

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.

Petitioner,

v.

FACET TECHNOLOGIES, LLC

Patent Owner.

Case No. IPR2023-00712

U.S. Patent No. 8,840,635

**DECLARATION OF PAUL HATCH IN SUPPORT OF PETITIONER'S
REPLY**

I, Paul Hatch, hereby declare as follows:

1. I have been retained as an expert by LifeScan, Inc. in connection with the ongoing assertions of patent infringement by Facet Technologies, LLC of U.S. Patent No. 8,840,635 in the underlying district court litigation of *Facet Technologies, LLC v. LifeScan, Inc.*, C.D. Cal. Case No. 2:22-cv-01717-MSC-MAR. I submit this Declaration to support Petitioner's Reply to Patent Owner's Response to Petition in IPR2023-00712. I have personal knowledge of the facts set forth in this declaration and could testify competently to them if asked to do so.

2. I am the recently retired CEO of TEAMS Design USA, a global product design consultancy. I have over 25 years of product and industrial design experience and have designed many healthcare and dentistry products, such as operation tools, MRI and CTA equipment, patient recovery chairs, IV poles, and tools for dental care. I designed many products for global companies such as Bosch, Siemens, Stryker, Dentsply, United Imaging, Honeywell, Johnson Controls, Intel, and Bissell. I have also designed many mass-produced products that center around ergonomics and visual communication for ease of use. In my company, I was actively involved in all phases of the development process, including the user research, idea conceptualization, styling, visual brand language, development, engineering and overseeing the final production stages.

3. I reside in Chicago, Illinois. I hold a Bachelor of Arts degree with honors (BA (Hons)) in Industrial Design from the University of Northumbria at Newcastle, United Kingdom. While studying to obtain my honors degree in Industrial Design, I took courses covering subjects including technical drawing, computer aided drawing, ergonomics, product styling and brand language, product evaluation, usability testing, production techniques, prototyping, mechanical engineering, and production techniques. I am currently a candidate for a doctorate degree in the Learning Sciences and have recently created and taught a graduate course on visual perception and cognitive psychology called "Perceptual Design."

4. In the course of my work as a designer and managing teams of designers, I have gained an understanding of the training, knowledge, skills, and abilities of a person skilled in the art of industrial design and mechanical engineering. Through this work, I have also gained an understanding of how a designer perceives and appreciates the functional merits of a product's design, and I use this understanding to opine on how a person having ordinary skill in the art ("POSITA") would answer questions raised in the examination of patent claims. Through user research of various types, I have also gained a good understanding of how consumers view, choose, and purchase products related to the fields I have designed in.

5. I am the named inventor of over 50 design and utility patents.

6. I was recently nominated into the prestigious IDSA Academy of Fellows. I have also been awarded many design awards, including the “Design of the Decade Award” from Business Week. In 2016, I was elected to the board of IDSA as Director-at-Large. I have previously provided expert testimony in many other patent-related matters.

7. On June 20, 2023, I signed my “Rebuttal Expert Report of Paul Hatch Regarding Non-Infringement of U.S. Patent No. 8,840,635,” which I understand is being submitted as Ex.1045 in this IPR.

8. I have reviewed Ex.1045. This exhibit is my “Rebuttal Expert Report of Paul Hatch Regarding Non-Infringement of U.S. Patent No. 8,840,635” signed on June 20, 2023.

