

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS L.L.C.,
Petitioner

v.

DNA GENOTEK INC.,
Patent Owner

Case IPR2022-01347
Patent 11,002,646

**DECLARATION OF KARL R. LEINSING, MSME, PE, IN SUPPORT OF
PETITIONER'S REPLY**

1. I, Karl R. Leinsing, MSME, PE, submit this declaration on behalf of Petitioner Spectrum Solutions, LLC (“Petitioner” or “Spectrum”) in support of Petitioner’s Reply to the Patent Owner’s Response. I have been asked by counsel to provide additional opinions as part of the *inter partes* review (“IPR”) proceedings in which Spectrum has challenged the validity of U.S. Patent No. 11,002,646 (“the ’646 patent”), which is assigned to Patent Owner DNA Genotek (“Genotek” or “Patent Owner”).

2. In addition to the materials that I cited in my original declaration (Ex. 1002), I have relied on the following materials in forming my opinions in this declaration:

- Ex. 1020: *Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program*, Center for Disease Control and Prevention (2008) (“CDC Workbook”). I downloaded the CDC Workbook from the CDC website at https://www.cdc.gov/sharpssafety/pdf/sharpsworkbook_2008.pdf
- Ex. 1021: *Injection Molding Handbook*, Ch. 8 (3d ed. 2000).
- Ex. 1022: Deposition Transcript of Steven Wereley (July 19, 2023).

The NSPA Is Consistent with a POSA’s Motivation to Eliminate Sharps

3. I explained in my opening declaration that it has long been known in the field of medical devices to avoid sharp objects if possible. Ex. 1002, ¶71. I pointed to the federal Needlestick Safety and Prevention Act (NSPA) (Ex. 1015) as evidence of the safety and design incentives a person of skill in the art would have been aware of and considered in developing medical devices that avoid the use of sharps. *Id.*

4. I understand that Patent Owner disputes that the NSPA is evidence of a skilled artisan’s motivation to eliminate the knife in Plante’s device and replace it with the valve used in Cho’s device. I understand, however, that Patent Owner recognizes that the NSPA teaches two ways to reduce the risk of occupational exposure from sharps: 1) “needless systems,” which eliminate the use of sharps completely; and 2) “engineering controls,” such as sharps with engineered sharps injury protections. Dr. Wereley also testified that “[o]ne possible way of eliminating the ability for a person to hurt themselves on a sharp element is to eliminate the sharp element.” Ex. 1022, 83:21-84:2.

5. A skilled artisan would prioritize removing the sharp as a way to reduce the risk of injury. This opinion is supported by a workbook developed by the Centers for Disease Control and Prevention (“CDC Workbook”) to assist healthcare organizations in preventing injuries from sharps and in satisfying existing regulatory

standards, including the NSPA. Ex. 1020, 3. The CDC Workbook describes the hierarchy of controls used to prioritize injury prevention steps and indicates that the top priority is eliminating sharps altogether where possible. *Id.*, 12-13 (“In the hierarchy for sharps injury prevention, the first priority is to eliminate and reduce the use of needles and other sharps where possible.”) If eliminating the sharps is not possible, the next option is to “isolate the hazard, thereby protecting an otherwise exposed sharp, through the use of an engineering control.” *Id.*, 13. And if neither of those options is available, “the focus shifts to work-practice controls and personal protective equipment.” *Id.* Thus, the CDC Workbook prioritizes eliminating the sharps altogether over implementing engineering controls. In the context of Plante’s knife, a person of skill in the art would have prioritized removing the knife over implementing any type of engineering controls.

Molding Challenges Provided Motivation to Eliminate Plante’s Knife

6. Regarding the motivation to replace Plante’s knife with Cho’s valve system, I stated in my opening declaration, “it is difficult to mold sharp thin features in plastics,” like Plante’s knife. Ex. 1002, ¶ 72. Dr. Wereley responded that a POSA would not have recognized injection molding as a difficulty in manufacturing the knife in Plante’s device. Ex. 2013, ¶¶ 52-64. Specifically, Dr. Wereley asserts that a “POSA would not have been motivated to combine Plante and Cho because a POSA would understand that injection molding could be used to create pointed

members.” *Id.*, ¶ 52. However, the fact that injection molding *could be used* to create pointed members, like Plante’s knife, does not negate that doing so was difficult and would have provided motivation to a person of skill in the art to consider other options, such as Cho’s valve system, for releasing the fluid from the reservoir in the cap.

