GENERIC LINE®

Vol. 26, No. 23
Nov. 25, 2009

INSIDE THIS ISSUE

Follow-on Biologics Makers Lose on Senate Bill Exclusivity

In a blow to generic-drug manufacturers, the Senate's $849 billion healthcare overhaul legislation, like the House version, gives biologics innovators 12 years of exclusivity.

The Patient Protection and Affordable Care Act, H.R. 3590, released Nov. 18, has been sent to the Senate floor for debate. If the full Senate approves it, the bill then must be reconciled with the House version, The Affordable Health Care for America Act, H.R. 3962 (*Generic Line*, Nov. 11).

The reconciliation of the two bills could prove difficult because they do not share important provisions. For example, the House bill would ban pay-for-delay agreements between brand-drug

(See **Bill**, *Page 2)*

Ruling in Generic Famvir Case Goes Against Teva's Gamble

Novartis has won a patent dispute in a district court with Teva Pharmaceutical Industries over the antiviral drug Famvir, which could make Teva liable for damages due to its short-lived at-risk 2007 launch of a generic version.

A jury in the U.S. District Court for the District of New Jersey decided that Novartis' patent on Famvir (famciclovir) was not invalid based on obviousness and that the drugmaker did not withhold or misrepresent information to the PTO, according to court documents filed earlier this month.

Teva did not provide clear and convincing evidence that an individual with ordinary skill in the art would have chosen Novartis' Denavir (penciclovir) as a lead compound as Novartis did, been motivated to modify penciclovir to make famciclovir, or expected its successful properties, according to the verdict. The jury also cited

(See **Famvir**, *Page 2)*

FDA Gives Tentative Approval To Generic Gleevec

The FDA has given tentative approval to Sun Pharmaceutical Industries to make a generic version of Novartis' Gleevec to treat chronic myeloid leukemia.

Sun's drug could become the first generic version sold in the U.S. The ANDA approval is for 100- and 400-mg tablets, the same strengths and formulation as Gleevec (imatinib mesylate), Mumbai-based Sun says in a statement Nov. 17.

Novartis' annual sales of the drug, named Glivec in Europe and Australia, were $3.67 billion worldwide last year, according to the company's annual report. The FDA approved Gleevec in 2001, in 50- and 100-mg capsules, which Novartis discontinued. — Meg Bryant

Bill, *from Page 1*

and generic-drug makers (Section 2573). The Senate version does not contain the provision.

Both bills would allow Medicare Advantage prescription drug plans to waive copayments for first fills of generic prescription drugs as an incentive for beneficiaries to try less expensive formulations (Section 6402 in the Senate bill) (*Generic Line*, Oct. 14).

Both bills also contain provisions to fund comparative-effectiveness research. The Senate legislation would create a nonprofit Patient-Centered Outcomes Research Institute to study comparative-effectiveness research, including the health outcomes, clinical effectiveness, and appropriateness of medical treatments and services, the bill says in Section 6302.

The two bills also contain provisions that effectively would expand discounts from drugs purchased through the 340B Drug Discount Program by including drugs bought by children's hospitals and cancer hospitals among other institutions.

The Congressional Budget Office and the Joint Committee on Taxation released a preliminary analysis of the bill Nov. 18, which estimates that the legislation would result in a net reduction in federal budget deficits of $130 billion from 2010 to 2019.

The Patient Protection and Affordable Care Act can be found at www.democrats.senate.gov/reform/patient-protection-affordable-care-act.pdf. H.R. 3962 is available at www.fdanews.com/ext/files/HR3962PatientProtection.pdf. — David Belian

Famvir, *from Page 1*

unsuccessful attempts by others to find the solution provided by the patent indicated that the patent was not obvious.

Novartis sued Teva for patent infringement in 2005, the same year the generic-drug maker filed an ANDA containing a Paragraph IV certification on Novartis' '937 patent for Famvir.

Teva received final approval from the FDA in August 2007 to market generic Famvir tablets in the U.S. (*Generic Line*, July 25, 2007). The U.S. Court of Appeals for the Federal Circuit issued an injunction prohibiting Teva from selling its generic version of the drug a month later (*Generic Line*, Sept. 19, 2007).

The jury also found that Teva did not provide evidence that Novartis knowingly withheld or misrepresented information to the PTO or intended to deceive the patent examiner in the case, and thus found that there was no inequitable conduct committed in the prosecution of the '937 patent, as Teva had tried to claim.