9. For purposes of this Declaration, I hereby adopt and swear to these opinions set forth in Ex.1045.

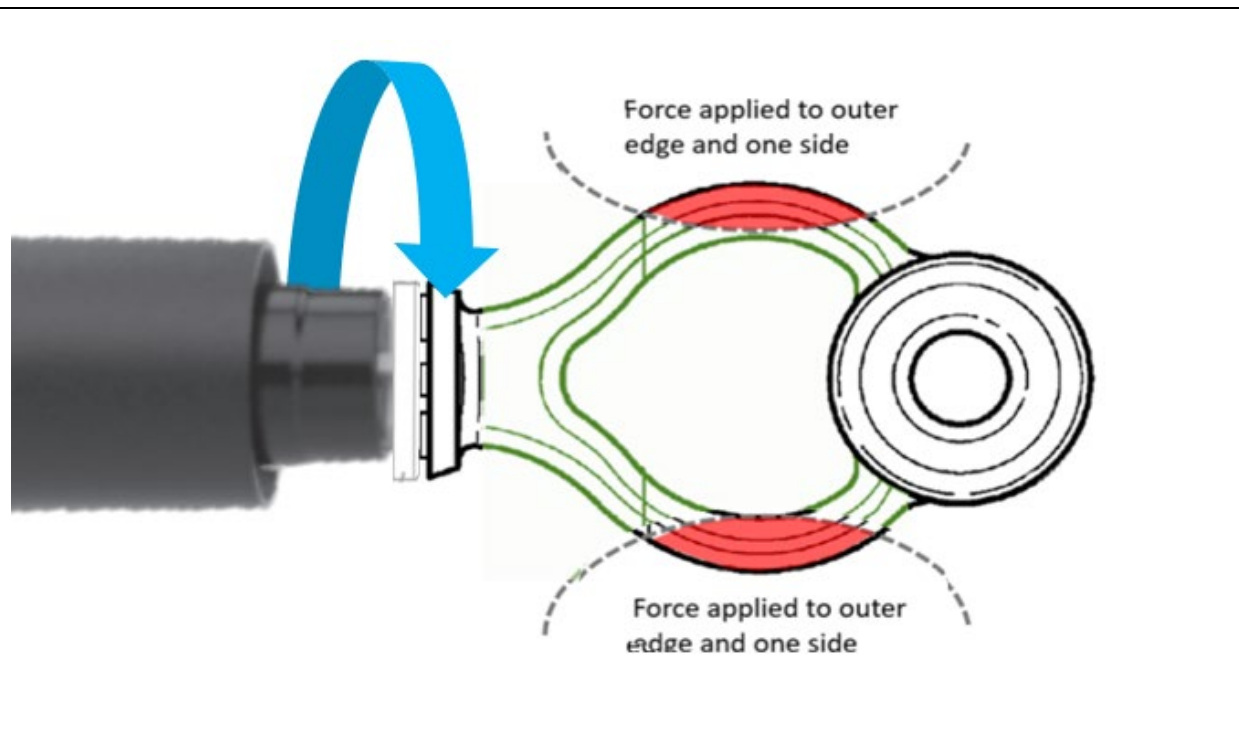
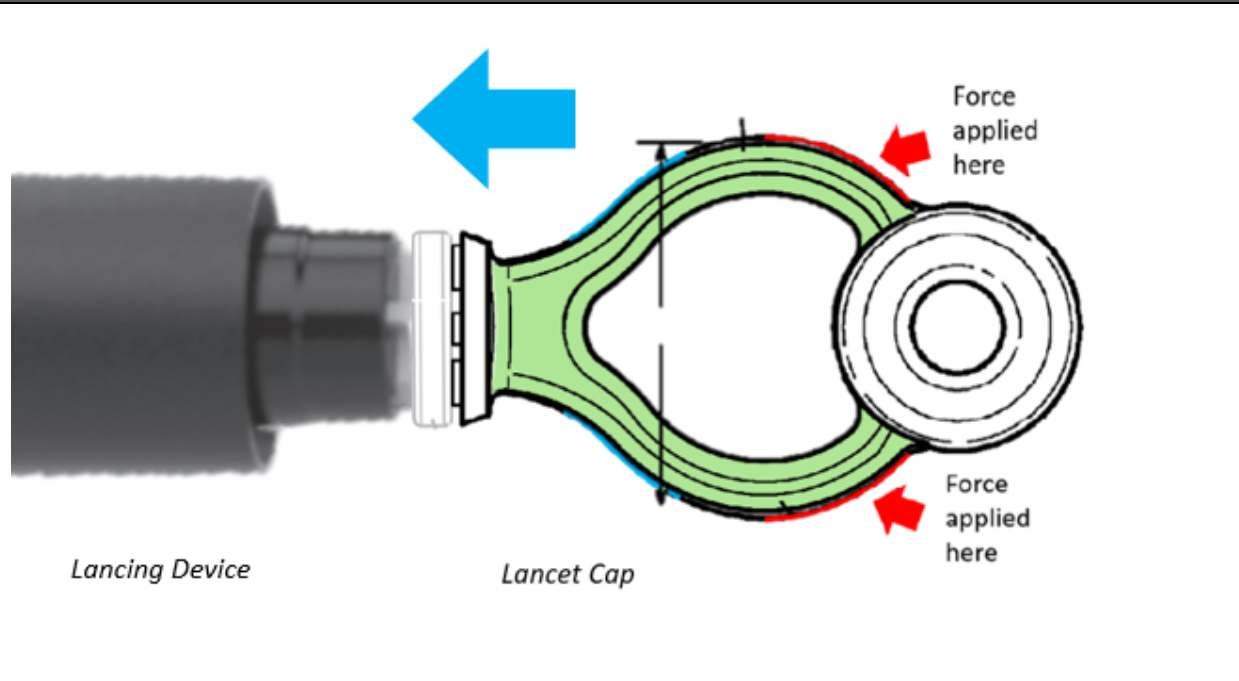
10. In my Rebuttal Report, I provided a detailed explanation and analysis as to why the protective cap on the Delica Plus lacks the “gripping handle portion extending between the primary sheath and the secondary sheath” required by the claims of the '635 patent. For purposes of this declaration, I have been asked to consider whether the protective cap on the Delica lancet meets the “gripping handle portion extending between the primary sheath and the secondary sheath” as required by the '635 patent. It is my opinion that the protective cap on the Delica

lancet fails to meet this claim limitation for substantially the same reasons that I already provided in my Rebuttal Report regarding the Delica Plus.

