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INSIDE THIS ISSUE

Patent: Brazil denies patent on Gilead HIV/AIDS drug.....Page 3

Sun and Taro continue battle over mergerPage 3

FTC requests more information from Teva and Barr on mergerPage 5

Agreements: Perrigo, Syntho sign agreement for XyzalPage 6

Drug Approval: FDA gives thumbs up to Sun's Fosamax.....Page 6

Product Launch: Biovail brings generic TriCor to market.....Page 7

Lawsuits: Pfizer sues to protect Detrol LAPage 7

Texas, Hospira settle in Medicaid case.....Page 7

FDA updates bioequivalence guidelines.....Page 8

Apotex loses appeal in Risperdal case.....Page 9

Appeals Court Rules for FDA In Risperdal Case

The U.S. Court of Appeals for the District of Columbia has vacated a ruling at the FDA's request that had granted Teva Pharmaceutical Industries 180-day exclusivity for its risperidone tablets, a generic version of Janssen's antipsychotic drug Risperdal.

Now the FDA may approve ANDAs from Teva's competitors for generic Risperdal (risperidone), according to Teva.

The agency's appeal stemmed from an April 11 decision by the U.S. District Court for the District of Columbia that found the delisting of the '952 patent covering Risperdal tablets from the Orange Book was unlawful (*Generic Line*, April 16). The FDA and intervenor-defendant Mylan Pharmaceuticals, which had filed an ANDA

(See **Risperdal**, Page 2)

FDA Asks Firms About Generic Cosopt Exclusivity

Roughly a week after Hi-Tech Pharmacal filed a complaint against the FDA to force it to confirm the company is entitled to a period of market exclusivity for generic Cosopt, the agency has requested comment about when ANDAs for the drug should be eligible for final approval.

The FDA has sent a letter to applicants with pending ANDAs for generic versions of Merck's glaucoma drug Cosopt (dorzolamide HCl/timolol maleate), a product for which Hi-Tech and Apotex have tentative approval. The first date an ANDA may be eligible for approval is Oct. 28, according to the letter.

In its letter, the FDA asks how the 180-day generic drug exclusivity forfeiture provisions apply in the case of Cosopt, particularly the applicability of sections dealing with a company's failure to market within 30 months and failure to market relating to the withdrawal of patent information.

(See **Cosopt**, Page 4)

Risperdal, from Page 1

for a generic version of the drug, appealed the decision in May (*Generic Line*, May 28).

Teva submitted the ANDA in August 2001. The FDA informed the company Oct. 12, 2001, that the '952 patent had been delisted from the Orange Book and the agency would not accept the application unless Teva modified it and removed the Paragraph IV certification, Teva said.

The company filed a citizen's petition in August 2007 asking the FDA to relist the patent and confirm its right to 180-day exclusivity. Teva cited a 2006 ruling by the U.S. Court of Appeals for the District of Columbia Circuit in *Ranbaxy Laboratories v. Leavitt* that held the FDA cannot delist a patent after a firm submits a Paragraph IV certification. The agency denied the petition Feb. 26.

Teva lodged a complaint March 4 in the D.C. district court against the FDA, Commissioner Andrew von Eschenbach and HHS Secretary Mike Leavitt. Teva said it was the first to submit an ANDA for Janssen Pharmaceutical's Risperdal tablets with a Paragraph IV certification for the '952 patent, which expires in 2009, making the company eligible for 180-day marketing exclusivity upon approval.

The just-overturned district court's decision had ordered the relisting of the patent and restoration of Teva's Paragraph IV certification, ruling that because the '952 patent applied to Risperdal when the company submitted its ANDA, Teva's certification was proper. He also enjoined the FDA from approving any ANDAs for generic risperidone tablets until the expiration of Teva's 180-day marketing exclusivity period.

As a result of the appeals court's ruling, Teva filed for a temporary restraining order in the district court to prevent the FDA from approving other ANDAs pending a status conference and expedited discovery. It also asked that the FDA be ordered to produce evidence showing that at the time Teva submitted its ANDA, Janssen no longer asserted the '952 patent as claiming Risperdal and that

patent had been removed from the electronic Orange Book query feature as the FDA has claimed.

In a court filing, the company also claims the FDA "adopted a new strategy" when it appealed the case, arguing that the Orange Book "was completely irrelevant, and what mattered was whether the brand manufacturer continued to assert that the patent claimed the listed drug."

