case filed last November in the U.S. District Court for the District of Nevada over Yaz (drospirenone/ethinylestradiol), another contraceptive. In that suit, Bayer is alleging that Watson infringed on the '564, '838 and '531 patents and has asked the court to issue a permanent injunction preventing Watson from marketing its product until after the patents and exclusivity expire next year.

Bayer said it is entitled to triple damages if Watson commercializes its product before then (*Generic Line, Nov. 14, 2007*). — Elizabeth Jones

ASK THE EXPERT

Earlier this year, the FDA issued decisions involving forfeiture of exclusivity — one determining that Teva retained exclusivity for granisetron and one rejecting Lupin's challenge of Cobalt's exclusivity for ramipril. *Generic Line* asked Chad A. Landmon, a partner with the law firm Axinn, Veltrop & Harkrider to explain the rulings and what companies can learn from them.

Why did the FDA allow Teva to retain exclusivity for granisetron though it did not market it within 30 months of filing its ANDA?

The FDA concluded that the forfeiture provisions added to the Hatch-Waxman Act by the 2003 Medicare Modernization Act (the "MMA") do not require a generic exclusivity holder to forfeit its exclusivity if more than 30 months have passed since the generic company filed its ANDA. Specifically, FDA determined that Teva had not forfeited its 180-day exclusivity period when it failed to market granisetron within 30 months of filing its ANDA because a court decision against the patent had not occurred and the patent had not been de-listed from FDA's Orange Book.

In siding with Teva that it should keep its exclusivity, FDA applied a plain language reading of the law. Addressing the "earlier of-later of" language in the forfeiture provisions, the agency held that, even if 30 months pass after the first filer submits its ANDA, the filer will not forfeit its exclusivity unless there has been an appellate court decision against the Orange Book patent, a district court settlement order or consent decree against the patent or the patent has been removed from the Orange Book.

What events did the FDA consider when making its decision to let Teva retain its exclusivity?

That neither Teva nor any subsequent generic applicant had been sued did not convince the FDA that it would be impossible for one of these triggering events to occur. In its January 17 letter, the FDA said:

Although at the time the FDA made its exclusivity decision, there was no litigation regarding the '548 patent pending that could result in a forfeiture event under subitem (AA) or (BB) of subpart (bb) [of 21 U.S.C. §355(j)(5)(D)(i)(I)], there was nevertheless the possibility that either an additional ANDA applicant would be sued as a result of a paragraph IV certification to the patent or one of the applicants would bring a declaratory judgment action against the NDA holder or patent owner. Either of these actions could result in a forfeiture event. In addition, the patent could be withdrawn by the NDA holder, resulting in a forfeiture event under subitem (CC).

The probability of the specific forfeiture events cited by the FDA occurring is remote at best. Under the FDA's ruling, a brand company and first filer may agree to park the generic exclusivity period until some date before the patent expires without risking forfeiture. Such a scenario would leave subsequent ANDA filers with little ability to obtain marketing approval. The FDA recognized this very risk in its letter, saying, "This inability to force a forfeiture of 180-day exclusivity could result in delays in the approval of otherwise approvable ANDAs owned by applicants that would market their generic drugs if they could but obtain approval. This potential scenario is not one for which the statute currently provides a remedy."

Why did the FDA permit the first filer for ramipril to retain exclusivity despite its agreement to delay market entry?

In its ruling last January, the FDA rejected a citizen petition challenging the first filer's exclusivity relating to ramipril, finding that the agreement between the brand company and first filer, Cobalt, which agreed to delay market entry, did not preclude Cobalt from maintaining its exclusivity

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period. Two later ANDA filers — Lupin and another, unidentified ANDA filer — challenged Cobalt's right to maintain its exclusivity period, arguing that Cobalt's Paragraph IV certification was inaccurate and no longer valid in light of the settlement. The later ANDA filers also argued that Cobalt should not be able to maintain its exclusivity because it was unwilling to stand behind its initial Paragraph IV challenge.

The agency rejected the challenge to the exclusivity period, determining that, under the forfeiture provisions adopted by the MMA, Congress provided that only a settlement agreement found to be an antitrust violation in a final, unappealable court decision will act as a forfeiture event. Because such an event had not occurred with respect to ramipril, Cobalt's agreement to settle the case and delay market entry did not lead to a forfeiture of exclusivity.

What is the impact of the FDA's granisetron and ramipril decisions?

Exclusivity parking is likely to continue, and the race for first filer status continues to be of paramount importance. Although many expected the MMA to be a quick fix to the perceived problem of exclusivity parking, the FDA's granisetron and ramipril rulings make it clear that, unless the patent is removed from the Orange Book, only certain court decisions, final approval for the first filer or failure to timely obtain tentative approval will lead to forfeiture. The granisetron and ramipril rulings reinforce the value of the exclusivity period by clarifying that a first filer can settle for a delayed market entry and maintain the exclusivity period.

The rulings largely return us to the pre-MMA law for issues relating to the parking of exclusivity through settlement agreements and the value of the exclusivity period. While Congress intended the marketing forfeiture provision to prohibit exclusivity parking through brand-generic settlement agreements, it appears that exclusivity parking is nevertheless here to stay.

Caraco Successfully Defends Against Patent Claim on Generic Painkiller

A district court judge has handed Caraco Pharmaceutical a victory in a patent infringement lawsuit brought by Ortho-McNeil Pharmaceutical over a generic version of the pain drug Ultracet.

Ortho-McNeil, a Johnson & Johnson company, had accused Caraco and co-defendants Kali Laboratories, Par Pharmaceutical and Barr Laboratories of infringing on the '221 patent on its brand drug Ultracet (tramadol HCl/acetaminophen tablets). But the U.S. District Court for the District of New Jersey rejected the claim, granting Caraco's motion for summary judgment.

