

Trans #	Acquiring	Acquired	Entities
20041160 .....	Emerson Electric Co .....	Marconi Corporation plc .....	Administrativa Marconi Communica- tions S.A. de C.V., Marconi Co- lumbia, S.A., Marconi Communica- tions Canada, Inc., Marconi Com- munications de Mexico S.A., de C.V., Marconi Communications Exportal, S.A. de C.V., Marconi Communications, Inc., Marconi In- tellectual Property (Ringfence) Inc., Marconi Polska Sp zoo.
20041166 .....	WebMD Corporation .....	Cornerstone Equity Investors IV, L.P	VIPS, Inc.
20041176 .....	Johnson Controls, Inc .....	Grupo IMSA, S.A. De. C.V .....	Enertec Colombia, Ltda., Enertec do Brasil, Ltda., Enertec Exports S. de R.L. de. C.V., Enertec Mexico, S. de R.L. de C.V., Enertec Ven- ezuela, SRL, Enertek Argentina, SRL, GES Battery Systems, LLC, GES Technologies, S. De R.L., de C.V.

## Transactions Granted Early Termination—07/30/2004

20041127 .....	HIP Foundation, Inc .....	Carlyle Partners III, L.P .....	ConnectiCare Holding Company, Inc.
20041170 .....	Stab Development S.a.r.l .....	KKR European Fund Limited Part- nership, Alberta, Canada, L.P.	Stabilus HoldCo3 (drei) GmbH.
20041173 .....	Wallace D. Malone, Jr .....	Wachovia Corporation .....	Wachovia Corporation
20041175 .....	Modern Times Group MTG AB .....	StoryFirst Communications, Inc .....	StoryFirst Communications, Inc.
20041177 .....	Time Warner Inc .....	Inner City Broadcasting Corp .....	Urban Cable Works of Philadelphia, L.P.
20041178 .....	Yamanouchi Pharmaceutical Co. Ltd	Fujisawa Pharmaceutical Co. Ltd .....	Fujisawa Pharmaceutical Co. Ltd.
20041180 .....	Wind Point Partners V, L.P .....	Industrial Growth Partners, L.P .....	Breeze Industrial Products Corpora- tion.
20041185 .....	Flextronics International Ltd .....	Peripheral Imaging Corporation .....	Peripheral Imaging Corporation.
20041189 .....	Thomas H. Lee Equity Fund V, L.P ..	Nortek Holdings, Inc .....	Nortek Holdings, Inc.
20041198 .....	Digitas Inc .....	Modem Media, Inc .....	Modem Media, Inc.
20041202 .....	DrugMax, Inc .....	Familymeds Group, Inc .....	Familymeds Group, Inc.
20041205 .....	Apax Excelsior VI, L.P .....	Spyder Active Sports, Inc .....	Spyder Active Sports, Inc.

**FOR FURTHER INFORMATION CONTACT:**

Sandra M. Peay, Contact Representative  
or Renee Hallman, Case Management  
Assistant, Federal Trade Commission,  
Premerger Notification Office, Bureau of  
Competition, Room H-303, Washington,  
DC 20580, (202) 326-3100.

By direction of the Commission.

**C. Landis Plummer,**

*Acting Secretary.*

[FR Doc. 04-18127 Filed 8-6-04; 8:45 am]

**BILLING CODE 6750-01-M**

**FEDERAL TRADE COMMISSION**

[File No. 041-0031]

**Sanofi-Synthelabo, et al.; Analysis To Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the

draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before August 26, 2004.

**ADDRESSES:** Comments should refer to “Sanofi-Synthelabo, *et al.*, File No. 041 0031,” to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form, as explained in the **SUPPLEMENTARY INFORMATION** section. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form (except comments

containing any confidential material) should be sent to the following e-mail box: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov).

**FOR FURTHER INFORMATION CONTACT:** Paul Frontczak, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-3002.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 28, 2004), on the World Wide Web, at “<http://www.ftc.gov/os/2004/07/index.htm>.” A paper copy can be obtained from the FTC Public Reference

Room, Room 130-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Written comments must be submitted on or before August 26, 2004. Comments should refer to "Sanofi-Synthelabo, *et al.*, File No. 041 0031," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H-159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If the comment contains any material for which confidential treatment is requested, it must be filed in paper (rather than electronic) form, and the first page of the document must be clearly labeled "Confidential."<sup>1</sup> The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form should be sent to the following e-mail box: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov).