11. In particular, a POSITA would not consider any portion of the Delica protective cap that extends between its primary and secondary sheaths (known as the “neck” portion) to be a handle. The neck portion of the Delica lancet does not have any structural elements or touchpoints (i) to physically fit or accommodate the users’ hand or fingers or (ii) to provide a mechanical advantage to the user. It is therefore my opinion that the neck portion of the protective cap for the Delica lancet does not have the structure of a handle.

12. Like the Delica Plus protective cap, the Delica protective cap contrasts starkly with the “extension arm” having outwardly bulging arms that is disclosed in the ’635 patent and discussed throughout my Rebuttal Report. As I explained in my Rebuttal Report, a POSITA would understand that these outwardly bulging arms in the ’635 patent provide a visual cue to a user regarding where to grasp the cap, accommodate the user’s fingers, and make it easier for a user to apply force when inserting or pushing the lancet into the lancing device as well as when twisting off the cap to perform a lancing operation. I illustrate both of these use cases in the below images.

Table 1: How the push and twist motions are accommodated by the gripping handle of the '635 Patent.



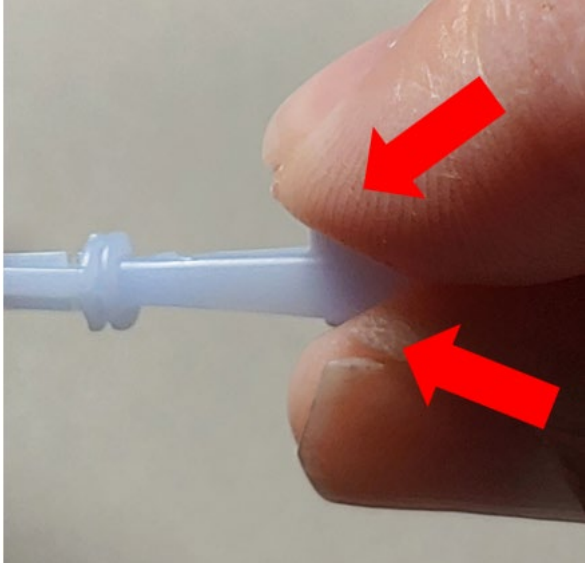
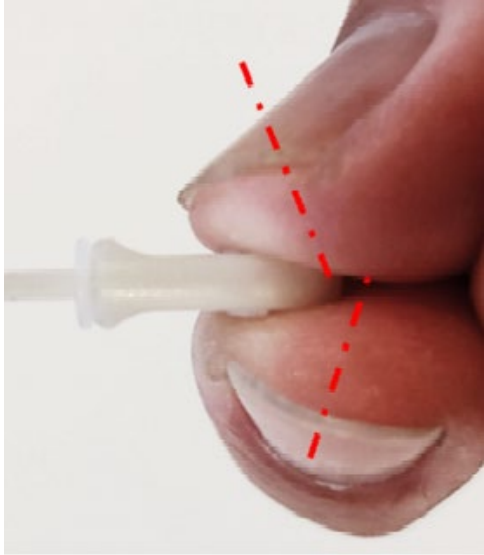
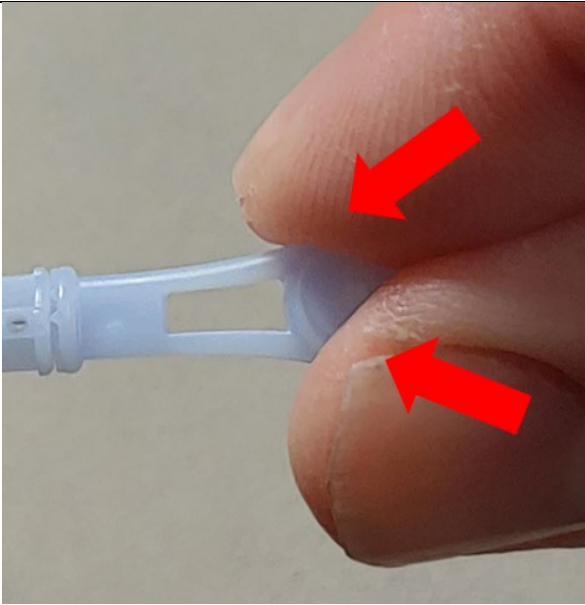
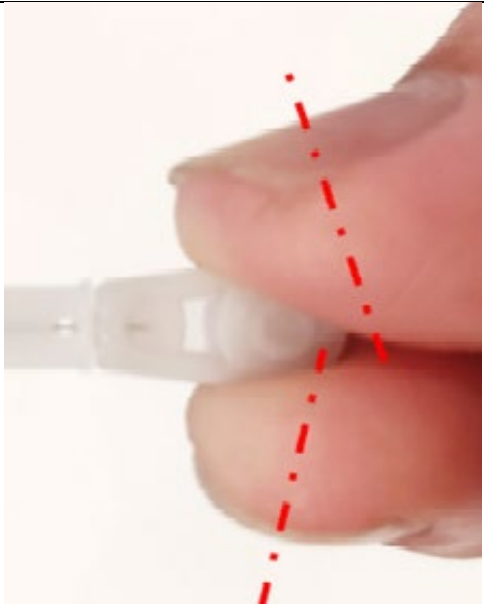
13. The neck of the Delica protective cap, by contrast, does not have any structure that is especially designed to physically fit or accommodate a user's hand or fingers, and does not bulge outward to provide a greater width for gripping as in the '635 patent. Furthermore, while a user's finger may have incidental contact with the neck portion on these caps, the neck structure on the Delica lancet protective cap is much narrower than the secondary sheath and does not make the cap wider or otherwise easier to grab or twist. These same conclusions also apply to the Delica Plus protective cap, as I explain throughout my Rebuttal Report.