Novartis is encouraged by the jury's advisory decision that the company did not commit inequitable conduct and hopes that the judge reflects this in his final ruling, it says in a statement. Teva did not respond by press time to requests for comment.

The verdict in *Novartis Pharmaceuticals Corporation, Novartis Pharma AG and Novartis International Pharmaceutical Ltd. v. Teva Pharmaceuticals USA, Inc.* was filed Nov. 18. — David Belian

Appellate Court Upholds Injunction Against PTO Final Rule

A federal court has upheld an injunction of a PTO final rule that would have affected generic-drug makers by changing the number of claims allowed for patent applications by innovator companies and the number of continuing applications such companies could file.

The U.S. Court of Appeals for the Federal Circuit dismissed the case at the request of the PTO and GlaxoSmithKline (GSK) after the PTO announced it would rescind the rule last month.

The rule was originally issued by the PTO in 2007 and stipulated that patent applicants would have to provide an examination support document to the PTO for all claims if an application contained more than five independent claims or more than 25 total claims.

Rule Opposition

The Biotechnology Industry Organization (BIO) had opposed the rule, and PhRMA says in an amicus brief that the rule exceeds the PTO's authority over continuing application practices, is unlawful and would "substantially erode" patent prosecution law that allows applicants to file many claims to protect their inventions (*Generic Line*, Jan. 9, 2008).

In its amicus brief, BIO says the final rule would harm biotechnology companies' ability to claim and protect their inventions. The group adds that it is "deeply concerned about the irreversible loss of patent rights and the disincentives to innovation that the final rules will cause."

The rule also would have modified the number of continuing applications parties could file after submitting an original application. Under the rule, any third or subsequent continuation or continuation-in-part application, as well as any second or subsequent request for continued examination, would have had to justify the reason for not submitting the new evidence earlier.

GSK and Triantafyllos Tafas, an inventor, sued the PTO in the U.S. District Court for the Eastern District of Virginia in August 2007, and the court responded by permanently enjoining the rule from taking effect.

The case, *Triantafyllos Tafas, et al. v. John J. Doll, et al.*, was appealed to the appellate court, which reversed most of the lower court's ruling but then agreed to rehear the case before the PTO's decision to rescind the rule. — David Belian

Barr Pharma Wins Right to Sell Generic Fentora in 2018

Cephalon has agreed to drop a patent suit against Barr Pharmaceuticals, allowing the company to market generic Fentora in the U.S. in 2018, a year before the disputed patents expire.

The company granted Barr a nonexclusive right to sell a generic of the pain drug Fentora (fentanyl citrate) beginning in October 2018, Cephalon says in an SEC filing this month. If another generic version enters the U.S. market before then, Barr may begin marketing on the same date, subject to any regulatory exclusivities of the other generic filer.

Cephalon claimed infringement of its '604 and '590 patents, which cover methods of use for Fentora and expire in 2019 (*Generic Line*, Aug. 6, 2008). The court was asked to enjoin Barr from selling the generic version before the two patents expire in March 2019. The company also claimed infringement of its '981 patent on solid formulations of fentanyl and other compounds — and methods of use.

The FDA approved Fentora in September 2006 to manage breakthrough pain in cancer patients who tolerate opioid therapy.

The agreement does not affect the status of a separate suit against Watson Pharmaceuticals, Cephalon says. Last year, Cephalon filed a patent infringement suit to prevent FDA approval of Watson's generic Fentora (*Generic Line*, June 11, 2008).

Barr did not respond to a request for comment by press time. — April Hollis

Report: Generic Drug Availability Doesn't Increase Drugs Dispensed

When generic drugs become available as brand drug patents expire, the total number of drugs dispensed doesn't change because the increase in use generated by the availability of less expensive drugs is offset by a reduction in use tied to the dropoff in marketing, a report finds.

Marketing expands the number of doctors prescribing brand drugs, increasing the number of drugs sold, according to an October report from the Center for Medical Progress. In 2007, consumers' out-of-pocket payments for drugs accounted for about 20 percent of drug spending in the U.S., according to the report. Prescription drug insurance coverage that pays for brand medicines could be another reason patent protection does not reduce use of drugs, and why lower prices don't cause a greater jump in usage, the report says, citing data on drugs sold from 2000 to 2004.

Recent court decisions have reduced the scope of patent protection. In 2007, the Supreme Court raised the bar for patents on new products that combine elements of preexisting inventions. Judges now have more leeway to dismiss patent infringement lawsuits without requiring a jury trial, and patent examiners, who generally grant patent applications unless they find prior references to the same invention, now are freer to deny them.