Teva says that it should be afforded expedited discovery to test the agency's assertion that the brand company did not assert the patent as claiming the drug at the time it submitted its ANDA. Furthermore, the company said it needs to have the temporary relief because it does not know on what basis the circuit court made its decision, according to court documents.

However, the court denied Teva's request, saying that any relief must come from the court of appeals.

Risperdal is used to treat schizophrenia and mania in bipolar disorder in adults and irritability associated with autistic disorder in children.

— Elizabeth Jones

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Gilead Rebuffed by Brazilian Patent Office

The Brazilian patent office has rejected an application by Gilead Sciences to cover its AIDS drug Viread.

According to a posting on the Brazilian patent authority's website, the anti-retroviral tenofovir had its patent denied. The decision was published in the *Review of Intellectual Property* of August 26, the posting said.

International medical humanitarian organization Médecins Sans Frontières (MSF) praised the decision, which means that Brazilian or foreign generic companies would be allowed to produce generic Viread (tenofovir disoproxil fumarate) and sell their versions for less than Gilead's drug. Companies in India, for example, manufacture World Health Organization-approved tenofovir disoproxil fumarate at one-tenth of Gilead's price — \$158 to treat one patient for a year, compared with the \$1,387 Gilead charges in Brazil, according to MSF.

Gilead told *Generic Line* that although “the terminology would appear to make it as such, this is not the ‘final’ step. It is typical in this process for a rejection to be issued and for the company to then provide detail and background on the patent. This was the process we followed during the recent re-examination proceedings with the U.S. Patent & Trademark Office, resulting in the confirmation of Viread patents, and we would envision following a similar process in this situation. If necessary, appealing a final decision will remain an option in Brazil.”

An estimated 31,000 people are receiving the drug through Brazil's universal AIDS treatment program — a number that could increase to about 37,000 by the end of the year, MSF says.

The patent application filed by Gilead was opposed by a coalition of Brazilian nongovernmental organizations and a government pharmaceutical laboratory. The patent office in Brazil rejected it on the grounds that it lacked inventiveness, according to MSF.

This patent is the first related to an antiretroviral medicine that has been rejected as a result of a pre-grant opposition in Brazil, says MSF. The patent office's decision could have consequences elsewhere, it adds.

Leena Menghaney, MSF's Access Campaigner in India, says Indian civil society organizations have filed a similar opposition to Gilead's patent application and are hopeful that the Indian patent office will take note of the Brazilian decision.

The company says the patent had been issued in several countries — most recently in China — and has been reissued in the U.S. after a thorough evaluation during the re-examination process.

“We remain confident in the strength of our intellectual property for Viread and plan to vigorously defend the patent and the scientific innovation on which it is based,” Gilead said. — Elizabeth Jones

Israeli Court Decision Stalls Sun Acquisition of Taro

The Israeli Supreme Court has issued a stay that prevents Sun Pharmaceutical Industries from closing its tender offer for Taro Pharmaceutical's shares until the appeals process has been completed.

The court will hear arguments in the case Dec. 8, according to a shareholder letter from Taro Chairman Barrie Levitt.

“The Company's counsel has advised that no immediate changes will take place in the control or management of the Company, and that you need do nothing at this time in terms of tendering your shares to Sun,” Levitt writes.

Taro has been able to maintain its momentum during the litigation, improving its operations and financial performance, Levitt adds.

(See [Taro](#), Page 4)

Cosopt, from Page 1

Hi-Tech submitted its ANDA in 2005 and won tentative approval in April. Apotex received tentative approval in July for its generic version of Cosopt.

There are three patents listed in the Orange Book protecting Cosopt. The '413 patent expired April 28 but is entitled to pediatric exclusivity until Oct. 28. The '735 and '443 patents expire in April 2011, but Merck requested that they be removed from the Orange Book April 26, 2006, according to the agency's letter.

Hi-Tech's complaint against the FDA was filed Aug. 28 in the U.S. District Court for the District of Columbia. The company brought its case seeking confirmation that it is entitled to a 180-day period of market exclusivity as the first applicant to submit an ANDA containing a Paragraph IV certification challenging the validity of

the brand company's patents, according to Hi-Tech (*Generic Line*, Sept. 3).

Apotex filed a motion with the court to intervene as a defendant last week, a motion that neither the FDA nor Hi-Tech opposes. Apotex is contending that Hi-Tech has forfeited its eligibility for 180-day exclusivity because it failed to market its product within 30 months of the submission of its application and within 75 days of the patent information being withdrawn by Merck, according to court documents.

