

categories, and narrower markets contained therein (including, but not limited to, the markets for HMG-CoA reductase inhibitors and ACE Inhibitors). It further alleges that the relevant market for PBM services by national full-service PBM firms, as well as the relevant markets for pharmaceutical products in specific therapeutic categories, are moderately to highly concentrated.

The Complaint further alleges that there are substantial barriers to entry into the relevant markets. Even if new entry were to occur, it would take a long time, during which time substantial harm to competition could occur.

The Complaint further alleges that as part of its PBM services, Medco maintains a drug formulary, which is a listing, by therapeutic category, of ambulatory drug products that are approved for use by the U.S. Food & Drug Administration, and which is made available to pharmacies, physicians, third-party payors, and other persons, to guide in the prescribing and dispensing of pharmaceuticals. Merck pharmaceutical products are included on the Medco formulary. Medco provides a variety of other PBM services, including claims processing, drug utilization review, pharmacy network administration, mail service, and related services. Medco negotiates with pharmaceutical manufacturers, including Merck, concerning placement of drugs on the Medco formulary, rebates, discounts, prices to be paid for pharmaceutical products purchased pursuant to pharmacy benefit plans managed by Medco, and similar matters. Medco thereby influences the prices of pharmaceutical products and the availability of such products under the Medco pharmacy benefit plans.

The Complaint further alleges that the effects of the acquisition of Medco by Merck may be substantially to lessen competition in the relevant markets in 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 following ways, among others:

(a) Products of manufacturers other than Merck are likely to be foreclosed from Medco's formularies;

(b) Reciprocal dealing, coordinated interaction, interdependent conduct, and tacit collusion among Merck and other vertically integrated pharmaceutical companies will be enhanced;

(c) Medco has been eliminated as an independent negotiator of pharmaceutical prices with manufacturers;

(d) Incentives of other manufacturers to develop innovative pharmaceuticals will be diminished; and

(e) Pharmaceutical prices are likely to increase and the quality of the pharmaceuticals available to consumers is likely to diminish.

The Complaint further alleges that the acquisition of Medco by Merck violates 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.

The Order requires Merck to cause Medco to maintain and make available an Open Formulary, and provides that the Medco "Universal Formulary" complies with this provision. A copy of this formulary is appended to the Order. For the purposes of the Order, an open formulary is defined as a formulary that allows the inclusion of any ambulatory (i.e., non-hospital) prescription drug product which the Medco independent Pharmacy and Therapeutics Committee ("P&T Committee") determines is appropriate for inclusion in such formulary.

The Order requires that Medco appoint an independent P&T Committee to administer the formulary. This committee will make all decisions concerning the inclusion and exclusion of drugs on the Open Formulary. The Order sets forth the parameters under which the P&T Committee is to operate.

The Order also requires that Merck cause Medco to accept all discounts, rebates or other concessions offered by any other manufacturer of pharmaceutical products on the Open Formulary, and requires that all such discounts, rebates and concessions be truthfully and accurately reflected in determining relative rankings of products on the Open Formulary. Nothing in the Order prohibits Medco from offering closed formularies as well as the Open Formulary.

The Order also prohibits Merck and Medco from providing, disclosing, or otherwise making available to each other Non-Public Information, with certain exceptions for attorneys and auditors. This includes information concerning other persons' bids, proposals, contracts, prices, rebates, discounts, and or other terms and conditions of sale.

The Order also requires Merck for five years to retain all documents, and to cause Medco to separately retain all documents, relating to the exclusion of any prescription drugs from the Open Formulary, any preference or ranking accorded to any prescription drug on the Open Formulary, and statements or indications of discounts, rebates or other concessions.

The Order also requires Merck and Medco to make known the availability of the Open Formulary to persons who currently have a PBM service agreement or formulary agreement with Medco, and (for a period of five years) to prospective customers.

The Order also compels Merck and Medco to fulfill certain standard notification, reporting and inspection requirements.

The Order terminates seven years from the date it becomes final.

It is anticipated that the Order would resolve the competitive problems alleged in the Complaint. The purpose of this analysis is to facilitate public comment on the Order, and it is not intended to constitute an official interpretation of the agreement and Order or to modify it in any way.

The proposed consent order has been entered into for settlement purposes only, and does not constitute an admission by Proposed Respondents that the law has been violated as alleged in the complaint.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98-23450 Filed 8-31-98; 8:45 am]

BILLING CODE 6750-01-M

FEDERAL TRADE COMMISSION

[Docket 9286]

Summit Technology, Inc.; and VISX, Inc.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreements.

SUMMARY: The two consent agreements in these matters settle 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 complaint that the Commission issued on March 24, 1998, and the terms of the consent orders—embodied in the consent agreements—that would settle most of these allegations.