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at <http://www.ftc.gov>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

#### Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an

Agreement Containing Consent Orders ("Consent Agreement") from Sanofi-Synthelabo ("Sanofi") and Aventis. The Consent Agreement contains an Order to Maintain Assets to preserve, among other things, the viability, marketability, and competitiveness of the assets to be divested pending their divestiture. The Consent Agreement also contains a Decision and Order that is designed to remedy the anticompetitive effects of Sanofi's proposed acquisition of Aventis. Under the terms of the Consent Agreement, the companies will be required to: (1) Divest all Arixtra® assets; (2) divest to Pfizer all United States intellectual property and key clinical trials, currently conducted by Aventis, related to Camptosar®; and (3) divest Aventis' royalty rights to Sepracor's Estorra®.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement and any comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed Consent Order.

Pursuant to a tender offer launched January 26, 2004, Sanofi proposes to acquire Aventis. The offer accepted by Aventis' Board values Aventis at approximately \$64 billion. The Commission's Complaint alleges that the proposed acquisition, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, in the markets for: (1) Factor Xa inhibitors; (2) cytotoxic drugs that treat colorectal cancer; and (3) prescription drugs that treat insomnia. The proposed Consent Agreement would remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

#### Factor Xa Inhibitors

Factor Xa inhibitors are anticoagulant products that are used in acute settings to treat and prevent venous thromboembolism ("VTE") and other conditions relating to excessive blood clot formation. Although unfractionated heparin was once the standard of care for the acute prevention and treatment of VTE and related complications, factor Xa inhibitors have become the treatment of choice due in large part to a better side effect profile and ease of use. Annual U.S. sales of factor Xa inhibitors totaled \$1.35 billion in 2003.

The U.S. market for factor Xa inhibitors is highly concentrated. Aventis' market leading Lovenox® currently accounts for over 90 percent of factor Xa inhibitor sales in the United States. Sanofi markets Arixtra®, a more recent market entrant whose competitive significance is likely to expand as it receives Food and Drug Administration ("FDA") approval for new indications. Although other factor Xa inhibitors are available in the United States—including Pfizer's Fragmin® and Pharmion's Innohep®—they have not been successful competitors in the market.

As with most pharmaceutical products, entry into the manufacture and sale of factor Xa inhibitors is difficult, expensive and time consuming. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture and sell factor Xa inhibitors. In addition, the approval for multiple indications is critical to the success of a new factor Xa inhibitor. Gaining FDA approval for each indication takes a significant amount of time because of the need to conduct clinical trials in support of each indication. New or expanded entry sufficient to deter or counteract the anticompetitive effects of the acquisition likely would not occur in a timely manner. New entry is unlikely to occur in the face of a 5 to 10 percent increase in the price of these drugs, and current factor Xa inhibitors also would be unlikely to counteract such a price increase. The only firm that is likely to launch a product in the United States in the foreseeable future is AstraZeneca, which recently filed a New Drug Application with the FDA for its own factor Xa inhibitor, Exanta®. However, Exanta® is a direct thrombin inhibitor rather than a factor Xa inhibitor. Further, AstraZeneca is seeking approval for only one of the indications that factor Xa inhibitors are approved for. Therefore, it is unlikely that entry by Exanta® would have a sufficient, timely effect on competition to resolve the competitive effects of the proposed acquisition.

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for factor Xa inhibitors by eliminating the actual, direct, and substantial competition between Sanofi and Aventis. This loss of competition likely would result in higher prices.

The proposed Consent Order maintains competition in the factor Xa inhibitor market by requiring that: (1) Sanofi divest Arixtra® to GlaxoSmithKline; (2) Sanofi transfer to GlaxoSmithKline the manufacturing

<sup>1</sup> Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

facilities used by Sanofi to produce Arixtra® in final finished form; (3) Sanofi contract manufacture the active pharmaceutical ingredient ("API") and certain intermediate step ingredients until such time as GlaxoSmithKline obtains the necessary regulatory approvals and supply sources that will allow it to manufacture the API independently; (4) Sanofi assist GlaxoSmithKline in completing three key clinical trials; (5) Sanofi provide incentives to certain employees to continue in their positions until the divestiture is accomplished; (6) for a period of time after the assets are divested, Sanofi provide GlaxoSmithKline an opportunity to enter into employment contracts with individuals who have experience relating to Arixtra®; and (7) Sanofi take steps to maintain the confidentiality of confidential information related to Arixtra®.

### **Cytotoxic Drugs for the Treatment of Colorectal Cancer**

Colorectal cancer is the second leading cause of cancer-related deaths in the United States for both men and women. Approximately 146,940 new cases of colorectal cancer will be diagnosed in 2004 and 56,730 people will die from the disease. Cytotoxic colorectal cancer drugs have been shown to be more effective than older, generic drug treatments. The U.S. market for cytotoxic colorectal cancer therapies currently generates approximately \$1 billion in annual sales.

The U.S. market for cytotoxic colorectal cancer drugs is highly concentrated. Two major cytotoxic products approved by the FDA for the treatment of colorectal cancer are Sanofi's product, Eloxatin®, and Camptosar®, a product developed by Yakult Honsha ("Yakult") and marketed in the U.S. by Pfizer. Combined, the two products have over 80 percent of the U.S. cytotoxic colorectal cancer drug market. Roche is the only other provider in the market with more than a 1 percent market share.

