located at 74 Harbor Road, Cold Spring Harbor, operates a pumpout. The pumpout is available 24 hours a day beginning May 1 through October 31 and is self-service. No fee is charged for the use of the pumpout. This facility is located outside of the proposed NDA and is not included as one of the ten landside facility. The facility has been included in the application for information purposes.

Vessel waste generated from the pumpout facilities located at West Shore Marina, Knutson's West Marina, Huntington Yacht Club, Brittania Yacht and Seymour's are hauled by privately operated waste haulers. The Town of Huntington provides waste hauling service to the municipally owned pumpout facilities located at Cold Spring Harbor, Halesite Marina, Mill Dam Marina, Woodbine Marina, and Gold Star Mooring and Launch Service. All hauled waste from the pumpout facilities is discharged into and treated at the Town of Huntington sewage treatment plant (SPDES Permit No. NY0021342) located on Creek Road in Halesite.

According to the State's petition, the maximum daily vessel population for the waters of Greater Huntington-Northport Bay Complex is approximately 3200 vessels which are docked or moored with an additional 700 vessels accessing the greater Harbor from boat ramps. An inventory was developed including the number of recreational, commercial and estimated transient vessels that occupy or traverse the greater bay complex. This estimate is based on (1) vessels (approximately 1600 vessels) docked or moored (including transients) in the proposed NDA, (2) vessels (approximately 1600 vessels) docked or moored (including transients) in the existing Huntington/Lloyd Harbor NDA and (3) vessels (approximately 700 vessels) which use the boat ramps in the Greater Bay Complex. While approximately one-third to one-half of the vessels operating in the Greater Bay Complex are not equipped with a MSD, the ratio of boats to pumpout facilities has been based on the total number of vessels which could be expected. With ten shore-side pumpout facilities and two pumpout facilities available to boaters, the ratio of docked or moored boats (including transients) is approximately 267 vessels per pumpout. If we include the vessels (approximately 700) using the available boat ramps, the ratio increase to 325 vessels per pumpout. Standard guidelines refer to acceptable ratios failing in the range of 300 to 600 vessels per pumpout.

The EPA hereby makes a tentative affirmative determination that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the Greater Huntington-Northport Bay Complex in the county of Suffolk, New York. A final determination on this matter will be made following the 30-day period for public comment and will result in a New York State prohibition of any sewage discharges from vessels in Greater Huntington-Northport Bay Complex.

Comments and views regarding this petition and EPA's tentative determination may be filed on or before May 3, 2000. Comments or requests for information or copies of the applicant's petition should be addressed to Walter E. Andrews, U.S. Environmental Protection Agency, Region II, Water Programs Branch, 290 Broadway, 24th Floor, New York, New York, 10007–1866. Telephone: (212) 637–3880.

Dated: March 16, 2000.

Jeanne M. Fox,

Regional Administrator, Region II.

[FR Doc. 00–8146 Filed 3–31–00; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 27, 2000.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. First Merchants Corporation, Muncie, Indiana; to merge with Decatur Financial, Inc., Decatur, Indiana, and thereby indirectly acquire Decatur Bank and Trust Company, Decatur, Indiana.

B. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. Leackco Bank Holding Company, Inc., Wolsey, South Dakota; to merge with C&L Investment Company, Inc., Miller, South Dakota, and thereby indirectly acquire Hand County State Bank, Miller, South Dakota.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. CBCT Bancshares, Inc., Baltimore, Maryland, to become a bank holding company by acquiring 100 percent of the voting shares of Community Bank of Central Texas, ssb, Smithville, Texas.

Board of Governors of the Federal Reserve System, March 28, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–8087 Filed 3–31–00; 8:45 am]

BILLING CODE 6210–01–P

[1]

Geneva not to enter the market during their ongoing patent litigation over the tablet product. According to the complaint, on the day it was granted approval to market its generic terazosin HCL capsules, Geneva contacted Abbott and announced that it would launch its generic terazosin HCL capsules unless it was paid by Abbott not to enter. Two days later, on April 1, 1998, Abbott and Geneva entered into an agreement, pursuant to which Geneva agreed not to enter the market with any generic terazosin HCL capsule or tablet product until the earlier of: (1) The final resolution of the patent infringement litigation involving Geneva's terazosin HCL tables product, including review through the Supreme Court; or (2) entry of another generic terazosin HCL product.

