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UNITED STATES PATENT AND TRADEMARK OFFICE

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Trademark Trial and Appeal Board

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Automedx, Inc.
v.
Artivent Corporation

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Opposition No. 91182429
to Application Serial No. 77017595
filed on October 10, 2006

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Stephen P. Hollman of Hogan & Hartson, L.L.P. for Automedx, Inc.

Omid A. Mantashi, Esq. for Artivent Corporation.

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Before Walters, Cataldo and Bergsman, Administrative Trademark Judges.

Opinion by Bergsman, Administrative Trademark Judge:

Artivent Corporation ("applicant") filed an intent-to-use application for the mark SAVE, in standard character form, for the goods set forth below:

> Medical devices, namely, resuscitation apparatus, manual ventilators, manual emergency ventilators, transport ventilators, powered ventilators, powered emergency ventilators, positive end expiratory valves, oxygen masks, oxygen tubing, oxygen filters, endotracheal tubes, nasopharyngeal airway tubing, laryngeal masks, airway nanometers, all for use during artificial ventilation or resuscitation, for regulating or controlling ventilation, and for regulating or

controlling resuscitation; accessories for the aforementioned ventilators and resuscitators, in Class 10.

We will refer to these goods collectively as "ventilators".

Automedx, Inc. ("opposer") opposed the registration of applicant's mark on the ground of priority of use and likelihood of confusion. Specifically, opposer alleged that it has used the mark SAVe to identify portable ventilators since prior to the filing date of the application at issue and that applicant's mark SAVE for ventilators so resembles opposer's previously used mark SAVe for portable ventilators as to be likely to cause confusion. Despite applicant's denial of opposer's allegations that the marks SAVE and SAVe are nearly identical and that the goods at issue, ventilators and portable ventilators, are similar, the only issue that was tried and argued by the parties was priority.

Preliminary Issue

Applicant objected to the rebuttal testimony deposition of Christopher Murphy, the Chief Operating Officer for the Armed Forces Institute for Regenerative Medicine, on the ground that Mr. Murphy's deposition constitutes improper rebuttal. Mr. Murphy testified regarding, *inter alia,* testing opposer's products in 2006, the purchase of opposer's products in 2006, and the military's practice of testing medical devices to develop battlefield-ready products.

We agree with applicant that Mr. Murphy's testimony constitutes improper rebuttal. Evidence which should constitute part of an opposer's case in chief, but which is made of record during the rebuttal period, is not considered when the applicant objects.

> Applicant is entitled to an opportunity to rebut, during its testimony period, any testimony and evidence proffered in support of the allegations in the notice of opposition. This opportunity is foreclosed if opposer withholds the evidence until its rebuttal testimony period, ***which is intended to be limited to denials, refutations or explanations of applicant's testimony and evidence.*** (Emphasis added).

General Electric Company v. Graham Magnetics Incorporated, 197 USPQ 690, 692 n.5 (TTAB 1977). Notwithstanding opposer's argument that Mr. Murphy's testimony "serves to deny, explain and discredit the evidence submitted by Applicant during its trial period," we find that opposer's rebuttal testimony, specifically the aforementioned testimony regarding testing opposer's products in 2006, the purchase of opposer's products in 2006, and the military's practice of testing medical devices to develop battlefield-ready products, does not refute or explain applicant's evidence, but rather adds to opposer's proofs made as part of its case in chief,. Accordingly, applicant's objection is sustained and Mr. Murphy's testimony submitted by opposer

during its rebuttal testimony period has not been considered.

The Record

By operation of Trademark Rule 2.122, 37 CFR §2.122, the record includes the pleadings and the application file for applicant's mark. The record also includes the following testimony and evidence:

A. Opposer's Evidence.

1. Opposer's notice of reliance on documents obtained from the Internet[1] and applicant's responses to opposer's requests for admission;

2. Testimony deposition of Ian Halpern, applicant's President and CEO, with attached exhibits;

3. Testimony deposition of James Evans, opposer's President and CEO, with attached exhibits; and

4. Rebuttal testimony deposition of William P. Wiesman, opposer's Chairman, with attached exhibits.

B. Applicant's Evidence.

Applicant filed three notices of reliance on various documents.