However, Apotex does admit that failure by the FDA to make exclusivity decisions sufficiently in advance of a launch date adversely affects manufacturers and consumers, according to court documents.

The agency asks companies to submit comments by Sept. 19. The letter is available at www.regulations.gov/search/index.jsp. — Elizabeth Jones

Taro, from Page 3

Sun agreed to acquire Taro in May 2007 for \$454 million. Some stockholders objected to the agreement's \$7.75-per-share offer and petitioned the Tel Aviv District Court for a temporary injunction, which the court never issued, to prevent Taro from harming minority shareholders (*Generic Line*, June 13, 2007).

In May, Taro said it was canceling a merger agreement with Sun signed by the two companies the previous year. Sun Chairman Dilip Shanghvi fired off a letter telling the Israeli drugmaker it could not exit the deal.

Shanghvi expressed disappointment that Taro made its announcement without discussion. He also pointed out that Taro had only \$47 million in cash as of March 31 and, without Sun's help, "Taro would have virtually negative cash — hardly the 'dramatic' improvement of which Taro has boasted."

Sun's Shanghvi subsequently sent another letter cautioning Taro against selling its Irish

operations. If the divestiture moves forward, Shanghvi said Sun would hold Taro's directors liable for breach of fiduciary or other duties. It also may publish an advertisement in the Irish press notifying potential buyers of its intentions.

Last month, Sun agreed to sell all rights to three generic formulations of the anti-convulsant drug carbamazepine to meet an FTC condition for the proposed acquisition.

The agency is requiring the divestiture to preserve competitive prices for three formulations of the generic product: immediate-release tablets, chewable tablets and extended-release tablets. Both companies either manufacture the generics and sell them in the U.S. or plan to introduce competing versions pending regulatory approval, the FTC says in a statement.

Carbamazepine tablets, which Novartis sells under the brand name Tegretol, are taken daily to prevent and control seizures (*Generic Line*, Aug. 20). — Elizabeth Jones

Second FTC Request Delays Teva-Barr Deal

Teva Pharmaceutical Industries will have to wait to complete its proposed acquisition of Barr Pharmaceuticals now that the FTC has sent a second request to both companies for information about the deal.

The companies say they had expected this request, which causes their waiting period under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 to extend as many as 30 days after they substantially comply with the information request, unless the FTC ends the extension sooner.

“The parties have been cooperating with the FTC staff since shortly after the announcement of the transaction and intend to continue to cooperate with the FTC to obtain HSR clearance as promptly as possible,” Teva and Barr say in a statement.

They still expect to complete the transaction later this year after clearing HSR requirements, getting other required antitrust approvals and satisfying all other closing conditions in the merger agreement, including the approval of Barr stockholders, they add.

Teva, the Israel-based generic drug company, announced last July that it planned to acquire Barr Pharmaceuticals, the fourth-largest generic drug company in the world. Teva agreed to pay \$7.46 billion in cash and stock and to assume Barr’s net debt of approximately \$1.5 billion.

The acquisition will strengthen Teva’s position in the U.S. and Europe, expanding its generic and proprietary offerings as well as its biologic product line. It also will bolster Teva’s specialty pharmaceutical platform through the addition of Barr’s women’s health portfolio to Teva’s respiratory franchise.

The deal came a month after Barr concluded supply and licensing agreements with Bayer for generic versions of the oral contraceptives Yasmin (drospirenone/ethinyl estradiol) and Yaz

(drospirenone/ethinyl estradiol). Bayer will supply Barr with an authorized generic version of Yasmin several years before the drug’s last patent expires. As part of a separate agreement, Bayer will supply Barr with an authorized generic version of Yaz for launch July 1, 2011, or earlier in certain circumstances.

The combined company will operate directly in more than 60 countries and employ approximately 37,000 people worldwide. It also will offer more than 500 marketed products, more than 200 ANDAs pending with the FDA, annual brand sales of more than \$120 billion and approximately 3,700 product registrations pending with regulatory authorities worldwide, primarily in Europe, according to the companies (*Generic Line*, July 23).

The agreement may be terminated under certain circumstances — for example, Barr’s board of directors could accept a better, unsolicited offer before approval of the merger by the company’s stockholders. If the merger agreement is terminated under some circumstances, Barr would have to pay Teva a termination fee of \$200 million. — Martin Gidron

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Perrigo Gets Xyzal Rights

Perrigo has acquired exclusive U.S. rights to sell and distribute levocetirizine tablets, the generic version of Xyzal, from Dutch drugmaker Synthon Pharmaceuticals.

