

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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Dale P. DEVORE et al.) Group Art Unit: 1617
)
Application No.: 13/813,557) Examiner: Ali Soroush
)
Filed: January 31, 2013) Confirmation No.: 3557
)
For: COLLAGEN-BASED IMPLANTS)
FOR SUSTAINED DELIVERY OF)
DRUGS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Commissioner:

Commissioner:

DECLARATION

I, Dr. Dale DeVore, declare:

1. I am one of the co-inventors of the subject matter described and claimed in Application No. 13/813,557.

2. In 1973, I received Ph.D. in Food Science & Technology with emphasis on biochemistry from Rutgers University. I have worked in research and development in the field of ophthalmology since 1976. My research and experience include, among other things, (1) developing of collagen-based viscoelastic solutions for cataract surgery, (2) developing of cornea grafts, *in situ* polymerizable intraocular lenses, and ocular drug delivery systems, and (3) developing methods to stabilize the cornea following orthokeratology procedures to correct myopia.

**Prolenium v. Allergan
IPR2019-01505, et al.
DeVore Depo. Ex. 72**

3. In forming the opinions expressed in this declaration, I have reviewed this application and its currently pending set of claims, the Office Action of March 31, 2015, and the references cited therein, including:

- U.S. Patent No. 5,259,998 to Reich et al. ("*Reich*"); and
- U.S. Patent No. 6,261,547 to Bawa et al. ("*Bawa*")

4. In my opinion, none of the references cited by the Examiner teach or suggest the claimed collagen-based films, wafers, or membrane constructs or methods for preparing such collagen-based films, wafers, or membrane constructs.

5. The Examiner asserts that the combination of *Reich* and *Bawa* teach or suggest claims 1-17. In my opinion, this is incorrect.

6. In general, *Reich* teaches a biosoluble ophthalmic shield that can be placed in or on the eye and can optionally contain an ophthalmic drug that is slowly released into the eye as the shield dissolves. *Bawa* describes ophthalmic compositions containing xanthan gum.

7. The shields taught by *Reich* all dissolve within one week. For example, at column 6, lines 23-31, *Reich*'s Examples 1-12 teach that, following drying and crosslinking by exposure to UV irradiation for 4 minutes, 6 minutes, and 10 minutes, the resulting shields "all showed excellent biosolubility properties in physiological fluids with no residue observable after one week." Similarly, in Example 13 (column 7, lines 2-9), the collagen shield crosslinked by UV light for 4-10 minutes "showed excellent biosolubility properties and should completely dissolve on an eye, with no residue observable on a subjects eye after one week."

8. In my opinion, the compositions and properties taught by *Reich* would not be suitable to produce a collagen based implant for drug delivery beyond one week, and certainly not for three or more months.

9. Furthermore, *Reich* does not teach or suggest that longer exposure to UV light could lead to collagen-based films, wafers, or membrane constructs capable of lasting at least three months. That is, *Reich* teaches that 4 minute exposure times and 10 minute exposure times both result in shields that dissolve in less than one week. Put another way, more than doubling the UV exposure time from 4 minutes to 10 minutes does not appreciably change the biosolubilization times. One of ordinary skill in the art would not have a reasonable expectation that increasing the UV exposure times to 17 to 19 minutes would greatly affect the biosolubilization time. And it is unexpected that collagen-based films, wafers, or membrane constructs could be made to last 3 months—12 times longer than *Reich's* shields—with less than a two-fold exposure compared to the longest time disclosed in *Reich*.

10. *Bawa* does not teach or suggest any type of collagen-based film, wafer, or membrane construct, and does not address the deficits of *Reich* noted above.

11. In sum, neither *Reich* nor *Bawa* teach or suggest a film, wafer, or membrane construct that can deliver drugs for at least three months. The ability of the claimed film, wafer, or membrane construct to prolong drug delivery 12 times longer than any shield taught by *Reich* is unexpected. And one of ordinary skill in the art would not have a reasonable expectation of success of obtaining the claimed collagen-based films, wafers, and membranes in light of the teachings of *Reich* and *Bawa*.

16. Thus, it is my opinion that the references discussed above and cited by the Examiner in the Office Action do not teach or suggest all of the features recited in the claims of this application.

17. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: August 23, 2015

By: 
Dr. Dale DeVore