[1] The parties stipulated to the admissibility of documents printed from the Internet through a notice of reliance. *See also Safer Inc. v. OMS Investments Inc.*, 94 USPQ2d 1031 (TTAB 2010) (documents obtained from the Internet may be admitted into evidence through a notice of reliance in the same manner as a printed publication in general circulation provided the documents

Standing

Opposer was formed to commercialize the automated, portable ventilator invented by Sekos, Inc. and since its formation in November, 2004, opposer has been manufacturing and selling SAVe portable ventilators.[2] This is sufficient to demonstrate that opposer has a real interest in this proceeding and, therefore, its standing. *Lipton Industries, Inc. v. Ralston Purina Co.*, 670 F.2d 1024, 213 USPQ 185, 189 (CCPA 1982).

Priority

In order for opposer to prevail on its Section 2(d) claim, it must prove that it has a proprietary interest in its SAVe mark and that it obtained that interest prior to the actual or constructive first use by applicant. *Herbko International Inc. v. Kappa Books Inc.*, 308 F.3d 1156, 64 USPQ2d 1375, 1378 (Fed. Cir. 2002); *Otto Roth & Co., Inc. v. Universal Corp.*, 640 F.2d 1317, 209 USPQ 40, 43 (CCPA 1981); *Miller Brewing Co. v. Anheuser-Busch Inc.*, 27 USPQ2d 1711, 1714 (TTAB 1993). For purposes of determining priority of use, applicant's date of first use

identify the date of publication or date accessed and printed, as well as their source).

[2] Wiesman Dep., pp. 14, 19, 20; Evans Dep., pp. 29, 31, 46, 50-55, 61, 209, 227-228, 246.

is October 10, 2006, the filing date of its intent-to-use application.[3]

Establishing opposer's first use date for its SAVe mark is more complex because opposer is relying on sales of its ventilators prior to October 10, 2006. Those sales were made for purposes of testing and were completed prior to the FDA approval of opposer's ventilators for human use. Applicant contends that such use is neither *bona fide* use nor lawful use.

A. Testimony and evidence regarding opposer's use of its SAVe mark prior to October 10, 2006.

William Wiesman is a medical doctor, a retired colonel in the United States Army, former Director of Combat Casualty Care Research for the U.S. Military, and an entrepreneur. BioStar Group is the trade name for the conglomerate under which Mr. Wiesman operates his many companies, including Sekos, Inc. and opposer.[4] Sekos, Inc. is a research and development company. Sekos, Inc. "was founded simply to develop products or ideas or take ideas into products that could be then commercialized."[5] "Sekos does not make, manufacture, or sell anything. We only do

[3] Applicant did not submit any evidence of earlier use of its mark.
[4] Wiesman Dep., pp. 10-11.
[5] Wiesman Dep., pp. 11-12; *see also* Evans Dep., p. 22.

research and development."[6] Mr. Wiesman is the CEO of Sekos, Inc.[7]

Opposer was formed to commercialize the portable ventilator developed by Sekos, Inc.[8]

> [Opposer] is a company that was built around a technology that was developed in Sekos, so the idea was to spin mature technologies developed in Sekos into other companies that could then manufacture and sell those devices or technologies, so [opposer] was specifically designed to manufacture and sell technology that was developed in Sekos."[9]

Dr. Wiesman is the Chairman of opposer. With the exception of Mr. Evans, all the shareholders of opposer are shareholders of Sekos, Inc.[10]

Sekos, Inc. created the ventilator that opposer sells. The SAVe ventilator "is a mechanical respiratory system that runs off a battery that runs a compressor with integrated sensors that control the delivery of air to an individual that cannot breathe. It is very small and compact. It's designed for the battlefield and military use. It's designed to be rugged and usable by nonmedical personnel."[11]