Xyzal (levocetirizine dihydrochloride), which is marketed by UCB and Sanofi-Aventis in the U.S., is approved to treat seasonal and perennial allergic rhinitis and uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years and older. Synthon says it is the first to file an ANDA for a generic version of the drug, entitling it to 180 days of exclusivity upon approval.

UCB and Sanofi are suing Synthon in the U.S. District Court for the Eastern District of North Carolina for infringing on Xyzal's '558 patent.

The firms also are suing Sun, Sandoz and Barr in the same court over their generic versions of Xyzal. — Elizabeth Jones

Sun Gets FDA OK For Fosamax

The FDA has granted final approval for Sun Pharmaceutical Industries' ANDA for generic Fosamax in 5-, 10-, 35- and 70-mg strengths.

Merck's Fosamax (alendronate sodium) tablets are used to treat glucocorticoid-induced osteoporosis and Paget's disease, to increase bone mass in men with osteoporosis and to prevent or treat postmenopausal osteoporosis.

Merck lost patent protection for Fosamax in February, and Barr Pharmaceuticals and Teva Pharmaceutical Industries subsequently shared 180-day marketing exclusivity.

Several other companies have approval for generic Fosamax tablets, including Aurobindo Pharma, Mylan Laboratories and Watson Pharmaceuticals, which sold the authorized generic version in 35- and 70-mg strengths.

— Elizabeth Jones

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Biovail Files Application for Fenofibrate Tablets

The FDA has accepted Biovail's ANDA for a generic version of Abbott Laboratories' cholesterol drug TriCor in 145- and 48-mg strengths.

TriCor (fenofibrate) is used to treat abnormal lipid levels in the bloodstream, including cholesterol and triglycerides. According to IMS Health, Tricor generated U.S. revenues of approximately \$1.45 billion in the 12-month period that ended June 30, with the 48 mg strength accounting for \$69.5 million.

The fenofibrate filing is the company's second successful ANDA filing in the past six months, according to Biovail CEO Bill Wells.
— Elizabeth Jones

Pfizer Sues Impax Over Detrol Patents

Pfizer and two of its subsidiaries have accused Impax in a lawsuit of infringing on patents covering long-acting (LA) Detrol, an overactive-bladder treatment.

In the case filed in the U.S. District Court for the District of New Jersey, the plaintiffs allege Impax has infringed on the '600, '162 and '295 patents. A Swedish subsidiary of Pfizer owns these patents, and Pharmacia & Upjohn holds the NDA.

Impax originally filed an ANDA to market a generic version of Detrol LA (tolterodine tartrate) in the 4-mg strength. However, in a letter dated July 21, Impax informed Pfizer that it had amended the application to include the 2-mg dose. Its ANDA amendment also included Paragraph IV certifications on the three patents, alleging they were invalid, unenforceable or not infringed upon by the manufacture, use or sale of the 2-mg product.

The '600 patent expires in March 2012 and has pediatric exclusivity until September 2012. The '295 and '162 patents expire in August and November 2019 respectively and also have an

additional six months of pediatric exclusivity after each expiration date.

The plaintiffs have asked the court to find that Impax has infringed on the patents covering the drug and to enjoin it from selling the 2-mg product in the U.S. before the expiration of the patents. In addition, they have asked that the effective date of any ANDA approval for Impax's generic product be no earlier than the latest expiration date of the patents, including any extensions.

They also have asked that they be awarded monetary relief should Impax sell the product in the U.S. before the expiration of the patents.

Detrol and Detrol LA had sales of roughly \$290 million in the second quarter, up from \$269 million for the same period last year.
— Elizabeth Jones

Texas AG, Hospira Settle in Medicaid Lawsuit

Texas Attorney General Greg Abbott has reached a \$28 million civil settlement with Chicago-based Abbott Laboratories and its former generics unit Hospira resolving a four-year dispute over whether the firms falsely reported drug prices to Medicaid.

Ven-a-Care of the Florida Keys brought the situation to the state's attention and became a plaintiff in the case. It will receive \$2.8 million as part of the settlement agreement.

Under state and federal law, drug manufacturers must inform the Medicaid program about pricing plans they offer to pharmacies, wholesalers and distributors. The program uses this information to estimate the amount pharmacies pay to acquire the drugs. Pharmacies bill the program for these costs and dispensing fees, and Medicaid reimburses them based on the manufacturer-reported prices.