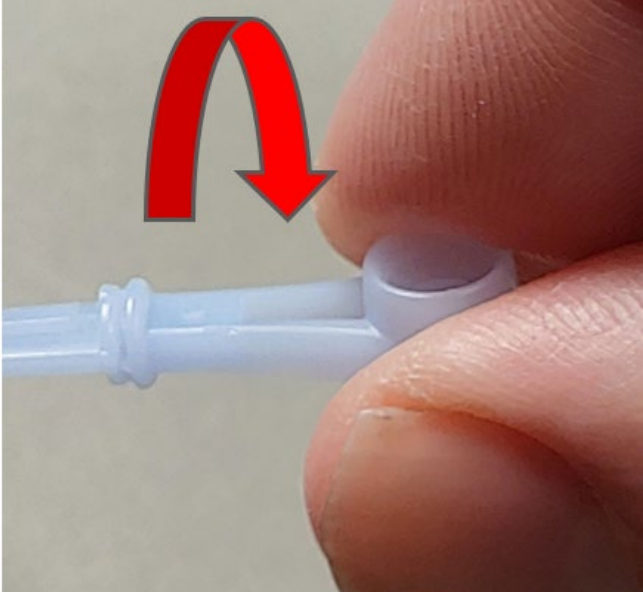
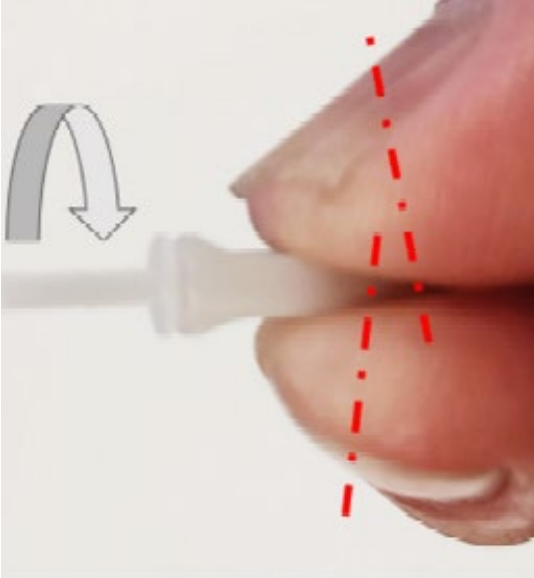
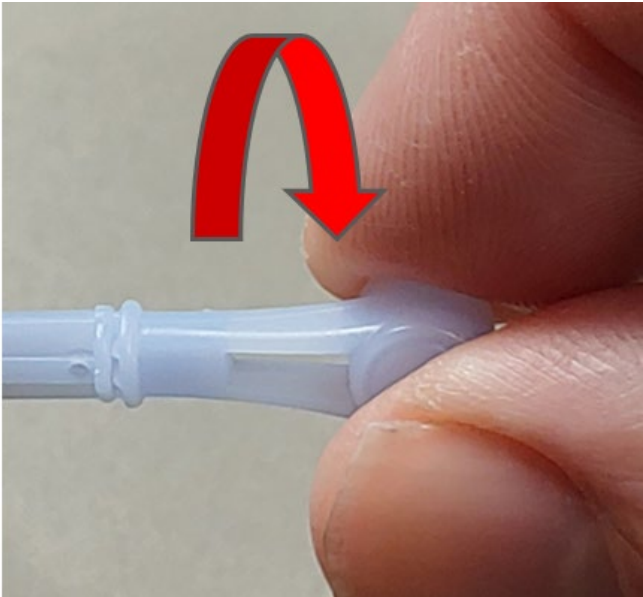
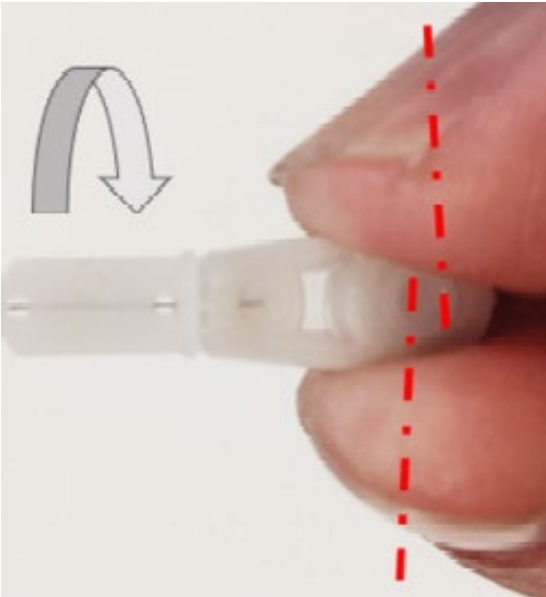
14. Like the Delica Plus, the only structure on the Delica protective cap that a POSITA would understand to act as a handle is the secondary sheath because that is the structure that physically accommodates the user's fingers and provides mechanical advantage when handling the lancet during normal use (such as pushing the lancet into the lancing device and twisting off the lancet cap prior to testing). In my opinion, only the relatively flat, round shape of the secondary sheath on the Delica and Delica Plus lancets accommodates a fingertip, providing both a surface that is easy to grasp and a visual cue for the user to employ a pinch grip when holding the Delica and Delica Plus lancets, as depicted in table 2.