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[6] Wiesman Dep., p. 33.
[7] Wiesman Dep., p. 12.
[8] Wiesman Dep., pp. 14, 20; *see also* Evans Dep., p. 29 (opposer was formed to commercialize the automated ventilator developed by Sekos, Inc.).
[9] Wiesman Dep., p. 14.
[10] Evans Dep., pp. 174-175, 283. There is a discrepancy in Mr. Evans' testimony as to whether all the shareholders of Sekos, Inc. were also shareholders of opposer. (Evans Dep., pp. 23 and 174-175).
[11] Wiesman Dep., 20.

The SAVe ventilator also has civilian functionality in connection with emergency transportation of patients, mass casualty situations, and in police cruisers.[12]

After opposer was incorporated in November 2004, opposer licensed patent rights, trade secrets and technical know-how for the portable ventilator from Sekos, Inc.[13]

> Q. This license, sir, did it include the entire business of Sekos that was pertinent to the micro-ventilator?
>
> A. Yes.
>
> * * *
>
> Everything related to that ventilator was transferred out of Sekos to the new entity. Sekos does not currently do any ventilator work anymore.[14]

In fact, Mr. Adrian Urias, the chief designer, became an employee of opposer.[15]

Opposer's "approach to rolling out the SAVe ventilator was to initially target the Special Forces community within the military and to use that as a platform to get into the larger military space and use the funds and revenues generated from those activities to launch into the pre-hospital market which would include ambulances, police

[12] Evans Dep., pp. 8 and 12 and Exhibit 2; *see also* Halpern Dep., p. 65 and Exhibits 6 and 11.
[13] Evans Dep., pp. 23, 28-29; Wiesman Dep., pp. 50-52.
[14] Wiesman Dep., p. 52.
[15] Wiesman Dep., pp. 40-41, 51; Evans Dep., pp. 294-295.

cruisers, fire trucks, emergency preparedness and pan flu readiness and potentially even hospitals."[16]

Sekos, Inc. proposed the idea of a simplified automated ventilator to the Air Force. The Air Force liked the idea and committed $200,000 to the effort.[17]

> Q. Did [opposer] assume any role in connection with the performance of that contract with the Air Force?
>
> A. Yes. [Opposer] was incorporated in November 2004. The five prototypes which were the final deliverable (sic) of the contract were not delivered to the Air Force Protection Battle Lab until I believe April 2005.
>
> Between November and April the work that was done was being done from our perspective under [opposer] but to keep things congruent for the Air Force we oftentimes interfaced with them under the name of Sekos. The contract was with Sekos and the Air Force.[18]

On cross-examination, Mr. Evans expounded on the relationship between Sekos, Inc., opposer and the Air Force.

> A. Actually, the contract was with, was formulated with Sekos.
>
> [Opposer] assumed the responsibility of executing that contract once the company was incorporated.
>
> * * *

[16] Evans Dep., pp. 46-47.
[17] Evans Dep., pp. 22, 30.
[18] Evans Dep., p. 31.

> Q. When you say [opposer] assumed that contract, I'm having a hard time understanding that so I want to ask you some questions about that.
>
> Did Sekos assign that contract to [opposer]?
>
> * * *
>
> A. There were no legal documents between [opposer] and Sekos assigning the contract.
>
> However, all the resources working the contract, namely the people, the engineers became employees of [opposer].
>
> * * *
>
> Sekos continued to pay for some of the resources in [opposer] in exchange for equity in [opposer].
>
> So Dr. Wiesman continued to pay salaries because [opposer] didn't have any money of its own and in exchange for that Dr. Wiesman received additional shares in [opposer].[19]

Opposer delivered its first prototypes to the Air Force Protection Battle Lab in April 2005.[20] Subsequently, in August 2006, opposer filled a second order for the ventilators, sending five units to a military contracting organization in Lexington, Kentucky for ultimate delivery to

