

MANELLI DENISON & SELTER PLLC
ATTORNEYS

June 24, 2004

Federal Trade Commission
Office of the Secretary, Room H-159 (Annex L)
600 Pennsylvania Avenue NW
Washington, DC 20580



Re: Contact Lens Study, Project No. V040010

Dear Sir/Madam:

These comments are submitted on behalf of the Contact Lens Manufacturers Association (CLMA), a 40 year old trade association whose member companies are engaged in the custom manufacturing of gas permeable (GP) and hydrophilic (soft) contact lenses.

A review of the Commission's request for public comment (69 FR 21833; 4/22/04) indicates that the issues noted for specific comment relate primarily to competition in the sale of soft (hydrophilic) contact lenses which are mass produced in specific sizes and parameters and thereafter held in inventory for sale (stock lenses).¹ These should be distinguished from lenses, both GP and soft, which are manufactured only in response to a prescription for a specified patient (custom manufactured lenses). Such lenses may be intended for specific indications (e.g., keratoconus, orthokeratology, post-lasik surgery), or they may be intended for general vision correction.

The CLMA has no comments to offer as to the issues stated in paragraphs 1. through 30. of the request for comments. As indicated, these relate primarily to competition in the sale of stock lenses. However, Section 10 of the Fairness to Contact Lens Consumers Act (15 U.S.C. 7601) mandates an FTC study and report which extends to all issues having an impact on competition in the sale of prescription contact lenses. This would include issues relating to competition between marketers of custom manufactured and stock lenses. CLMA believes that the Commission should carefully consider issues relating to competition between typically large companies which market stock lenses and the smaller companies which market custom manufactured lenses.

¹ This would also include the Commission's references to "custom labeled" lenses, as CLMA understands that term; i.e., lenses which, aside from a private label, are identical to other, differently labeled, lenses made by the same manufacturer.

As one such example, in response to question 31 of the request for comments, CLMA directs the Commission's attention to the issue of professional education. Specialized continuing education of ECPs is of particular importance to GP lens manufacturers.

Throughout the United States, continuing education (CE) is a condition for maintaining a license to practice optometry. The advantages of GP lenses, including recent and ongoing advances in their applications in orthokeratology and the slowing of myopia development are important subjects for ECP professional education programs.


The education efforts of individual companies and the CLMA have been hindered by restrictions on continuing education (CE) credit for such programs. These restrictions are imposed by the Association of Regulatory Boards of Optometry (ARBO) whose Council on Optometric Practitioner Education (COPE), with only isolated essentially *ad hoc* exceptions, now denies CE credit for any course or seminar not given by a "doctorate level" presenter. This effectively excludes qualified presenters having specialized expertise in GP lens fabrication, fitting and clinical applications. Since COPE is appointed to act on behalf of state regulatory boards of optometry, with some state boards specifying that only COPE-approved CE courses qualify for license renewal, its actions have a significant impact on professional education available to optometrists in the United States. CLMA recommends that the Commission's forthcoming study consider the competitive impact of denial of CE accreditation for professional courses, meetings and seminars. .

Another area of concern relates to the operations of a patent consortium which has asserted proprietary rights over the use of GP lenses for orthokeratology and has imposed significant licensing restrictions on the sale of GP lens blanks intended for fabricating such lenses. Since orthokeratology is one of the most significant applications of custom manufactured GP lenses, these restrictions have the potential for adverse effects on competition and future development of this technology.

Based on present information, the participants in this patent pool did not submit the proposed arrangement in advance to either the Antitrust Division or to the Commission for antitrust analysis. Because of its potentially long range effects on the industry, CLMA recommends that the Commission undertake such an analysis in connection with its study. This should include consideration of whether the arrangement restricts competition and whether the pooled patents could be licensed and used in competition with each other. In the latter case, the patent pool could be a means of eliminating competition among the participants.

CLMA appreciates the opportunity to comment on this important study.

Sincerely,


Daniel J. Manelli

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Re: Contact Lens Study, Project No. V040010

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