



BNA, INC.

PHARMACEUTICAL LAW & INDUSTRY



VOL. 7, NO. 38 PAGES 1093-1120

REPORT

SEPTEMBER 25, 2009

HIGHLIGHTS

Court Upholds U.S. Mircera Sales Ban, Remands Double Patenting Issue

In an 81-page decision containing wins for both sides, the Federal Circuit keeps in place a lower court's earlier ban on sales of Roche Holding AG's anemia drug Mircera in the United States during the life of patents owned by biotechnology rival Amgen, but remands the issue of whether Amgen improperly double patented certain of its patents to the lower court for further analysis. The court also vacates a ruling of noninfringement in favor of Roche on one of the patent claims and orders a new trial on that claim. **Page 1097**

Wyeth Sues FDA Over Approval of Generic Zosyn, Contends Generic Unsafe

Wyeth files a complaint in a federal district court seeking to require FDA to withdraw or suspend its approval of Orchid Chemicals & Pharmaceuticals Ltd.'s generic version of Wyeth Pharmaceuticals's injectable antibiotic Zosyn. Wyeth says FDA's approval of Orchid's generic is incorrectly based on a now-superseded formulation of Zosyn that lacks two functional inactive ingredients critical to the product's compatibility with other drugs with which it often is co-administered. **Page 1099**

FDA Warns Bioniche Web Pages for Drug Fail to Include Risk Information

The FDA issues a warning letter to Bioniche Pharma that two web pages for Sotradecol are false and misleading because they fail to communicate risk information, broaden the drug's approved indication, and overstate its efficacy. Separately, the agency announces a November hearing on the promotion of FDA-regulated products using the internet and social media tools. **Page 1109**

Plaintiffs in Class Suit Voluntarily Dismiss Antitrust Action Over Singulair

A group of drug wholesalers voluntarily dismiss their proposed class action alleging that Merck & Co. and Merck Sharp & Dohme Pharmaceuticals engaged in anti-competitive tactics to block generic copies of Singulair from entering the market. The wholesalers' complaint claimed that Merck's patent suit against Teva was a sham, but a federal district court in August ruled that Merck's patent on the drug was valid. **Page 1099**

FDA Proposes Rule on Industry Practices for Making Combination Products

The FDA publishes a proposed rule intended to give makers of combination products—such as a drug combined with a medical device—a “transparent and streamlined regulatory framework” for demonstrating compliance with good manufacturing practice requirements. **Page 1106**

Albany Molecular Research Sues Dr. Reddy's, Sandoz Over Allegra Patent

Albany Molecular Research Inc., the owner of a patent covering the allergy drug Allegra and Allegra D, sues Dr. Reddy's Laboratories Inc. and Sandoz Inc. in twin complaints filed in federal court in New Jersey, accusing the companies of infringing Albany's patent on the drug. **Page 1100**

ALSO IN THE NEWS

PATENTS: Shire and Teva Pharmaceutical Industries settle all legal actions over Shire's Carbatrol. **Page 1100**

DRUG PRICING: Utah recovers \$1 million from Dey to resolve allegations that the drugmaker overcharged Utah's Medicaid program, the state attorney general announces. **Page 1112**

ADVERTISING AND MARKETING:

The FDA is working to improve accuracy and balance in drug and device advertising, FDA official Janet Woodcock tells a Food and Drug Law Institute conference. **Page 1107**

PATENTS: A federal district court orders the dismissal of some drugmakers from Forest's lawsuit over its Alzheimer's disease treatment, Namenda. **Page 1100**

PRODUCT LIABILITY: A federal judge orders Boston University researchers to produce correspondence with GSK over Paxil research. **Page 1101**

CLINICAL TRIALS: PhRMA releases new principles on conducting clinical trials and communicating results. **Page 1112**

DRUG SAFETY: The FDA continues to receive reports of serious viral infections with MS drug Tysabri. **Page 1113**

NEW PRODUCTS: An FDA advisory panel recommends approval of Xiaflex. **Page 1113**

CER is important to reform efforts, but it is only a "first step," Wilensky said.

Wilensky noted the need for better incentives to reward high quality and efficient care, saying it was part of good decision making practices. "We are taking baby steps towards precision medicine. I see us trying to break down areas of ignorance," Wilensky said.

"CER is a component of better decision making. It is an enabler of more effective and efficient delivery [of care]. But as long as there are perverse incentives, we won't change from where we are," Wilensky said. "It's as much changing the mindset for payers as it is providers."

Information Technology

Federal Incentive, Penalty Schemes Seen Driving E-Prescription Trend

CHICAGO—At least half of all prescriptions will be transmitted electronically within five years due to the federal government's campaign for wider adoption and utilization of electronic health records, an expert in health information technology predicted Sept. 22.