Because Abbott allegedly reported false prices of various medical products, Medicaid

(See Texas, Page 8)

FDA Provides Update on Bioequivalence Guidelines

The FDA has updated its bioequivalence guidelines for several drugs as part of an effort to develop a full set of online product-specific bioequivalence recommendations that generic drug applicants can use instead of submitting requests for assistance in bioequivalence study design.

The drugs involved are Proctor & Gamble and Sanofi-Aventis' osteoporosis drug Actonel (risedronate sodium), Bristol-Myers Squibb's hypertension drug Monopril-HCT (fosinopril sodium/hydrochlorothiazide), Eli Lilly's psychiatric drugs Zyprexa (olanzapine) and Prozac (fluoxetine HCl), Genetech and OSI Pharmaceuticals' cancer drug Tarceva (erlotinib HCl), and morphine sulfate.

The guidelines that appear in Friday's *Federal Register* were previously posted to the FDA website in accordance with last year's draft guidance, "Bioequivalence Recommendations for Specific Products." Since last October, 66 other product-specific guidelines have been posted.

The FDA's latest bioequivalence update can be viewed at www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2007-D-0369-NAD.pdf. — Martin Gidron

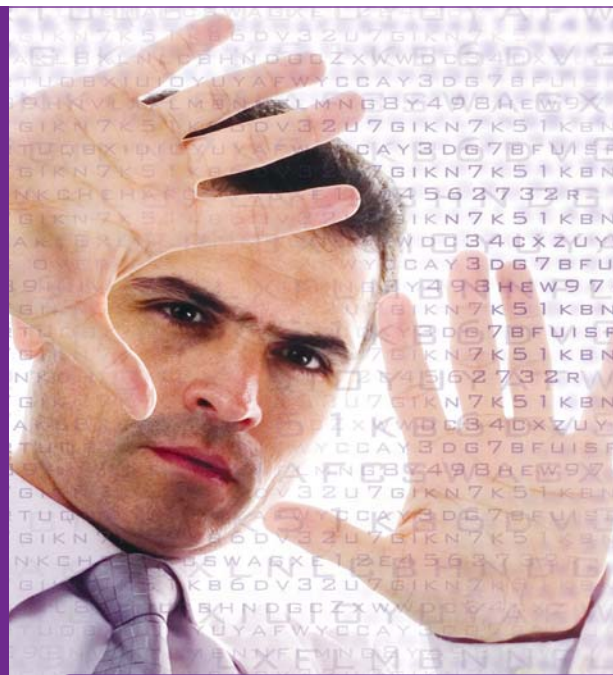
Texas, from Page 7

reimbursed pharmacies at inflated rates. The reporting dates back to the 1990s, according to the attorney general's office.

In May 2004, at about the time the attorney general announced the lawsuit, the defendant spun off its generic pharmaceuticals business unit and created Hospira. The agreement with Hospira will govern its price-reporting practices in the future.

Abbott and Hospira deny all of the plaintiffs' claims and allegations but will settle to "avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these disputed claims," according to court documents.

(See **Texas**, Page 10)



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Appeals Court Rebuffs Apotex in Risperdal Case

A federal appeals court has handed Janssen a win that prevents Apotex from selling an oral solution of the antipsychotic drug Risperdal.

The U.S. Court of Appeals for the Federal Circuit affirmed a decision made by the U.S. District Court for the District of New Jersey. The district court had dismissed Apotex's request for a declaratory judgment with respect to two Janssen patents.

Janssen originally brought suit against Apotex in the New Jersey court in March 2006 after the generic firm amended an ANDA to include a Paragraph IV certification on the '663 patent on Risperdal.

The '663 patent has been the subject of prior litigation. In May 2007, the circuit court found the patent to be infringed, valid and enforceable in the case *Janssen Pharmaceutica v. Mylan Pharm., Inc.* While Apotex was not a party in that trial, it did stipulate to the infringement, validity and enforceability of the patent based on the Federal Circuit decision.

Teva was the first company to file an ANDA for generic Risperdal (risperdone). However, the drugmaker filed Paragraph IV certifications only on the drug's '425 and '587 patents. Because Teva filed a Paragraph III certification for the '663 patent, its product could not have been approved until the pediatric exclusivity expired this past June. The '425 and '587 patents expire in 2014.

Apotex's ANDA initially had only contained a Paragraph IV certification on the '425 and '587 patents, according to court documents.

Janssen did not sue Apotex over the '425 and '587 patents, leading Apotex to assert four counterclaims in its April 25, 2006, answer to the brand drugmaker's complaint. Specifically, Apotex sought a declaratory judgment of noninfringement with respect to the two unasserted patents under the Declaratory Judgment Act.