Judge Dennis Cavanaugh also noted that Ortho-McNeil's 1991 patent application for Ultracet was originally rejected by the U.S. Patent and Trademark Office (USPTO) on the grounds of obviousness since a similar patent had been filed in 1972 by Ernst Frankus and Kurt Flick. However, in 1994, the office partly reversed itself and granted some of Ortho-McNeil's patent claims by issuing the '691 patent. In 2004, Ortho-McNeil cancelled some of the claims in the patent and filed a reissue application. The USPTO reissued the '691 patent as the '221 patent in 2006. — Martin Gidron

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DRUG APPROVALS

Teva Products Get Tentative Approval

The FDA has granted tentative approval to Teva Pharmaceutical's ANDA to market a generic version of Merck's migraine treatment Maxalt.

Maxalt (rizatriptan benzoate) was approved by the FDA in 1998 for the short-term treatment of migraine attacks in adults. Final approval of the generic is anticipated when the brand drug's patent expires in June 2012.

Annual sales of Maxalt in the U.S. were approximately \$193 million for the 12 months ending Dec. 30, 2007, Teva said, citing IMS Health data.

Separately, Teva also received tentative approval for its ANDA to market its generic version of Eli Lilly's osteoporosis treatment Evista (raloxifene HCl) 60-mg tablets.

The brand product had annual sales of approximately \$691 million in the U.S. for the twelve months ending Dec. 31, 2007, based on IMS sales data.

Teva is involved in patent lawsuit with Eli Lilly in the U.S. District Court for the Southern District of Indiana over the drug. In the suit, Lilly alleges Teva's product will infringe on four patents covering Evista — the '050, '968, '049 and '086 patents.

FDA Approves Mylan's Felodipine

Mylan Pharmaceuticals has received final approval from the FDA for its ANDA for felodipine extended-release tablets, a treatment for hypertension.

Felodipine is the generic version of AstraZeneca's Plendil, which had U.S. sales of approximately \$35 million in 2007.

AstraZeneca recently settled a patent infringement suit with Ranbaxy Laboratories, which enabled the Indian drugmaker to sell generic Nexium (esomeprazole magnesium) in

2014. It also designated Ranbaxy as U.S. distributor for authorized generic versions of Plendil.

Mylan will start shipping felodipine immediately.

FDA Gives Thumbs Up to Generic Activella

Breckenridge Pharmaceutical has received FDA approval for its ANDA to market its generic version of Novo Nordisk's Activella tablets.

Activella (estradiol/norethindrone acetate) is used to treat moderate to severe vasomotor symptoms associated with menopause and for preventing postmenopausal osteoporosis. Breckenridge is the first company to receive approval for a generic Activella and has begun shipping the product, the company said.

Based on industry sales data, the brand product had trailing 12-month sales of \$57 million, according to Breckenridge.

APP Gets Approval for Colistimethate ANDA

The FDA has approved APP Pharmaceuticals' ANDA for the antibiotic colistimethate for injection, USP, 150 mg.

The drug is the generic equivalent of JHP Pharmaceuticals' Coly-Mycin M Parenteral. APP said it has already begun marketing and shipping the latex-free product. U.S. sales of colistimethate totaled approximately \$15.4 million in 2007.

Colistimethate is indicated to treat acute or chronic infections due to sensitive strains of certain gram-negative bacilli, particularly when the infection is caused by *Pseudomonas aeruginosa*.

Last June, the FDA issued a MedWatch alert saying it was investigating a possible connection between the death of a patient with cystic fibrosis

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and the use of a liquid solution of colistimethate premixed for inhalation with a nebulizer. However, the possible hazard of lung tissue damage does not apply to injectable or IV versions of the drug.

FDA Approves Generic Nausea Drug

Akorn-Strides, a joint venture between Indian drugmaker Strides Arcolab and Illinois-based Akorn, has received approval for ondansetron injection 4-mg/2-mL single dose and 40-mg/20-mL multiple dose vials.

The product is indicated for the prevention of nausea and vomiting associated with cancer chemotherapy and postoperative conditions. It is a generic version of GlaxoSmithKline's (GSK) Zofran. The FDA approved the ANDA submitted by Teva and Sicor after GSK agreed to waive the remainder of its six-month exclusivity period in November 2006.

IMS data estimates an annual market size of approximately \$67 million, according to Akorn.

Lannett Cardiovascular Drug Approved

Lannett Company has received FDA approval for its dipyridamole tablets ANDA, the generic equivalent of Persantine manufactured by Boehringer Ingelheim.

Dipyridamole is indicated as an adjunct to coumarin anticoagulants in the prevention of

postoperative thromboembolic complications of cardiac valve replacement. The company said it expects to launch the product this quarter.

According to Wolters Kluwer, sales of generic dipyridamole were \$46 million in 2007 at average wholesale price.

Ranbaxy to Sell Generic Zyrtec

Ranbaxy Laboratories has received final FDA approval to manufacture and market cetirizine HCl oral solution to treat allergies and hives in children.

The solution will be sold by Ohm Laboratories, Ranbaxy's New Jersey-based subsidiary, and is a generic version of McNeil Consumer Healthcare's Zyrtec. The product is indicated for the temporary relief of runny nose, sneezing, itching of the nose or throat and itchy, watery eyes due to hay fever or other upper respiratory allergies.

Total sales for prescription cetirizine HCl syrup were \$157 million in 2007.

Separately, Ranbaxy Laboratories and Orchid Chemicals & Pharmaceuticals Limited have entered a business alliance involving multiple markets and therapies for both finished dosage formulations and active pharmaceutical ingredients.

The agreement will establish a framework for enhanced future co-operation between the two companies, Ranbaxy said.

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