But weakened patent protection for brand drugs does not increase access to treatments and would reduce the number of new drugs developed, according to the report. Also, less expensive generic drugs produce savings for insurers or pharmaceutical benefit managers that don't necessarily get passed on to consumers, the report says.

Generic competitors tend to enter the market after 12 to 16 years of a typical drug's lifecycle. In that period, prices fall for formerly patent-protected drugs and the marketing spending drops about 60 percent. However, the number of drugs dispensed doesn't change.

If patent critics are right, the number of prescriptions dispensed should increase as prices drop, the report says.

Chad Landmon, partner with Axinn, Veltrop & Harkrider says both the brand and generic industries largely agree that a robust patent system is necessary.

"The question really boils down to how far that patent protection should go for patents directed to certain formulations or methods of use that are not major innovations," Landmon told *Generic Line*. He noted many extended-release formulation patents merely claim a known active ingredient in a formulation that has been used with many other active ingredients in the past.

The report, "Time Release: The Effect of Patent Expiration on U.S. Drug Prices, Marketing and Utilization by the Public," can be seen at www.manhattan-institute.org/pdf/mpr_11.pdf.
— April Hollis

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Liability Suit Over Generic Reglan Won't Include Wyeth, Schwarz

Liability for labeling of a generic version of Wyeth and Schwarz Pharma's Reglan doesn't include the innovators, a district court says in a summary judgment.

The U.S. District Court for the Southern District of West Virginia dismissed the innovator companies from a lawsuit that would have held them responsible for inadequate warning of potential adverse events suffered by a patient taking a generic version of their product, which is indicated to treat gastroesophageal reflux disease. The companies did not manufacture the product that injured the plaintiff, according to court documents posted online recently.

The plaintiff in the case, Shirlean Meade, had alleged that a doctor prescribed Wyeth and Schwarz's Reglan (metoclopramide) to treat her reflux disease but was given a generic version of the drug by her pharmacy. While taking the drug she developed symptoms of the neurological disorders tardive dyskinesia and akathisia.

Meade acknowledged that she hadn't taken the brand version of Reglan, but argued that Wyeth and Schwarz are liable for inaccuracies and deficiencies in the generic version's safety information because generic manufacturers are permitted to rely on brand manufacturers' warnings.

The court rejected this argument, however, citing several similar cases that determined that the company that controls the manufacturing and labeling of the product and gets the profits should bear legal liability for any resulting injury (*Generic Line*, Nov. 12, 2008).

The ruling followed a decision in a separate case by a federal judge in March that found

(See **Reglan**, *Page 6)*

Brand, Generic Drug Cost Report Sought by House Committee

Allegations that drugmakers are raising prices in anticipation of healthcare legislation that may reduce pharmaceutical costs or curb growth have led several House committee leaders to request a Government Accountability Office (GAO) investigation on recent price trends.

Three House Ways and Means Committee members, Chairman Charles Rangel (D-N.Y.), Reps. Pete Stark (D-Calif.) and John Lewis (D-Ga.), and House Energy and Commerce Committee Chairman Henry Waxman (D-Calif.) requested the report in a Nov. 17 letter.

The lawmakers also asked the GAO to draft a proposal to continue monitoring of brand and generic pharmaceutical prices and periodically report the findings to Congress.

The legislators pointed to a 2007 GAO report that found in the year before the 2003 Medicare Modernization Act creating the Medicare Part D prescription drug benefit, the price for a particular index of brand drugs rose almost 7 percent, while the previous two annual price increases were closer to 4 percent.

As part of its report to Congress, the lawmakers request that the GAO provide:

- An analysis of recent annual price trends for commonly purchased brand and generic pharmaceuticals;
- A comparison of these drug price trends with commonly used benchmarks of price trends for other goods and services, such as the Consumer Price Index;
- An analysis of the particular pharmaceutical products that account for significant increases or decreases in the price trends of brand or generic drugs; and
- An examination of whether certain pharmaceutical manufacturers demonstrate anomalous drug pricing trends relative to overall pharmaceutical price trends.

The letter is available at energycommerce.house.gov/Press_111/20091117/gao_drugpricing_letter.pdf. — David Belian

UK Court Decision Denies Levofloxacin Patent Challenge

The UK Supreme Court has refused to accept an appeal by Generics (UK), ending the company's attempt to open the market to generic levofloxacin rivals in the UK.