7. Dr. Wereley asserts that “a POSA would have known that the piercing members could be made from routine molding in a routine manufacturing process of sample collection and preservation device.” Ex. 2013, ¶ 64. But Dr. Wereley’s assertion is contrary to a skilled artisan’s understanding that it was difficult to manufacture sharp points, like Plante’s knife, by injection molding. The Injection Molding Handbook states:

[V]arying wall thicknesses from thick and thin sections in a part will lead to problems in molding. Having a uniform wall throughout a part gives it good strength and appearance. Thick and thin sections will have molded-in stresses, different rates of shrinkage (causing warpage), and possibly void formation in the thick portion.

Ex. 1021, 729. The Injection Molding Handbook also explains that “part quality can be considered a direct outcome of a plastic melt’s flow behavior in its mold cavity or cavities. Excessive restrictions and obstructions to the flow of material spell trouble in injection molding.” *Id.*, 733.

Cho Is Analogous Art to the '646 Patent

8. I understand that Patent Owner alleges that Cho is not analogous art to the '646 patent and is therefore not available as prior art to combine with Plante. I have been informed by counsel that a prior art reference is considered analogous art if it is within the same field of endeavor as the challenged patent or, if not within the same field of endeavor, is reasonably pertinent to the particular problem being addressed by the challenged patent.

9. It is my opinion that the that Cho is analogous art to the '646 patent because it is within the same field of endeavor as the '646 patent. The '646 patent includes a section titled “Field of the Disclosure.” Ex. 1001, 1:19-29. In this section, the '646 patent states: “The disclosure relates to devices, solutions and methods for collecting **samples of bodily fluids or other substances...**” *Id.*, 1:21-23 (emphasis added). Also, under the section titled “Summary of the Disclosure,” the '646 patent states:

It is worth noting that while some embodiments of the sample collection devices disclosed herein are set forth for use with the collection of bodily fluids, the same also has **particular use with the collection of any other substance**, including hazardous and/or toxic fluids.

Id., 8:20-24 (emphasis added). Thus, the specification of the '646 patent emphasizes that the disclosed devices can be used with “any other substance,” not just bodily fluids or biological samples.

10. The '646 patent explains that once the substance is collected in the tube, the device permits easy and safe mixing of the substance with a separate substance in the reservoir within the cap. For example, the '646 patents states: “The sample collection device may also allow easy and safe collection of a donor specimen...with no risk of exposure of the donor to the toxic solution.” *Id.*, 4:1-4. Thus, in view of the disclosure in the '646 patent, it is my opinion that the field of endeavor is the easy and safe mixing of a substance in a cap with a substance collected in the tube.

11. Cho is in the same field of endeavor as the '646 patent because Cho's disclosure also relates to a bottle that permits easy and safe mixing of two substances, one substance contained in the cap and the other substance contained in the bottle. For example, Cho states:

As described above, the present invention makes it possible to contain, keep and circulate two different kinds of materials in isolated spaces of one bottle. When using the materials, the isolated spaces communicate with each other as a result of a predetermined operation, **so that a user can mix and use the two materials easily.**

Ex. 1004, 55:13-17 (emphasis added). Cho additionally states that an “object of the present invention is to provide a bottle which can mix two materials together at an exact mixture ratio using only a simple action.” *Id.*, 1:19-27.

12. If the field of endeavor was narrowed to capture specific types of substances to be mixed, such as chemicals (such as included in the preservative of

the '646 patent), it is my opinion that Cho is within the same field of endeavor as the '646 patent. For example, Cho states that the disclosed bottle can be used “in a variety of industrial fields,” including mixing of “**medicines and chemicals.**” Ex. 1004, 1:9-12 (emphasis added).

13. Cho is also analogous to the '646 patent because it is reasonably pertinent to the particular problem addressed in the '646 patent. A person of skill in the art would have looked to the bottle in Cho to solve problems related to safety and ease of use discussed in the '646 patent. In particular, the '646 patent raises safety issues with “the use of sharp extruding objects and thin pierceable membranes” in prior art devices. Ex. 1001, 4:16-36. These safety issues were well known, as I explained above and in my previous declaration, and are solved with Cho’s valve for storing and releasing the substance in the cap.