[19] Evans Dep., pp. 293-296; *see also* Wiesman Dep., p. 61 (the contract was not assigned to opposer).
[20] Evans Dep., pp. 31, 46, 50-51, 61, 67, 77, 302.

the Special Forces Unit stationed at Fort Bragg, North Carolina.[21]

All ventilators noted above were labeled as SAVe ventilators.[22] They also displayed opposer's name.[23] However, the operator's manual accompanying the ventilators delivered to the Air Force displayed the Sekos, Inc. name on the cover. Internally within the operator's manual, opposer's name, not Sekos, Inc., appeared on photographs of the unit.[24] According to Mr. Evans, the Sekos, Inc. name appeared on the cover of the operator's manual for clarity because "this contract was originally formulated with Sekos and for consistency purposes for the Air Force we included that."[25] The operator's manuals that accompanied the units delivered to the Special Forces Unit displayed opposer's name, not Sekos, Inc.[26] On cross-examination, Mr. Evans reiterated that prior to FDA approval, opposer was the only company that had distributed any of the SAVe units.[27] Dr.

[21] Evans Dep., pp. 51, 105-108, 111 and Exhibits 28 and 29.
[22] Evans Dep., pp. 46, 67-70, 117-118 and Exhibits 14-17.
[23] Evans Dep., Exhibits 14 and 15.
[24] Evans Dep., Exhibits 20 and 21.
[25] Evans Dep., p. 76; *see also* Evans Dep., p. 353 ("So there was a transition period as far as the Air Force was concerned where we would start off with Sekos and we became known as [opposer]"). On the other hand, Dr. Wiesman testified that since the Air Force had contracted with Sekos, Inc., it was appropriate for Sekos, Inc. to provide the Air Force with the contract deliverables (*i.e.*, the ventilators and operator's manuals). (Wiesman Dep., pp. 65-66)
[26] Evans Dep., Exhibit 39.
[27] Evans Dep., pp. 209-210.

Wiesman confirmed that Sekos never used the SAVe trademark.[28]

Because the ventilators initially shipped were not FDA approved for human use, they were designated as prototype or demonstration units, not for human use.[29] On September 6, 2007, the FDA granted opposer approval to use its SAVe ventilators for human use.[30] The initial sales noted above were test models to perfect the SAVe ventilator for human use.

> There were a number of things that had to be done before we felt comfortable that the device was fit to be used in humans.
>
> The device was tested multiple times in a swine model, it was tested multiple times in what we refer to as a bench test, it was used multiple times by the military in field exercises.
>
> All this had to come together to make us feel comfortable that we had a product that was not only safe but was ready for the market.
>
> In addition, there are a number of FDA standards that the device has to meet before you can submit to the FDA.
>
> So it took us two and a half years or so to get to that point.[31]

[28] Wiesman Dep., p. 33.
[29] Evans Dep., pp. 70-71, 78, 118-119, 128 and Exhibits 18-19, 31-36, 41.
[30] Evans Dep., p. 130.
[31] Evans Dep., pp. 131-132.

"The devices were used on animals to test the efficacy and safety of the device and to establish that they could be used safely in human subjects."[32] Applicant's President, Ian Halpern confirmed that animal research is useful for testing the efficacy of a device on living organisms and for safety.[33] In fact, the military tested prototypes of applicant's SAVE ventilator.[34]

Dr. Wiesman testified 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.[35]

> Q. And on the document sir, do you see where it says demonstration unit?
>
> A. Yes.
>
> Q. What does that refer to?
>
> A. The demonstration unit implies that it would not be used on humans.
>
> Q. Based on your experience in the medical device industry, sir, can you tell me whether a demonstration unit is suitable for sale in the ordinary course of business?
>
> * * *
>
> A. [W]e would sell this unit with the label on it, absolutely.[36]

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[32] Evans Dep., p. 134. Swine are often selected for studies because the anatomy of their respiratory system is similar to the human respiratory system. (Evans Dep., pp. 139-140).
[33] Halpern Dep., pp. 31-32.
[34] Halpern Dep., p. 70.
[35] Wiesman Dep., pp. 56-57.
[36] *Id.*

B. Whether opposer's sales of demonstration units constitute *bona fide* use of a mark in the ordinary course of trade, and not merely to reserve a right in a mark?