Geneva also agreed-at Abbott's insistence-not to transfer, assign, or relinquish its 180-day exclusively right. The effect of this provision was to ensure that no other company's generic terazosin HCL product could obtain FDA approval; and enter the market during the term of the agreement, because Geneva's agreement not to launch its product meant that the 180-day exclusivity period would not expire.

In exchange, Abbott agreed to pay Geneva $4.5 million per month until a district court judgment in the parties' patent infringement dispute, and then (assuming Geneva won in the district court) to pay the $4.5 million monthly payments into an escrow fund until the final resolution of the litigation, which Geneva would then receive if its district court victory was upheld.

Abbott's payment to Geneva of $4.5 million a month was well over the $1 to $1.5 million per month that, the complaint states, Abbott believed Geneva would forego by staying off the market. The complaint alleges that Abbott was willing to pay Geneva a ''premium'' to refrain from competing because of the substantial impact that launch of a generic version of Hytrin would have on Abbott's overall financial situation. Abbott forecasted that entry of generic terazosin HCL on April 1, 1998 would eliminate over $185 million in Hytrin sales in just six month. Accordingly, the complaint charges, Abbott sought to forestall Geneva—and all other potential generic competition to Hytrin-from entering the market because of the threat they represented to the high profits it was making from Hytrin.

The complaint further charges that, in accordance with the terms of the agreement, Geneva did not enter the market with its generic terazosin HCL capsules, even after the district court and the court of appeals upheld Geneva's position that Abbott's patent was invalid. In August 1999, Abbott and Geneva—aware of the Commission's investigation—terminated their agreement (which by its terms would not have ended until disposition of the litigation by the Supreme Court). Geneva finally brought its generic terazosin HCL capsule product to market on August 13, 1999.

Competitive Analysis

The complaint charges that the challenged agreement prevented competition that Abbott's Hytrin product would otherwise have faced from generic products of Geneva and other potential generic competitors. Generic drugs can have a swift marketplace impact, because pharmacists generally are permitted, and in some instances are required, to substitute lower-priced generic drugs for their branded counterparts, unless the prescribing physician directors otherwise. In addition, there is a ready market for generic products because certain third-party payers of prescription drugs (*e.g.*, state Medicaid programs and many private health plans) encourage or insist on the use of generic drugs wherever possible. Abbott's forecasts, the complaint states, projected that generic terazosin HCL would capture roughly 70% of Hytrin sales within the first six months following its launch. The agreement, however, ensured that Geneva would not offer generic terazosin HCL in competition with Hytrin, and would not take action-such as relinquishing exclusivity rights-that would have permitted the entry of any other generic manufacturer.

These restraints on generic competition had direct and substantial effects on consumers. Without a lower-priced generic alternative, consumers, government agencies, health D(sve, cosao'r agle5tf66r $(Tj, ev.(high pro.fmillv TDd that gen i8

[2] Federal Trade Commission and United States Department of Justice, Antitrust Guidelines for the Licensing of Intellectual Property at § 1.1 n.6(1995)

exclusivity rights; (4) prohibited Geneva from developing or marketing non-infringing generic products. Moreover, the restraints contained in the agreement were entered into without any judicial finding that Abbott was likely to succeed on the merits of its infringement suit, without any consideration of whether Abbott would suffer irreparable injury, and without any weighing of the equities, including any consideration of the public interest.

The complaint also charges that Abbott had a monopoly in the market for terazosin HCL, and, by entering into the agreement with Geneva, Abbott sought to preserve its dominance by delaying the entry of Geneva and other generic companies into the market. As detailed above, there were no countervailing justifications for Abbott's conduct. In addition, the complaint alleges that Abbott and Geneva conspired to monopolize the market for terazosin HCL. As stated in the complaint, Abbott and Geneva acted with specific intent that Abbott monopolize the market for terazosin HCL, and entered into a conspiracy to achieve that goal. Finally, the parties' agreement otherwise amounts to an unfair method of competition in violation of Section 5 of the FTC Act.