14. I understand that Patent Owner contends that Cho is solving a different problem than the '646 patent because the mixture in Cho’s bottle is allegedly intended for immediate use. I do not read Cho’s disclosure to require immediate use of the mixture. Also, the '646 patent does not exclude immediate use of the mixture. In fact, the '646 patent includes only one example, which involves the immediate use of the mixture: “Saliva is collected, and the saliva is mixed with preservation solution. The cells are then pelleted by centrifugation and the processing solution is removed.” Ex. 1001, 18:61-66.

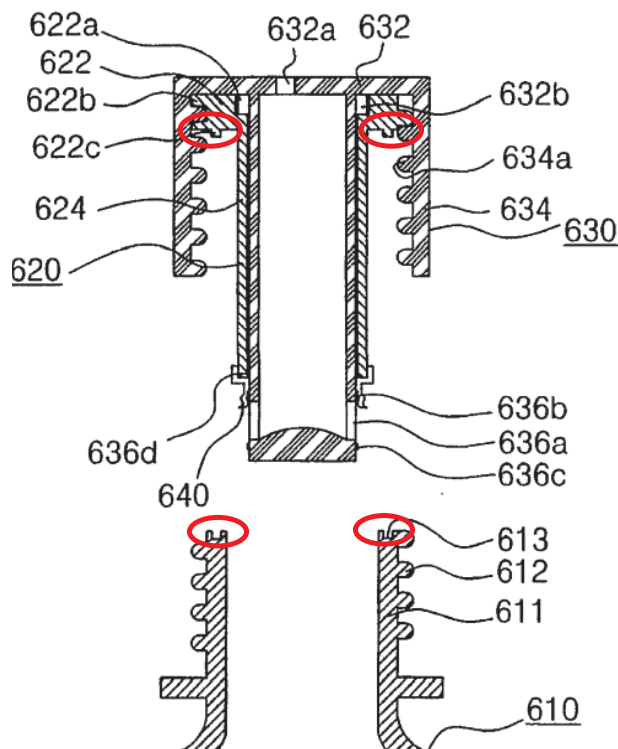
15. Dr. Wereley asserts that “[u]nlike Plante and the ’646 Patent, Cho does not teach a fluid-tight interaction between its cap and bottle.” Ex. 2013, ¶ 70. Dr. Wereley refers specifically to the embodiment in Figs. 43-45B in Cho and alleges that “Cho has no need for a fluid-tight seal between the cap and bottle and does not provide any detail that suggests otherwise.” *Id.*, ¶¶ 69, 71. I disagree.

16. Cho teaches that the cap provides a sealed or fluid-tight engagement with the bottle, which is what a POSA would expect. For example, Cho states that the bottle “stores two kinds of materials separately in a bottle when the bottle is distributed on the market,” Ex. 1004, 1:19-24, and that the bottle “maintains a good seal on the interior space of an additive storage container...” Ex. 1004, 1:28-2:3. A skilled artisan would understand that in order for Cho’s bottle to maintain the two kinds of materials separately (in the bottle and the cap) for distribution to the market, it must have a fluid-tight seal between the bottle and the cap. Providing a cap that creates a fluid-tight seal with a bottle or container as Cho teaches is quite conventional and would have been well known to a POSA.

17. And Cho shows such a conventional engagement used to provide a sealed or fluid-tight connection between a cap and a bottle, namely a tongue-and-groove engagement. This is depicted in Cho’s 21st embodiment, which is the subject of Figures 43-45.

18. The cross-sectional view in Fig. 45B shows the tongue portion on the cap and the groove portion on the bottle:

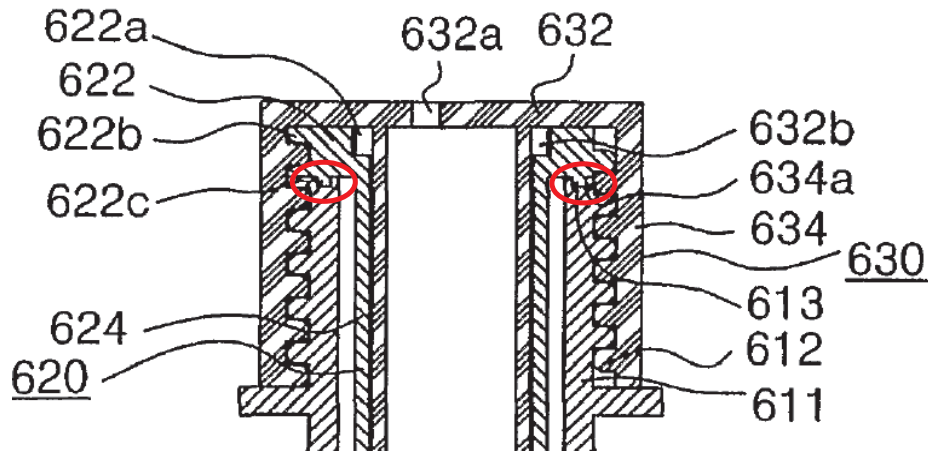
FIG. 45B



Ex. 1004, Fig. 45B (annotated).