Section 45 of the Trademark Act, 15 U.S.C. §1127, defines "use in commerce" as the "bona fide use of a mark in the ordinary course of trade, and not merely to reserve a right in a mark."

> A key factor is that the sale or sales made cannot be "token" in the sense that they are artificially made solely to reserve a right in a mark and not made as part of a usual product or service launch. Thus, even sales made in a test marketing program will probably suffice as a bona fide use of the mark in the ordinary course of trade because test market sales are a common harbinger of a proposed new product launch.

McCarthy On Trademarks And Unfair Competition §19:109 (4th ed. 2010).

Use in commerce should be interpreted with flexibility to account for different industry practices.

> The legislative history of the Trademark Law Revision Act reveals that the purpose of the amendment was to eliminate "token use" as a basis for registration, and that the new, stricter standard contemplates instead commercial use of the type common to the particular industry in question.

Paramount Pictures Corp. v. White, 31 USPQ2d 1768, 1774 (TTAB 1994), *aff'd*, *White v. Paramount Pictures Corp.*, 108 F.3d 1392 (Fed. Cir. 1997) (non-precedential).

In this regard and apropos to the facts in this case, the legislative history of the 1988 Revision Act references a "company's shipment to clinical investigators during the Federal approval process" as being in the ordinary course of trade.[37] The Senate Judiciary Committee Report made the following comment:

> The committee intends that the revised definition of "use in commerce" be interpreted to mean commercial use which is typical in a particular industry. Additionally, the definition should be interpreted with flexibility so as to encompass various genuine, but less traditional, trademark uses, such as those made in test markets, infrequent sales of large or expensive items, or ongoing shipments of a new drug to clinical investigators by a company awaiting FDA approval, and to preserve ownership rights in a mark if, absent an intent to abandon, use of a mark is interrupted due to special circumstances.

S. Rep. No. 100-515, p. 44-45 (September 15, 1988).

We also note that test marketing has been recognized as sufficient to establish use of a mark. *See Game Power Headquarters Inc. v. Owens,* 37 USPQ2d 1427, 1431 (E.D. Pa. 1995) ("Test marketing of the service mark, "Game Power Headquarters", constitutes a bona fide use in commerce . . . Sales of goods under a brand name in test marketing area are actual sales from which rights in a mark can accrue"); *see*

[37] House Judiciary Committee Report on H.R. 5372, J.R. No. 100-1028, p. 15 (October 3, 1988).

also E.I. du Pont de Nemours and Co. v. G.C. Murphy Co., 199 USPQ 807, 812 (TTAB 1987) ("[s]ales of goods under a brand name in a test marketing area are actual sales from which rights in a mark can accrue"); *cf. Paramount Pictures Corp. v. White,* 31 USPQ2d at 1769 n. 9 (the use at issue was not genuine trademark use, it was *de minimis* and noncommercial in nature and not made in the ordinary course of trade in games). The Board has held that *bona fide* test marketing and experimental sales in small volumes are sufficient to show use of a mark. *E.I. du Pont de Nemours and Co. v. Big Bear Stores, Inc.*, 161 USPQ 50, 51 (TTAB 1969) (test marketing of the mark SUPER SHIELD for a premium exterior clear finish proved unsatisfactory and plaintiff assigned the mark to another product considered near in quality but lower in price). The issue in all the above-referenced cases was whether there was genuine use of the mark in commerce.

Thus, the issue we must decide is whether opposer's April 2005 and August 2006 sales were test sales for legitimate commercial purposes in the ordinary course of trade or token sales to reserve the mark for registration. If the sales at issue were made for legitimate marketing or other commercially reasonable reasons in the ordinary course of trade (*i.e.*, genuine use of the mark), then we must find

that the sales constitute *bona fide* use of the mark in commerce.

