Applicant respectfully submits that its specimens, as filed, are acceptable, and respectfully requests that the Applicant Mark be registered on the Principal Register.

I. Background

On May 31, 2019, Applicant filed an application for "Virtuoso," in Class 010, in connection with "surgical apparatus and instruments for use in ophthalmic surgery, namely, phacoemulsification surgery; surgical apparatus and instruments for use in ophthalmic surgery, namely, phacoemulsification and vitreoretinal surgery" ("Applicant Mark"). The Applicant Mark was published for opposition on September 4, 2019. Applicant timely filed specimens ("Specimens") and statement of use on November 1, 2022. The Specimens show a box of Applicant's surgical equipment, with the wording "for training purposes, not for human use," on the box.

On November 12, 2022, the USPTO issued a non-final action refusing registration on the grounds that the Specimens did not show the Applicant Mark in use in commerce. Applicant timely responded. On December 8, 2022, the USPTO maintained and continued the refusal to register on the grounds that the Specimens show a box of goods "not for human use," while Applicant's goods are for human use, and thus the Specimens allegedly do not show the specified applied-for goods used in commerce. Applicant responds below.

II. Argument

"When the sale or transportation of any product for which registration of a trademark is sought is regulated under an Act of Congress, the Patent and Trademark Office may make appropriate inquiry as to compliance with such Act for the sole purpose of determining lawfulness of the commerce recited in the application." 37 C.F.R. § 2.69. "The U.S. Patent and Trademark Office views the Lanham Act requirement of use in commerce as requiring a 'lawful use in commerce.' Under this interpretation, a sale of a product in interstate commerce in violation of any federal law (such as a labelling law) is not a use in commerce and furnishes no basis for federal registration of a trademark for such a product." *McCarthy on Trademarks and Unfair Competition* §19:123 (5th ed.). "Thus, the goods or services to which the mark is applied, and the mark itself, must comply with all applicable federal laws." TMEP §907.

It is also noted that "although the product listed in the application for registration and the product actually used in commerce must have some degree of similarity, they need not be identical." *McCarthy on Trademarks and Unfair Competition* §19:122. It is enough that they share the same "inherent and identifiable character." *See*, *Ralston Purina Co. v. On-Cor Frozen Foods, Inc.*, 746 F.2d 801 (Fed. Cir. 1984) (rejecting rule that *bona-fide* use requires use of mark in connection with exact goods specified in application and adopting test of whether "inherent and identifiable" character of product matches that of specimen). *See, Wallace Computer Services, Inc. v. Sun Microsystems, Inc*., 13 U.S.P.Q.2d 1324, 1327 (N.D. Ill. 1989) (Version of computer program shipped in 1984 and used as basis for use-based application was proper since it had the same "inherent and identifiable character" as the program commercially marketed in 1986.) *See also, General Mills, Inc. v. Health Valley Foods*, 24 U.S.P.Q.2d 1270, 1276 (T.T.A.B. 1992) (1984

token sale of WHEATIES breakfast cereal was a proper foundation for registration of FIBER ONE for high-fiber cereal. Both had the same inherent and identifiable character of ready-to-eat breakfast cereals.)

FDA regulations require that surgical instruments and apparatus which have not yet received approval may not be used on humans. Such goods may however be used for training purposes. FDA approval is a slow process and the Trademark Trial and Appeal Board ("TTAB") has accordingly recognized that commercial distribution of medical equipment made prior to such approval will satisfy the use in commerce requirement. Otherwise, applicants would be punished merely because one federal regulatory agency takes longer to issue its approval than another.

In *Automedx, Inc. v. Artivent Corp.*, the TTAB found ventilators designated as "not for human use" to provide adequate support for use in commerce for a mark associated with portable ventilators. 915 U.S.P.Q.2d 1976. The ventilators were sold with this designation because they had not yet received FDA approval. *Id.* The TTAB noted expert testimony that "the sale of a demonstration unit of a medical device not approved for human use constitutes a sale made in the ordinary course of business." *Id.*

Here, Applicant's Specimens are also designated "not for human use." Because commercial distribution of "a demonstration unit not approved for human use" can constitute use in the ordinary course of business," the Specimens show use of the Applicant Mark in commerce. The Examining Attorney did not contest this. The Examining Attorney solely objected on the basis that the Specimens show goods designated for training purposes, while the identification lists goods for use in surgery.

The Examining Attorney sought to distinguish *Automedx* on the grounds that it was an *inter partes* case dealing with priority of use and "whether sales of a good marked 'not for human use' constituted bona fide and/or lawful use in commerce." Office Action at 2. In contrast, the Examining Attorney categorized the instant issue as "whether the box description matches the goods." *Id.* Contrary to the Examining Attorney's assertion, the central issue here is the same as in *Automedx*. Registration of the Applicant Mark, as a legal matter, turns on whether the Specimen, which is marked "not for human use," constitutes *bona fide* use in commerce. There is no legal requirement that the label on a specimen match the identified goods exactly.

This additional requirement of matching labels to goods conflicts directly with TTAB and Federal Circuit precedent. *See, supra.* In *Automedx,* the TTAB assumed that there was no distinction between ventilators used for training purposes and ventilators for human use. The mark at issue was for "portable ventilators," not "portable ventilators for training purposes." Nevertheless, the TTAB understood that the pre-FDA approval sales of ventilators, designated "not for human use" constituted *bona fide* use in commerce of the mark in connection with ventilators. *Automedx* makes it clear that any distinction between medical goods pre- and post-FDA approval is immaterial because the "inherent and identifiable character" of the goods remains the same.

It is additionally noted that the Specimens consist of two images, the second of which shows individually-packed, sterilizable pouches. These are packaged as is customary in medical

and surgical applications. The Examining Attorney did not object to this second image, which shows the Applicant Mark used in commerce in connection with the identified goods.

Lastly, it is noted that the distinction drawn by the Examining Attorney between "artificial limbs for medical instruction purposes" in Class 009, and "artificial limbs," for medical use, in Class 010, is inapposite to surgical instruments. Applicant searched the USPTO ID Manual for the terms "surgical instruments" and "surgical apparatus." "Surgical instruments" and "surgical apparatus" are generally classified in Class 010, with services related thereto (disinfecting, repairing, cleaning, and the like) being classified in Class 037. There is no related Class 009 listing. Thus, even if Applicant's surgical instruments were for training purposes rather than surgery, this distinction would still be immaterial. The ID Manual makes no such distinction, and it would be illogical for surgeons to train for surgery with different tools than the ones they ultimately used during the procedure.

In light of the foregoing, Applicant respectfully submits that the Specimens are acceptable, and show the Applicant Mark used in commerce. Applicant respectfully requests that the Applicant Mark be registered on the Principal Register.

III. Requirement for Information

1. Presently, without FDA approval, goods are used for training purposes. After FDA approval, goods will be made available for human use.
2. The typical consumers of Applicant's goods are ophthalmologists and other medical and surgical professionals.
3. The normal trade channels of Applicant's goods are direct sales and/or through distributors.
4. The Applicant's goods are intended for use in eye surgery (with proper regulatory approval).

IV. Conclusion

Favorable action is earnestly solicited. If there are any questions or if any additional information is required, please contact Applicant's attorney at (973) 486-4114.