DATES: Comments must be received on or before November 2, 1998.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: William Baer or Willard Tom, FTC/H-374, Washington, DC 20580. (202) 326-2932 or 326-2786.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade

Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 3.25(f) of the Commission's Rules of Practice (16 CFR 3.25(f)), notice is hereby given that the above-captioned consent agreements containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, have been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreements, and the allegations in the complaint. An electronic copy of the full text of the consent agreement packages can be obtained from the FTC Home Page (for August 21, 1998), on the World Wide Web, at "<http://www.ftc.gov/os/actions97.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted agreements to proposed consent orders from Summit Technology, Inc. ("Summit"), located at 21 Hickory Drive, Waltham, Massachusetts 02154 and VISX, Inc. ("VISX"), located at 3400 Central Expressway, Santa Clara, California 95051.

The proposed consent orders ("Orders") have been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreements or make final the agreements' proposed orders.

On March 24, 1998, the Commission issued a complaint alleging that Summit and VISX violated Section 5 of the FTC Act, as amended, 15 U.S.C. § 45 (the "Complaint"). The Orders, if issued by the Commission, would settle all of the allegations of the Complaint against Summit and settle part of the allegations of the Complaint against VISX (the "Complaint").

The Complaint alleges that Summit and VISX are competitors in the market for photorefractive keratectomy

("PRK"), a form of eye surgery that corrects refractive vision disorders through the use of specialized, computer-guided laser equipment that reshapes the cornea. Summit and VISX each own patents related to PRK, and are also the only firms whose PRK laser systems have received marketing approval from the U.S. Food and Drug Administration.

As set forth in the Complaint, on or about June 3, 1992, VISX and Summit pooled most of their existing patents related to PRK (as well as certain future ones) in a newly created partnership called Pillar Point Partners ("PPP"). According to the Complaint, this pooling arrangement eliminated horizontal competition between VISX and Summit.

The U.S. Department of Justice and the Federal Trade Commission's Antitrust Guidelines for the Licensing of Intellectual Property (April 6, 1995) (the "Guidelines") address the analysis of intellectual property licensing in general, and patent pool arrangements such as that between Summit and VISX in particular. The Guidelines recognize that intellectual property licensing arrangements are "typically welfare-enhancing and procompetitive." Guidelines § 3.1. However, "antitrust concerns may arise when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the license"—what the Guidelines call a "horizontal relationship" *Id.* With respect to pooling arrangements, the Guidelines repeat the same analytical principles. The Guidelines note that pooling arrangements "may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation." Guidelines § 5.5. However, where pooling arrangements "are mechanisms to accomplish naked price fixing or market division," or where they "diminish competition among entities that would have actual or likely potential competitors in a relevant market in the absence of the cross-license" they are subject to challenge. *Id.*

In this case, the Complaint alleges that Summit and VISX were horizontal competitors at the time they formed PPP, because they could and would have competed with one another in the sale or lease of PRK equipment by using their own technology embodied in their respective patents. In addition, Summit and VISX could have engaged in competition with each other in connection with the licensing of

technology related to PRK. The pooling arrangement restricted both forms of competition. Price competition in the sale or lease of PRK equipment was restricted because, under the PPP agreement, VISX and Summit were required to pay a fixed "per procedure fee" to PPP for each PRK procedure performed with its machinery. That "per procedure fee"—set at the higher of the two proposals submitted by VISX and Summit to PPP (\$250)—functioned as a price floor. Because each firm was obligated to pay \$250 per use into the pool, neither had any incentive to lower the usage charge below that level. In the absence of the pool, Summit and VISX would have competed with each other, resulting in lower prices to doctors and consumers for the use of each company's PRK equipment.

PPP has also had an anticompetitive effect in the market for PRK technology licensing. Under the PPP agreement, only PPP can license to third parties the PRK patents contributed by VISX and Summit, but VISX and Summit each retain a veto power over licensing of any of the patents in the pool. In effect, this provision of the pool gave each firm a veto over the licensing of the other's patents. Whereas prior to the pool, each firm could have licensed its own patents unilaterally, after the pool no patent could be licensed without the consent of both companies. Since its formation, the Complaint alleges that PPP has not licensed its patents to any third-party manufacturers and any offers have been economically prohibitive.