Anthony Schueth, chief executive of the Coral Springs, Fla.-based HIT consulting firm Point-of-Care Partners LLC, said momentum is building for "e-prescribing" despite some resistance from providers and certain practical implementation challenges. He said interest in e-prescribing continues to grow based on the ability of such systems to provide drugs to patients in a safe and efficient manner while wringing billions of dollars of savings out of the health care system. Schueth said federal government has become the major driver of the trend as it mixes incentives for HIT implementation into health system reform measures.

"The greatest market influencer, the greatest driver of electronic prescribing and electronic health records today is the federal government," Schueth said during the E-Prescribing Forum sponsored by World Research Group. "The leader of this effort is the President of the United States. I call President Obama the HIT advocate in chief."

Schueth said the percentage of drugs prescribed by physicians electronically stood at 2 percent in 2007 and doubled to 4 percent by the end of 2008. The figure is projected to rise to at least 10 percent by the end of 2009.

Predicting the trajectory of the e-prescribing trend over the next decade is challenging based on potential "accelerators" and "decelerators" that may or may not emerge, Schueth said. At the same time, Schueth said his firm is projecting an e-prescribing rate of at least 50 percent by 2014. He noted that the Congressional Budget Office and the Pharmaceutical Care Management Association (PCMA, an industry group for pharmacy benefit managers) both are predicting a slightly higher trend line.

"When we get 50 percent of scrips flowing electronically, that is where we really can make an impact on doctors' offices," he said. "By 2014 all three of us are projecting we will be over 50 percent. So we are on a rapid uptick right now."

Schueth described e-prescribing as the electronic media transmission of prescription or prescription-related

information between a prescriber, dispenser, pharmacy benefit manager or health plan, either directly or through an intermediary. The process includes two-way transmissions between the "point of care" and the dispenser, and decision-support processes featuring reviews a patient's medical history and benefits information.

Schueth said nearly 140,000 doctors currently are prescribing drugs electronically and 46,000 pharmacies are dispensing e-prescribed drugs to their customers. He said 240 million prescriptions were sent online to pharmacies last year. Industry group PCMA recently predicted that wider adoption of e-prescribing would prevent 3.5 million adverse drug events. The Center for Information Technology has projected e-prescribing would generate \$29 billion in annual savings if adopted by all medical providers.

Push From Federal Laws. Schueth said an early federal push for e-prescribing came with the Medicare Drug Improvement and Modernization Act of 2003, which created the Medicare Part D program. Under the law, the Department of Health and Human Services developed e-prescribing standards and operated an e-prescribing pilot project. This was followed by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which included incentives for providers adopting e-prescribing through 2013 and a penalty system for providers that fail to adopt electronic processes beginning in 2012.

But Schueth said the American Recovery and Reinvestment Act (ARRA), signed by President Obama earlier this year, could provide the most significant fuel to the e-prescribing trend. The act provides economic incentives to encourage the utilization of certified electronic health records (EHR) used in a "meaningful" manner. While the federal government still is trying to define this "meaningful use" standard, Schueth said e-prescribing is core to the definition.

He said ARRA includes grant funding to help physicians offset costs associated with HIT adoption and funds for "regional extension centers," which may be used to encourage HIT implementation including e-prescribing. In the much larger entitlement funding portion of ARRA, Schueth said doctors making meaningful use of HIT by 2012 would receive the maximum \$44,000 in incentives between 2011 and 2015. Following this period, physicians not making meaningful use of HIT would be stung with various penalties. He said the penalties ultimately may prove to be a more useful driver than the incentives.

"The important thing may not be the incentives as much as the penalties," he said. "As the federal government encourages doctors to adopt technology, we are beginning to see more and more penalties if they don't adopt technology by a certain timeframe."

Schueth said the nation's ability to reap the benefits of e-prescribing over the next five years will depend on several practical issues that have emerged after the enactment of ARRA. He noted that the government could embrace a definition of meaningful use that does not encourage electronic transmission of prescriptions—a scenario that would dramatically decelerate acceptance of e-prescribing.

Regional Extension Centers. Schueth said he also fears that the federal government has focused primarily on incentives and is underfunding implementation sup-

port. He noted that while ARRA set aside billions of dollars to encourage doctors to adopt electronic health records, just \$598 million has been earmarked for regional extension centers that could assist with implementation. In his experience, Schueth said, every \$5 invested in incentives must be accompanied by a \$1 investment in implementation and training support. Under ARRA, he said, the 5-to-1 ratio will not be achieved.