The court decided to let stand a lower court's ruling that Daiichi Sankyo's supplementary protection certificate (SPC) for the broad-spectrum antibacterial levofloxacin is valid — which allows Sanofi-Aventis to continue to market the agent without competition.

Generics (UK), a subsidiary of Merck KGaA, was attempting to overturn a July 2, 2009, decision by the England and Wales Court of Appeal, Daiichi says in a statement Nov. 16. Sanofi has an exclusive license to make and sell preparations containing Daiichi's levofloxacin in the UK under the trade name Tavanic, Daiichi says.

The generic-drug maker had challenged the SPC — an extension of patent that is intended to compensate for the long time required to obtain regulatory approval of products in various markets — and the underlying EU patent on which the SPC was based. Generics' claims included that the original patent lacked novelty and therefore was invalid and could not support the SPC.

Daiichi's fiscal 2008 worldwide sales of levofloxacin totaled $1.1 billion. — Meg Bryant

Reglan, *from Page 5*

that state law doesn't compel Wyeth and Schwarz to warn patients about potential risks associated with taking generic versions of Reglan manufactured by other companies (*Generic Line*, April 1).

It also follows another Reglan failure-to-warn-related ruling by the U.S. District Court for the District of Vermont not to allow generic-drug makers to rely on a preemption defense — which potentially could make the innovator drugmakers liable for the failure — in their appeal in *Ethel Kellogg v. Wyeth, et al.*

That ruling denied defendants Actavis Elizabeth, Teva Pharmaceuticals USA, Pliva and Barr Pharmaceuticals' request for summary judgment and a stay of the proceedings.

"The generic manufacturers' argument is that … failure to warn claims against them are preempted because the FDA regulations applicable to the approval of an ANDA require that the generic label be the same as the branded manufacturer's label. The court in Kellogg found that the claims were not preempted," Kimberly Martin, a litigator and co-chair of the Life Sciences Industry Group at Bradley Arant Boult Cummings, told *Generic Line* at the time.

The latest case decision was made in *Shirlean Meade and Elmer Meade v. Deidre E. Parsley, D.O.; Wyeth, Inc., doing business as Wyeth; Schwarz Pharma Inc.; Pliva Inc.; and John Doe Defendants # 1-6*. The motion for summary judgment was filed July 31 in the District Court. — David Belian

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Teva Amends Infringement Claims For Copaxone Patents

Teva Pharmaceutical Industries is seeking to add infringement of three additional patents on its multiple sclerosis drug Copaxone to its infringement claims against Momenta Pharmaceuticals and Sandoz.

The company first sued the two drugmakers last year, claiming infringement of seven Copaxone (glatiramer acetate) patents covering the drug's chemical composition, pharmaceutical composition and methods of use in the U.S. District Court for the Southern District of New York.

The amended complaint was filed under seal with the same court and seeks to include additional patents related to the characterization of Copaxone's active ingredient, Teva says in a statement Nov. 10.

Teva says it doubts "any generic applicant's ability to demonstrate conclusively that the composition of its product is identical to that of Copaxone. … Even minor changes in the synthetic process or molecular weight distribution of a glatiramoid can have severe ramifications on the safety and mechanisms of action of the product."

Momenta declined to comment on the lawsuit.

Teva is also defending its Copaxone patents against a challenge from Mylan Pharmaceuticals and Natco Pharma in a suit filed in the U.S. District Court for the Southern District of New York last month. The suit followed Mylan's ANDA filing for generic Copaxone in September (*Generic Line*, Sept. 16). It accuses Mylan of infringing seven patents covering the product — all of which expire in May 2014, according to court documents (*Generic Line*, Oct. 28).

Earlier this year, the FDA declined to review a citizen petition submitted by Teva in September 2008 asking the agency not to accept applications for generic versions of Copaxone until certain conditions are met (*Generic Line*, April 1).

The first lawsuit is *Teva Pharmaceuticals USA, Inc. et al v. Sandoz, Inc. et al., and the second is Teva Pharmaceuticals USA, Inc., et al. v. Mylan Pharmaceuticals, Inc., et al.* — David Belian

Lupin's ANDA Challenges Depomed On Diabetes Drug Glumetza Patent

Lupin has filed an ANDA for a generic version of Depomed's Type 2 diabetes medication Glumetza.

The company sent Depomed a Paragraph IV certification notice claiming four of its patents on the drug are invalid and will not be infringed by Lupin's manufacturing and selling of Glumetza (metformin HCl), Depomed says in a statement Nov. 10.