Entry into the market for cytotoxic colorectal cancer drugs is difficult, time consuming, and costly because of the lengthy development periods, the need for FDA approval, and the substantial sunk costs required to research, develop, manufacture and sell these drugs.

Although Aventis does not directly market a cytotoxic colorectal cancer drug in the United States, there are significant contractual entanglements between Aventis and Pfizer that affect the U.S. market. Pfizer licenses

irinotecan (under the brand name Camptosar®) from Yakult for sales in the United States. Aventis licenses irinotecan (under the brand name Campto®) from Yakult for sales in other territories. Under a data transfer agreement, Pfizer and Aventis share the results of key clinical trials. Aventis also possesses a number of U.S. patents relating to Camptosar®. These entanglements allow Aventis to impact the Camptosar® business. The proposed acquisition thus creates an overlap in the U.S. market between Sanofi's Eloxatin® and Aventis' contractual ties to Camptosar®. This overlap affords the combined firm (1) access to competitively sensitive information from its main competitor, Pfizer, and (2) control over key clinical trials that Pfizer relies on for FDA applications that would expand Camptosar® indications in the United States. Therefore, the proposed acquisition would cause significant anticompetitive harm in the U.S. market for cytotoxic colorectal cancer drugs by reducing the actual, substantial competition between Sanofi and Pfizer.

The proposed Consent Agreement eliminates the potential anticompetitive effects of the acquisition in the U.S. cytotoxic colorectal cancer drug market by requiring the parties to: (1) Divest to Pfizer key clinical studies for Campto® that are currently conducted by Aventis, together with certain U.S. patents and other assets pertaining to territories where Pfizer currently markets Camptosar®; (2) provide Pfizer with the opportunity to enter into employment contracts with certain employees involved in the key clinical trials; (3) deliver to Pfizer all confidential business information regarding Camptosar® that Aventis has in its possession; and (4) commit to maintain the assets to be divested in a manner that preserves the integrity, viability, and value of the assets, until the divestitures are accomplished.

### *Prescription Drugs for the Treatment of Insomnia*

More than 50 million people in the United States suffer from insomnia, the perception or complaint of inadequate sleep. The U.S. insomnia treatment market is estimated to have generated approximately \$1.65 billion in 2003 sales and is projected to increase to \$3.36 billion by 2010.

Sanofi dominates the market for prescription drugs that treat insomnia with its well known product, Ambien®. Sanofi's market share in the United States exceeded 85 percent in 2003. Sepracor is developing a product called Estorra®, which is expected to be

launched in the beginning of 2005 and is likely to become a significant competitor to Ambien®. Although Aventis does not market a prescription sleep drug in the United States, there are financial and informational entanglements between Aventis and Sepracor relating to the Estorra® product. Therefore, the acquisition creates an overlap between Ambien® and Aventis' royalty rights to Estorra®.

The proposed acquisition would create anticompetitive effects in the market for prescription drugs that treat insomnia by diluting competition between Sanofi and Sepracor. Although several new products are expected to enter the market in the next five years, it is unlikely that the entry of these products, alone or in combination, could counteract the anticompetitive effects of the acquisition. Accordingly, allowing Sanofi to acquire Aventis' rights to Estorra would reduce Sanofi's incentives to compete against Sepracor in the prescription sleep drug market and would be likely to lead to higher prices.

The proposed Consent Agreement remedies the acquisition's anticompetitive effects by requiring the parties to divest their contractual rights to Estorra®. No later than 90 days after the Order becomes final, the parties are required to divest their rights to Estorra® royalties in a manner that receives Commission approval, either to Sepracor or to a third party approved by the Commission.

### *Interim Monitor*

The Commission has appointed Francis J. Civile as Interim Monitor to oversee the asset transfers and to ensure Sanofi's and Aventis' compliance with all of the provisions of the proposed Consent Order. Mr. Civile has over 35 years of experience in the pharmaceutical industry and is well-respected in the industry. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Order requires Sanofi and Aventis to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the Consent Agreement or to modify its terms in any way.

By direction of the Commission,  
Commissioner Harbour recused.