Schueth stressed the importance of implementation support, noting that doctors never have been natural adopters of information technology.

"There is a lot to implementing this," he said. "Doctors are schooled in practicing medicine, seeing patients and diagnosing problems. In many cases they don't know anything about technology. Some larger physician groups have hired people to implement technology and support their technology. That's where you see success. But solo practitioners or small group practices don't have that kind of investment money and need some hand-holding."

By MICHAEL BOLOGNA

FDA

Former FDA Leader von Eschenbach Joins Center for Health Transformation

The Center for Health Transformation (CHT) Sept. 22 announced that Andrew von Eschenbach, commissioner of the Food and Drug Administration during the George W. Bush administration, has joined the center as a senior adviser.

Nancy Desmond, CHT's president and chief executive, said that von Eschenbach will lead the 21st Century FDA Modernization Project. That project will identify key priorities to improving the effectiveness and efficiency of FDA, she said. CHT was founded by former House Speaker Newt Gingrich.

"It currently takes 17 years for a life-saving drug or treatment to make it from the lab to the patient—a delay that costs countless lives every year," Desmond said. "We are so excited to have Dr. von Eschenbach join us to launch the Center's 21st Century FDA Project—a project dedicated to accelerating the creation and adoption of new drugs and discoveries that will save millions of lives and dramatically improve the health of every American."

Von Eschenbach was the acting head of FDA starting in 2005, and was confirmed by the Senate in 2006. Before leading FDA, von Eschenbach was director of the National Cancer Institute at the National Institutes of Health. Von Eschenbach also will be actively involved in CHT's Eliminating Cancer as a Cause of Death and Suffering Project and the Alzheimer's Solutions Project.

More information about the group is at <http://www.healthtransformation.net/>.

In Brief

Genzyme Provides Update on Cerezyme, Fabrazyme

Genzyme Corp. Sept. 23 provided an update on its progress to restore supplies of Cerezyme (imiglucerase

for injection) and Fabrazyme (agalsidase beta), saying that it expects to begin meeting patient demand for both products during the first quarter of 2010.

In June, Genzyme announced that it had detected a virus that impairs cell growth in a bioreactor used for Cerezyme production at its Allston facility in Massachusetts (7 PLIR 718, 6/19/09). The company decided to temporarily stop production at the plant, which was manufacturing Cerezyme and Fabrazyme. Cerezyme treats Gaucher's disease and Fabrazyme treats Fabry's disease.

In the new update, the company said all six bioreactors at the Allston plant are fully operational and have reached the point in their production cycles when their anticipated output and the timing of product release can be predicted with more certainty.

Adolor Acquires Rights to OpRA III

Adolor Corp. Sept. 21 announced that it has acquired from Eli Lilly and Co. the exclusive worldwide rights to OpRA III, a clinical-stage product candidate.

OpRA III is a potent opioid receptor antagonist, with potential use in multiple therapeutic indications, the Exton, Pa.-based company said. Adolor said it intends to initially develop the drug to treat opioid bowel dysfunction and will initiate clinical trials for this indication in early 2010.

Financial terms of the agreement include an upfront payment of \$2 million to Eli Lilly, royalties on net sales of any approved product, and up to approximately \$70 million in milestone payments upon achievement of predefined, late-stage clinical and regulatory events and achievement of certain sales targets, Adolor said.

Valeant Meets With FDA to Discuss Epilepsy Drug

Valeant Pharmaceuticals Sept. 21 announced that it met with the Food and Drug Administration in August to discuss the technical aspects of the planned new drug application submission for retigabine, a neuronal potassium channel opener for the adjunctive treatment of adult epilepsy patients with partial-onset seizures.

The Aliso Viejo, Calif.-based company said the application is now being finalized based on the outcome of this discussion and it expects to submit the NDA to the agency on or before Oct. 23.

Valeant also announced that three retigabine modified release (MR) technologies will be assessed in a phase I clinical study commencing in September. The purpose of the study is to evaluate these candidate formulations to identify a lead MR compound that will be advanced in further research intended to support a product with either a once-daily or twice-daily dosing regimen.

Application for Generic Duac Sold by KV

KV Pharmaceutical Co. Sept. 21 announced the sale to Perrigo Co. of KV's first-to-file paragraph IV abbreviated new drug application for a generic version of Duac gel (clindamycin, 1 percent, benzoyl peroxide, 5 percent).

Under the terms of the transaction, KV will receive \$14 million from Perrigo at closing and an additional \$2 million milestone payment upon the completion of a successful technical transfer. The ANDA already is filed with the Food and Drug Administration.

Duac is indicated for the topical treatment of mild to moderate acne vulgaris, the St. Louis-based company