15. As I further explained in my Rebuttal Report, raised ribs are included on the two major faces of the secondary sheath on the Delica Plus lancet protective

cap. This ribbed surface design increases the friction and contact surface area with a user's finger making it easier for the user to remove the lancet cap. These same conclusions also apply to the secondary sheath on the Delica lancet's protective cap, which also has a ribbed surface design. In further support of my opinions, the secondary sheath on both the Delica and Delica Plus protective caps provides the only outwardly oriented surfaces against which the user can push, and is also the widest structure on both caps, thus providing the most mechanical advantage for twisting during removal of the cap before undergoing a lancing operation. The insertion action or 'push' movement and the twist movement to release the cap from the body are both illustrated in the table below.

16. As discussed throughout my Rebuttal Report, I conducted a handleability assessment of the Delica Plus protective cap and confirmed that the secondary sheath is the only structure that physically accommodates the human finger while providing advantages when handling the lancet during normal use. For purposes of preparing this declaration, I also conducted a similar handleability analysis the Delica protective cap and reached the same conclusions. To support my opinions, I took the following photographs of my fingers handling the Delica and Delica Plus lancets in "push" and "twist" positions to illustrate how both lancets do not practice the claims of the '635 Patent.

Table 2: Gripping Positions	
Push Movement	
Delica	Delica Plus
	
	

Twist Movement	
Delica	Delica Plus
	
	

Declaration of Paul Hatch
Supporting Petitioner's Reply

17. I understand that in addition to these photos showing my fingers handling the Delica and Delica Plus lancets, my photograph of a 3-D printed model of the lancet shown in Figure 7A of U.S. Patent Application Publication No. 2004/0138588 ("Saikley") was included in Mr. Joel Delman's Rebuttal Declaration submitted with Petitioner's Reply. I confirm that the photo of the 3-D printed model of the "Saikley" lancet was taken by me and provided to counsel.

18. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further 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 and that such willful false statements may jeopardize the results of these proceedings.

Executed on March 22, 2024 in Chicago, IL.

A handwritten signature in dark ink, appearing to read "P. Hatch", is written above a solid horizontal line.

Paul Hatch