**Donald S. Clark,**  
Secretary.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Office for Civil Rights; Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Chapter AT, Office for Civil Rights (OCR), as last amended at 65 FR 193279-81, dated April 11, 2000, is being amended to primarily realign the OCR Headquarters functions. The Changes are as follows:

I. Under Chapter AT, Office for Civil Rights (OCR), delete in its entirety and replace with the following:

##### *AT.00 Mission*

##### *AT.10 Organization*

##### *AT.20 Functions*

*Section AT. Mission:* OCR conducts public education, outreach, complaint investigation and resolution, and other compliance activities to prevent and eliminate discriminatory barriers, to ensure the privacy of protected health information, and to enhance access to HHS-funded programs. OCR's activities concentrate on ensuring integrity in the expenditure of Federal funds by making certain that such funds support programs that ensure access by intended recipients of services free from discrimination on the basis of race, national origin, disability, age, and gender; and by maintaining public trust and confidence that the health care system will maintain the privacy of protected health information while ensuring access to care. These OCR activities enhance the quality of services funded by the Department and the benefit of those services by working with covered entities to identify barriers and implement practices that can avoid potentially discriminatory impediments to quality services and protect the privacy of health information. The Department's goal of providing quality health and human services cannot be met when individuals do not receive these services as a result of practices that violate their fundamental rights of nondiscrimination or privacy.

*Section AT.10 Organization:* The Director of the Office for Civil Rights

reports to the Secretary and is responsible for overall coordination of the Department's civil rights and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule compliance and enforcement activities. The Director also serves as the Secretary's Special Assistant for Civil Rights. The Office is comprised of the following components:

- Office of the Director (ATA)
- Office of the Deputy Director for Civil Rights (ATB1)
- Office of the Deputy Director for Health Information Privacy (ATB2)
- Office of the Deputy Director for Management Operations (ATB3)
- Regional Offices for Civil Rights (ATD1 through ATDX)

*Section AT.20 Functions: A. Office of the Director (ATA).* As the Department's chief officer for the enforcement of civil rights and the HIPAA Privacy Rule, and as adviser to the Secretary on civil rights and the HIPAA Privacy Rule, the Director: Is responsible for the overall leadership and operations of the Office for Civil Rights; establishes policy and serves as adviser to the Secretary on civil rights issues and the HIPAA Privacy Rule, including intra-departmental activities aimed at incorporating civil rights and HIPAA Privacy Rule compliance into programs the Department administers and/or operates directly; represents the Secretary before Congress and the Executive Office of the President on matters relating to civil rights and the HIPAA Privacy Rule; sets overall direction and priorities of the Office through budget requests, strategic planning, and results-oriented operating and performance plans; maintains liaison with other Federal departments and agencies charged with civil rights enforcement responsibilities and compliance with the HIPAA Privacy Rule; coordinates with the White House on civil rights, the HIPAA Privacy Rule and related policies; maintains liaison with the Congress in coordination and consultation with the Assistant Secretary for Legislation; and determines policies and standards for civil rights and HIPAA Privacy Rule investigations, enforcement and voluntary compliance and outreach programs in coordination with the Secretary and other Federal agencies.

A Principal Deputy Director performs duties with the authority of the Director as delegated by the Director, assists in coordination and integration of the functions of all Deputy Directors, including cross-cutting activities such as media, public, and inter-

governmental relations, and acts for the Director in his/her absence.

*B. Office of the Deputy Director for Civil Rights (ATB1).* This office is headed by a Deputy Director who reports to the Director, OCR. The Deputy Director for Civil Rights oversees civil rights program operations, policy development, and public education and outreach activities nationwide.

The Office of the Deputy Director for Civil Rights includes operations, policy and public education and outreach functions that are managed through cross-functional teams that focus on: (1) Title VI of the Civil Rights Act of 1964, the Multi-Ethnic Placement Act (MEPA), Title VI and XVI of the Public Health Service Act (Hill-Burton Community Services Assurance provisions), Section 1808 of the Small Business and Job Protection Act, and Title IX; (2) Disability, Age and other nondiscrimination statutes and regulations; and (3) Medicare pre-grant certification reviews, program reporting, surveys and civil rights training.

These teams develop policy and assist in implementation of OCR's civil rights compliance and enforcement program; plan and coordinate OCR's high priority civil rights program initiatives; advise OCR staff nationwide on case development and quality; assist in developing negotiation, enforcement, and litigation strategies; identify training needs and design civil rights-specific training programs for OCR staff; review challenges to OCR civil rights findings; conduct policy and HHS program-related research; coordinate OCR's government-wide responsibilities for implementation of Age Discrimination Act requirements; develop civil rights surveys, and provide civil rights and program advice to OCR staff nationwide, other HHS components and external stakeholders.

Through the team structure, the Office of the Deputy Director for Civil Rights also provides technical assistance to and conducts pre-grant reviews of health care providers seeking Medicare certification and other program participation funded by the Department to determine their ability to comply with civil rights requirements; provides guidance and assistance to OCR Regional Offices to ensure uniform and efficient implementation of pre-grant processing policies and procedures; maintains civil rights assurance of compliance forms for permanent reference; and maintains liaison with and provides civil rights technical assistance and advisory services to HHS Operating Divisions (OPDIVS), as well as national advocacy, beneficiary, and