19. And once the cap is secured on the bottle as shown in Fig. 45A, the tongue on the cap is engaged in the groove on the bottle, which provides the fluid-tight seal between the cap and bottle:

FIG. 45A



Ex. 1004, Fig. 45A (excerpted and annotated).

20. Figure 43 of Cho is a simplification of the embodiment to illustrate the ratchet structure. The ratchet engagement is actually within the groove of the bottle as depicted in Figures 44 and 44A and 45B. Cho describes the operation of the ratchet when describing the operation of the bottle in connection with Figures 45A and 45B at page 50, lines 4-27. The detail would have been difficult to illustrate without simplifying as Cho did in Figure 43. The ratchet would not interfere in any way with Cho's cap providing a fluid-tight seal as Cho specifically teaches and depicts in the conventional tongue-and-groove engagement in his drawings.

A POSA Had a Reasonable Expectation of Success in Making the Combination

21. Dr. Wereley opines that “[a] POSA would not have a reasonable expectation of success substituting Plante's cap with Cho's cap.” Ex. 2013, ¶ 89.

Dr. Wereley asserts that using Cho’s cap would increase the risk of sample contamination due to the axial length of the annular valve and based on how a user would pick up the cap. *Id.*, ¶¶ 90-93. I disagree with Dr. Wereley’s opinion. It would have been well within the ability of a skilled artisan to adjust the length of the annular valve in Cho’s cap to avoid any perceived risk of contaminating the device. In fact, Dr. Wereley agreed that “a POSA in 2012 would realize that the axial length of the additive compartment could be changed to some extent.” Ex. 1022, 69:20-70:2. He also testified that “one of skill in the art would recognize that . . . the size or the volume of the additive storage container could be changed to accommodate some operation [of] holding some material.” *Id.*, 35:15-19.

22. It is my opinion that a POSA would know to design packaging to influence how a user interacts with a product, e.g., to encourage a user to hold the cap by its top. Dr. Wereley appears to be in agreement when he stated, “one of skill in the art in 2012 . . . would have some ideas about how to distribute a device to encourage a person to pick it up in a certain manner.” *Id.*, 73:10-16. Even without such packaging, however, a user would typically handle a cap as one conventionally does, i.e., by holding the sides of the top portion that would then be turned to screw the cap onto the bottle.

23. Dr. Wereley also asserts that “a POSA would not have a reasonable expectation of success in substituting Plante’s cap with Cho’s cap because Cho’s cap

would not fit in Plante’s receiving vessel.” Ex. 2013, ¶ 94. Dr. Wereley attempts to support this contention by superimposing the image of Cho’s cap over the image of Plante’s receiving vessel. *Id.*, ¶¶ 95-100. Dr. Wereley’s approach to physically combining the components of these references is not logical. For example, as Dr. Wereley depicts the combination, the volume of the reservoir in Cho’s cap would be greater than the volume of the tube in Plante’s device. *See id.*, ¶ 99. Rather than simply superimposing patent figures as Dr. Wereley has done in his declaration, it is my opinion that a skilled artisan would have adjusted the size of Cho’s cap and/or Plante’s receiving vessel to make the components fit properly, and doing so would have been well within the POSA’s ability. Indeed, Dr. Wereley acknowledged in his deposition that “the size or the volume of [Cho’s] additive storage container could be changed to accommodate some operation.” Ex. 1022, 35:15-19. This is consistent with Cho’s explicit teaching that the invention permits mixing two materials in precise ratios (*see, e.g.* Ex. 1004, Abstract, 1:25-27), which tells a skilled artisan that the volumes of the additive compartment in the cap, as well as the bottle, could be adjusted as one desires for their particular application. Regarding Plante, Dr. Wereley also testified that “one of ordinary skill in the art in 2012 would have understood that they could change some dimensions of Plante.” Ex. 1022, 66:3-12.

I 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.

Executed on July 31, 2023, in Dover, NH.



Digitally signed by Karl R.
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Karl R. Leinsing, MSME, PE

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