Depomed says it has confidence in Glumetza's patents — the first expiration date is in 2016. The company has 45 days to file a patent infringement lawsuit against Lupin to automatically stay or bar the FDA from approving the ANDA for 30 months or until a district court decision is made that is adverse to Depomed.

The company will file if need be, Matt Gosling, Depomed general counsel, told *Generic Line*.

Two of the patents being challenged by Lupin, '475 and '280, had also been challenged by Ivax (*Generic Line*, April 16, 2008).

Depomed filed a complaint Jan. 9, 2006, against Ivax in the U.S. District Court for the Northern District of California for patent infringement, and in December 2007, a judge granted Depomed's motion for summary judgment against Ivax and denied all three Ivax motions related to the validity and enforceability of the patents and its lack of willful infringement.

As a result, Depomed received $7.5 million and Ivax continued to market Glucophage XR. Depomed also receives royalty payments from sales of the drug. — David Belian

Caraco Wins FDA Approval Of Generic Allergan Drug

Caraco Pharmaceutical Laboratories has received FDA approval for a generic version of Allergan's Acular.

Caraco, a unit of Sun Pharmaceutical Industries, will market ketorolac tromethamine ophthalmic solution 0.5 percent, indicated for temporary relief of ocular itching from seasonal allergic conjunctivitis. The solution also is used to treat postoperative inflammation in cataract extraction patients, Sun says in a statement Nov. 6. — April Hollis

Par's Generic Ultram ER Gets 180-Day Exclusivity

Par Pharmaceutical won FDA approval and 180 days of marketing exclusivity for a generic version of Ortho-McNeil's pain-management drug Ultram extended release (ER).

The approval follows an August ruling by the U.S. District Court for the District of Delaware that two patents on Ultram ER (tramadol HCl) were invalid, clearing the way for Par to market the generic versions (*Generic Line*, Aug. 19). Par has begun shipping the product, which is approved in 100- and 200-mg strengths.

Judge Kent Jordan decided the '887 and '430 patents owned by Purdue Pharma Products were invalid as obvious in light of prior art, according to court documents. Both patents expire in May 2014. This prior art reference includes the previously issued '578 patent, according to the documents.

Ultram ER had about $156 million in annual U.S. sales for the 100- and 200-mg strengths, Par says, and it competes with Purdue's Ryzolt (tramadol HCl) and Ortho-McNeil's Ultracet (acetaminophen/tramadol HCl).

The suit, *Purdue Pharma Products L.P., et al. v. Par Pharmaceutical, Inc., et al.*, was originally filed in May 2007. — David Belian

Takeda Prevacid Exclusivity Shouldn't Overlap Generic Drug's

Teva Pharmaceuticals USA was forced to wait one more day than it expected to introduce its generic of Takeda Pharmaceutical's heartburn drug Prevacid because of a district court ruling.

The U.S. District Court for the District of Delaware ruled that Takeda's patent exclusivity, which ended Nov. 10, should not be overlapped by Teva's plan to begin selling its generic the same day. Teva, which filed an ANDA for a generic Prevacid (lansoprazole), waited until Nov. 11.

Teva cited several cases to support its contention that a generic manufacturer may market its product on the date the brand drug's exclusivity expires, according to the opinion in the case. The court notes a lack of precise ruling, adding Takeda should hold its exclusive rights until the end of the day its patent and exclusivity expires, in *Takeda Pharmaceutical Company LTD., et al. v. Teva Pharmaceuticals USA, Inc., et al.*

The company also sued Teva this month over Teva's ANDA for generic Rozerem (ramelteon) 8-mg tablets, an insomnia treatment. — April Hollis

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President: Cynthia Carter; **Publisher:** Matt Salt; **Editorial Director:** David Grant; **Executive Editor:** Theresa Barry

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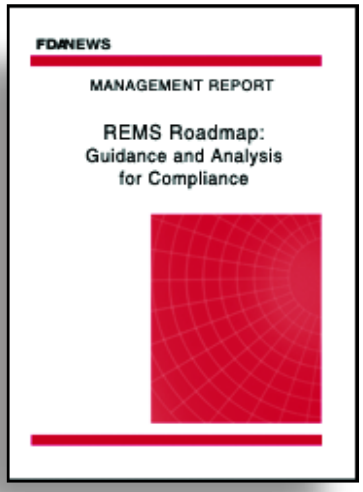

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