The Proposed Orders

The proposed orders are designed to remedy the unlawful conduct charged in the complaint. Although the particular agreement challenged in the complaint has been terminated, prospective relief is necessary to prevent a recurrence of similar agreements with respect to other drugs. Private agreements in which the brand name drug company (the NDA holder) pays the first generic to seek FDA approval (the first filer) not to enter the market can substantially delay generic competition and raise serious antitrust issues. Moreover, the FDA, which has expressed concern about such private agreements, has observed that the incentives for companies to enter into such arrangements are becoming greater, as the returns to the brand name company from extending its monopoly increasingly exceed the potential economic gains to the generic applicant from its 180 days of market exclusivity.[3]

In essence, the proposed orders:

- Bar two particular types of agreements between brand name drug companies and potential generic competitors—restrictions on giving up Hatch-Waxman 180-day exclusivity rights and on entering the market with an non-infringing product;
- Require that agreements involving payments to the generic company to stay off the market be approved by the court when undertaken in the context of an interim settlement of patent litigation, with notice to the Commission to allow it time to present its views to the court;
- Require respondents to give the Commission written notice 30 days before entering into such agreements in other contexts; and
- Require that Geneva waive its right to 180-day marketing exclusivity for its generic terazosin HCL tablet product, so thathe unls-0.004 TDr 5ehat Ge ive thsafth noticent litdxpressf thT*such.e -1.0222 (Prregraph II 5ehhibive Bar kindtypes of)T10155 -1.1 TD(agreem

[3] FDA Proposed Rule Regarding 180–Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 FR 42873, 42882–83 (August 6, 1999).

The form of notice that Abbott and Geneva must provide to the Commission under Paragraphs III and IV of the orders is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, they are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the orders require them to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product a issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, they must provide the Commission with all documents that evaluate the proposed agreement.

In addition, the proposed order against Geneva requires that it waive its 180-day marketing exclusivity period for its generic terazosin HCL tablet product. Although Geneva's exclusivity right with respect to the terazosin capsules product has expired, its exclusivity period for the tablet product still remains as a barrier to entry. This provision of the order will therefore open the market to greater generic competition in terazosin HCL products.

The proposed orders also contain certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The orders will expire in 10 years.

Opportunity for Public Comment

The proposed orders have been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreements or make the proposed orders final.

The purpose of this analysis is to facilitate public comment on the agreements. The analysis is not intended to constitute an official interpretation of the agreements, the proposed complaint, or the proposed consent orders, or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary

The Analysis to Aid Public Comment, published today along with proposed consent orders against Geneva Pharmaceuticals, Inc. and Abbott Laboratories, describes the conduct of those two companies in agreeing that Abbot would pay Geneva to refrain from selling a generic version of Hytrin, Abbott's branded version of terazosin hydrochloride. It also describes relevant provisions of the Drug Price competition and Patent Term Restoration Act of 1984 (''Hatch-Waxman Act''), including particularly the provision that gives the first generic company to seek FDA approval a 180-day period during which it has the exclusive right to market the generic version of a brand name drug.

Pursuant to a private agreement not reviewed by any court, Abbott paid Geneva substantial sums not to enter the market with its generic version of Hytrin, and not to transfer, assign or relinquish its 180-day exclusive marketing right to any other producer of generic products that might compete with Abbot. By not selling its generic version. Geneva prevented the start of the 180-day exclusivity period, with the result that neither Geneva nor any other company could introduce a generic version of Hytrin into the market.

These consent orders represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act, and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

We have today issued an administrative complaint against two other pharmaceutical companies with respect to conduct that is in some ways similar to the conduct addressed by these consent orders. We anticipate that the development of a full factual record in the administrative proceeding, as well as the public comments on these consent orders, will help to shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisors.

Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions