

From: DBELLMD
Sent: Thursday, June 24, 2004 2:10 PM
To: CONTACTLENSSTUDY
Subject: Specialty Lens Concerns

June 24, 2004 Federal Trade Commission
Office of the Secretary, Room H-159
(AnnexL)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 Corneal Design Corporation, a private business engaged in the custom manufacturing of gas permeable (GP) and sale of 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 relates 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). 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, ortho-keratology, post-lasik surgery), or they may be intended for general vision correction.

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 inventory 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

As one such example, in response to question 31 of the request for comments, CLMA directs the Commission's attention to the following 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. Many U.S. schools of Optometry have discontinued all courses related to the analysis and fitting techniques associated with specialty GP contact lenses.

My background as an inventor of many lens designs and my clinical experience of 25 years does not qualify me to present potential healthcare solutions to practitioners and allow them to receive CE approval at professional meetings. This fact has had a negative impact on our ability as a small company to explain the unique advantages of products that are designed to solve many problems associated with the eye. Larger manufacturers of soft lens products support education for their own lens products and simply pay for the consultant practitioner to present and promote their options to the doctors for approved CE. I believe that this elimination of one group that previously had been allowed to present for over 20 years is a self serving policy that does not benefit the healthcare system.

As a small manufacturer, we compete against much larger domestic and foreign corporations. I am particularly concerned with the development of a patent consortium which has asserted property rights over all forms of corneal reshaping or ortho-keratology GP lenses. I am, in particular, concerned over the restrictions which are being imposed on small companies for the privilege of fabricating such lenses. Since the future of our business is bound up in these types of GP lenses, the FTC should review all aspects of the patent licensing arrangement.

We have also become aware of large price variations in the cost of the lens blanks which we must purchase to fabricate GP lenses. We cannot continue to compete indefinitely with larger manufacturers who are evidently receiving discounts that allow them to sell their finished lenses at nearly the same price as we must pay for the raw material. Our understanding is that some of these lens blanks are initially being sold overseas at heavily discounted prices (\$3.00 each, for example, as opposed to \$6 to \$7 here), and then being brought back into the country and made available to selected manufacturers. This could explain some, but not all, of the pricing variations we are seeing. We respectfully request that the Commission study the pricing differences for GP lens blanks.

The GP segment of the market continues to suffer a decline (5 to 8 %) for the past 7 years while international use of these products remains relatively stable. U.S. soft lens manufacturers have flooded the market with misleading and sometimes damaging information about GP lenses. One large soft lens manufacturer owns the largest supplier of GP lens raw material and without regard to the healthy benefits of GP lenses has spent millions of dollars on consumer advertising to replace the GP lens with cheaper to manufacture and more frequently replaced soft lens products. These marketing campaigns do not address the "health of the eye" issues that GP lenses represent.

Savings to the consumer in the U.S. can be estimated at 1.4 billion annually if the appropriate patients are selected to be fit in GP lenses as compared to soft disposable lenses. The average patient pays \$ 300 / year for disposables and we find that the average GP wearer sees more clearly, has less potential risk of complications, and saves \$ 200 / year. Again these GP lenses are made by small manufacturers and not the larger soft lens producers. We respectfully request that the Commission study the industry trends and conditions that reflect the decline in usage of lower priced, healthier lenses.

Most sincerely ; Daniel Bell - President / Corneal Design Corporation