The plaintiff, Janssen, moved to dismiss the two counterclaims on the '425 and '587 patents June 28, 2006, on the grounds that Apotex did not present a case or controversy as required by Article III of the Constitution. It offered Apotex a covenant-not-to-sue with respect to these patents Dec. 8, 2006, and requested that the drugmaker withdraw its counterclaims. Apotex refused to do so, but the court found for Janssen, ruling there was "no case or controversy" regarding the two patents.

In its appeal, Apotex argued that it was suffering three actual and continuing injuries that created a controversy substantial enough to warrant an immediate issuance of a declaratory judgment. The claims are:

- The company is unable to promptly launch its generic product and compete on the market upon the expiration of the '663 patent;
- The approval of its noninfringing product is being indefinitely delayed; and
- Its affiliates, suppliers and downstream customers face patent uncertainty because Janssen's covenant does not cover them.

Apotex contended that the court's decision in a declaratory judgment case in which Forest Laboratories pledged not to sue Caraco Pharmaceutical over a '941 patent on Lexapro (escitalopram oxalate) applied in this case. In that case, after Caraco sued Forest for a declaratory judgment of noninfringement of the patent, Forest filed a motion to dismiss.

Forest had sued Caraco in the U.S. District Court for the Eastern District of Michigan over Forest's '712 patent on Lexapro. Although Caraco's ANDA contained Paragraph IV certifications for both the '712 and '941 patents, which expire in 2012 and 2023, respectively, Forest sued Caraco only for infringement of the '712 patent.

The district court agreed with Forest that there was no controversy and dismissed Caraco's

(See **Apotex**, Page 10)

Apotex, from Page 9

declaratory judgment action. However, the U.S. Court of Appeals for the Federal Circuit issued a 2 to 1 ruling April 1 reversing a lower court's dismissal of Caraco's declaratory judgment action, remanding the decision to the district court (*Generic Line*, April 16).

However, the court ruled that because Apotex had stipulated to the validity of the patent, the Caraco decision could not be controlling in this case. Furthermore, the harm in the case — Apotex's inability to launch its generic product immediately upon the expiration of the patent — is not sufficient to give rise to declaratory judgment jurisdiction.

The court also held that Apotex's alleged harm of indefinite delay of approval was too speculative to create an actual controversy to warrant the issuance of a declaratory judgment, as there was no basis to conclude Teva would hold up the introduction of its generic product when the New Jersey court rendered its final decision Nov. 2, 2007.

Finally, the court rejected Apotex's argument that Janssen's covenant-not-to-sue is deficient because it does not protect the Apotex's affiliates, suppliers and downstream customers. The court found the following part of the covenant protected the parties:

"Janssen unconditionally covenants not to sue or otherwise seek to hold Apotex liable based on its manufacture, having manufactured, importation, distribution, use, sale and/or offering for sale of the risperdal oral solution 1 mg/mL that are described in and the subject of [the ANDA] ... Similarly, Janssen would not sue or otherwise seek to hold Apotex's customers or

distributors liable based upon the importation, distribution, use, sale and/or offering for sale of the risperdal oral solution."

The court ruled there is no jurisdiction for declaratory judgment action and affirmed the lower court's dismissal.

Risperdal is indicated to treat schizophrenia in adults and adolescents age 13–17 and to treat irritability associated with autistic disorder in children and adolescents age 5–16. It also is indicated for the short-term treatment of bipolar mania in acute manic or mixed episodes associated with bipolar I disorder, as monotherapy or in combination with lithium or valproate in adults or as monotherapy in children and adolescents age 10–17. — Elizabeth Jones

Texas, from Page 8

Under the agreement, within 45 days after the last day of each calendar quarter, Hospira must report to the average manufacturers' price of each of its drugs on the Texas Drug Code Index, according to court documents.

Texas has settled civil Medicaid fraud cases against several companies, including Dey in June 2003 for \$18.5 million, Schering-Plough and subsidiary Warrick Pharmaceuticals in May 2004 for \$27 million total, Boehringer Ingelheim and its subsidiary Roxane Laboratories in November 2005 for \$10 million total and Baxter Healthcare in June 2006 for \$8.5 million.

Enforcement actions against several other manufacturers, including Alpharma, Barr Pharmaceuticals, B Braun Medical, Par Pharmaceutical and Watson Pharmaceuticals, are pending (*Generic Line*, July 23). — Elizabeth Jones

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