The Guidelines add that if a pooling arrangement has an anticompetitive effect in the relevant markets, the Commission should consider whether the pool is "reasonably necessary to achieve procompetitive efficiencies." Guidelines, § 4.2. In analyzing whether the pool is "reasonably necessary," the Guidelines further instruct that

The existence of practical and significantly less restrict alternatives is relevant to a determination of whether a restraint is reasonably necessary. If it is clear that the parties could have achieved similar efficiencies by means that are significantly less restrictive, then the [FTC] will not give weight to the parties' efficiency claim. In making this assessment, however, the [FTC] will not engage in a search for a theoretically least restrictive alternative that is not realistic in the practical prospective business situation faced by the parties.

Id.

Summit and VISX contended that PPP reduced the uncertainty and expense associated with the patent litigation that would have inevitably ensued without PPP, and PPP allows both parties to be in the market, when patent infringement

might have precluded one or both from coming to market. As to the first part of that argument, Summit and VISX could have achieved these efficiencies by any number of significantly less restrictive means, including simple licenses or cross-licenses that did not dictate prices to users or restrict entry. As to the second part of that argument, the Complaint alleges that patent infringement would not have precluded either firm from coming to market.

After concluding that there was reason to believe that the pooling of patents by VISX and Summit was anticompetitive and that PPP was not reasonably necessary to achieve any procompetitive efficiencies, the FTC issued the Complaint. Thereafter, Summit and VISX decided to enter into agreements with the FTC to end the dispute. The Order achieve all of the goals of Counts I and II of the Complaint. As discussed below, PPP has been dissolved and the Orders require Summit and VISX to make pricing and licensing decisions independently. In essence, the Orders return VISX and Summit to the status of competitors in the PRK industry.

The Orders prohibit Summit and VISX (a) from agreeing in any way to fix the prices they charge for the use of their PRK lasers and patents, including the "per-procedure fee" charged to doctors each time he or she uses one of the firms' PRK lasers, and (b) from agreeing in any way to restrict each other's licensing rights and decisions for their PRK lasers and patents.

The Orders require Summit and VISX to cross-license, on a royalty-free and non-exclusive basis the patents each firm contributed to PPP. Although the Complaint contends that VISX and Summit could have competed absent the pool, subsequent sunk-cost investments in reliance on the pool make a cross-license desirable to approximate the competitive conditions that would have been achieved by this point in time had the pool not been formed.

The Orders also require Summit and VISX (a) to take no action inconsistent with the dissolution of PPP, except to the extent necessary for PPP to wind up its affairs and to defend or settle litigation in which it is a defendant, and (b) to return the PPP patents to the firm that contributed them to PPP.

The Orders further require Summit and VISX to give notice of the Orders to any person that previously requested a license to use any of the PPP patents in the manufacture, assembly or sale of PRK equipment since June 3, 1992 (the date PPP was created). Summit and VISX must also give notice to their

customers that they have the opportunity to stop using the lasers without any penalty or continuing obligation (with certain exceptions as set forth in the Orders). Customers that entered into any agreement with Summit or VISX between June 3, 1992 (the date PPP was formed) and June 5, 1998 (the date of PPP's dissolution) that included an obligation to pay a per-procedure fee to license any of the PPP patents will have the opportunity to stop using the laser covered by the patents and negotiate a new licensing agreement with their current licensor or, alternatively, seek a licensing agreement with a competitor. This provision is necessary to restore competitive conditions to those which would have existed had there been no pool at the time these contracts were entered into.

The Orders also compel Summit and VISX to fulfill certain standard notification, reporting and inspection requirements.

The Orders will terminate upon the expiration of the last PPP patent to expire.

The purpose of this analysis is to facilitate public comment on the Orders, and it is not intended to constitute an official interpretation of the agreements and the Orders or to modify them in any way. Additionally, the proposed consent orders have been entered into for settlement purposes only, and do not constitute admissions by Summit and VISX that the law has been violated as alleged in the Complaint.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98-23448 Filed 8-31-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO-98-27]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and

instruments, call the CDC Reports Clearance Officer at (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice. Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Projects

1. *Mammography Rescreening Rates and Risk Factor Assessment—New*

The National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Control and Prevention proposes to conduct Mammography research to reduce breast cancer deaths by detecting tumors while they are still small and easier to treat. Because new tumors can develop in women previously free of breast cancer, older women who face higher risks of developing breast cancer should complete mammography screening every one to two years. To provide cancer screening for low income women, Congress passed the Breast and Cervical Cancer Mortality Prevention Act (Pub. L. 101-354) in 1990. The Division of Cancer Prevention and Control (DCPC) in the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC) was given funding to establish the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The NBCCEDP now provides mammography and cervical cancer screening services to low income and medically under-served women in all 50 states, the District of Columbia, 4 territories, and 13 tribes. To assist state, territorial, and tribal programs with efficient service delivery, new data are needed to [1] estimate scientifically valid, statistically precise estimates of mammography rescreening rates and [2] identify the factors associated with