

DECISION OF THE COMMISSIONER

UNOBVIOUS: New Structure Producing New Result.

The perforations of applicant's sponge serve a completely different function from that of the prior art.

FINAL ACTION: Overruled.

\*\*\*\*\*

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated October 22, 1971 on application 957,123. This application was filed in the name of Richard L. Kronenthal and refers to "Collagen Sponge". The Patent Appeal Board conducted a hearing on April 24, 1972. Mr. L. Dauphin and Mr. R. Jackson represented the applicant.

In the prosecution terminated by the Final Action the examiner refused the claims of the application in view of prior art. The prior art cited is as follows:

United States Patents		
2,610,625	Sept. 16/52	Sifferd et al
2,508,214	May 16/50	Biederman

(The decision quotes parts of the Final Action and the response dated January 24, 1972. The rejection was based on the premise that the increased absorbency of the sponge as in the prior art, rather than allowing passage of blood completely through the pad.)

This application relates to a perforated collagen sponge that is useful in surgical procedures. The applicant has requested that claims 1-6 presently on file be replaced by new claims 1-6. The assumption here is that the applicant intends no further consideration of the claims to be cancelled. Claims 7-12 are dependent claims which stand or fall with new claim 1. New claims 1-6, and 7-12 as dependent on new claim 1, will be considered on their merits. Claim 1 reads:

A surgical sponge, comprising, a flat homogeneous wafer-like sheet of collagen having a body formed with an interconnected cellular structure resulting from freezing a dispersion of collagen fibrils and lyophilizing the frozen dispersion to remove volatile components, thus providing a mass of collagen fibrils containing a network of channels extending in heterogeneous directions, said

structure having a high blood-absorbing capacity but normally in the hemostasis of actively oozing tissues rendering the sheet susceptible to the phenomenon of being floated away in the absence of direct pressure, said body also being perforated with small regularly spaced holes extending over the entire surface and having a size from 0.1 mm to 3 mm in diameter extending directly through the body from one surface to the other and adapted to permit excess blood to flow into and through the sponge during clot formation thereby to avoid the floating away phenomenon and to improve hemostasis of actively oozing tissue surfaces.

The reference to Biederman discloses a surgical device formed from a pad of loosely matted fibers of cotton or the like having a high absorbency. A plurality of perforations are formed through the pad and serve to conduct fluids, such as blood, so that the fluids are distributed throughout the pad and do not remain at the surface to coagulate. The reference to Sifferd discloses a surgical sponge pad made from collagen and is effective as a sponge for various types of surgical techniques.

The applicant admits that collagen sponges are known and brings attention to United States Patent 2,610,625 which is one of the cited references. The problem which faces the applicant involves the hemostasis of actively oozing tissue surfaces wherein even the more absorbent sponge structures tend to float away unless direct pressure is maintained.

The object of the invention in Biederman relates to pads having increased capacity for absorbing fluids for conveying fluids from the area of contact to remote parts of the pad (note page 1 lines 1-10 of this patent). It is clear that the objective then is to increase the absorbency of the pad and not to flow liquid through the pad as this would completely defeat the purpose of said pad.

The object of the present invention is to permit excess blood to flow into and through the sponge during clot formation, thereby to avoid the floating-away phenomenon and to improve hemostasis of actively oozing tissue surfaces. It is clear that the purposes of the perforations in the sponge as disclosed in this application is to allow blood to flow completely through the sponge thereby preventing flotation of the sponge and at the same time does not prevent coagulation at the surface. If the Biederman's device was to be used for hemostasis purposes, then coagulation would be a desired result. However, on the contrary, Biederman is concerned with preventing coagulation

to achieve maximum capacity and thus seeks the opposite of hemostasis.

The perforations of applicant's device may be considered as relief valves and serving a completely different function to the perforations or channels in the device of Biederman and this reference must therefore be considered non-analogous, at least in purpose.

The Board is satisfied that the applicant has made an advance in the art and a prima facie showing of ingenuity. The new claims, which are now restricted to a flat homogeneous wafer-like sheet being perforated with small regularly spaced holes extending over the entire surface, overcome the prior art applied by the examiner. The Board recommends that new claims 1 to 6 be entered and that these claims and claims 7 to 12, as dependent on new claim 1, be considered allowable in so far as the matters herewith are concerned.

R. E. Thomas,  
Chairman, Patent Appeal Board.

I concur with the findings of the Patent Appeal Board and direct the amendment to be entered. This application will be returned to the examiner for resumption of prosecution.

Decision accordingly,

A. M. Laidlaw,  
Commissioner of Patents.

Agent for Applicant

Messrs. Alan Swabey & Co.,  
Montreal, Quebec

Dated at Ottawa, Ontario,  
this 27th day of April/72