Based on the testimony and evidence of record, we find that opposer's April 2005 and August 2006 sales of the ventilators to the military were for legitimate business reasons (*i.e.*, to test and refine the portable ventilators) and not merely to reserve the right to register the marks.

We are not persuaded by applicant arguments, as set forth below, that opposer's use of its mark is not *bona fide* commercial use:

1. Opposer failed to show use of its mark on medical devices. According to applicant, because opposer did not receive FDA approval to sell its portable ventilators for human use until September 6, 2007, any prior use was not in connection with medical devices.[38]

> [Opposer's] claimed activities in selling and shipping prototypes not intended for use as medical devices intended for humans can only be considered pre-marketing activities: [opposer] was not testing the market through the sale of medical devices in a limited market, it was in fact engaging in product research and development, and market research and development. There is no evidence indicating that [opposer] advertised the availability of products for sale to the public. It transported or sold only a handful of devices to selected recipients who, by [opposer's] own admission, were cooperatively engaged in product testing, research, and development with [opposer].

[38] Applicant's Brief, pp. 9-10 and 21-26.

* * *

> [Opposer] is claiming the exclusive right to use the SAVE (sic) trademark on medical devices intended for humans, yet it did not place such goods in trade on the open market in a limited area so that it could be said to be testing the market for such products. Rather, by its own admission, [opposer] was cooperatively testing its own devices with certain key potential customers, in a private manner, in order to ultimately manufacture a product that could be sold on the open market to those customers.[39]

We disagree with applicant's premise that the products sold by opposer to the military were required to be FDA approved before the sales of those product may constitute *bona fide* use of the mark in commerce. Opposer sold prototype or demonstration units to the military for a legitimate commercial purpose: that is, to "test and evaluate the technology to decide whether or not they were interested in buying a more significant number of human use units in the future," even though the units the military purchased were not approved for human use.[40] The military was testing the efficacy, ease of use and portability of the ventilators.[41] The fact that these initial sales to the military were mutually beneficial in that they allowed the military to test the initial units before committing to a

[39] Applicant's Brief, p. 26.
[40] Evans Dep., pp. 335-336.
[41] Evans Dep. p. 336.

larger purchase, and they permitted opposer to refine the product to make it commercially attractive so the military would purchase a significant number of units, supports the legitimate commercial basis for the sales.

2. Opposer's use of the mark in units sold for product testing is not a *bona fide* commercial use sufficient to support priority.[42] We disagree with applicant's argument. We find that opposer's sales of its products to the military were an arm's length transaction in which properly labeled SAVe ventilators, *albeit* for testing and not human use, were sold and transported in commerce. Based on the nature of the products at issue and the evidence of record in this case, the fact that the products were sold and transported to the customer for testing does not make the sale and transportation of those products any less legitimate.

3. Opposer has not proven that private product testing is typical commercial use in connection with medical devices.[43] This argument misses the point. As indicated above, the issue is whether opposer's sales for "private product testing" were for a legitimate, commercial reason in the ordinary course of trade and not merely to reserve the right to register the mark. Whether private product testing

[42] Applicant's Brief, pp. 26-27.
[43] Applicant's Brief, pp. 27-30.

constitutes typical commercial use in connection with medical devices is a fact that we may consider in determining whether opposer's sales were for a legitimate, commercial reason in the ordinary course of trade, but it is not the test in and of itself. In this regard, we have determined that the sales of opposer's portable ventilators to the military so the military could test the units for efficacy, ease of use and portability constitutes a legitimate, commercial use regardless of whether sales of medical devices for testing purposes is typical.

4. Opposer's product testing does not establish *bona fide* use in commerce because opposer was not selling its intended goods in trade.[44] In other words, according to applicant, "opposer is attempting to rely on the putative sale or shipment of a few investigational use prototypes not intended for human use to establish technical priority with respect to medical devices intended for human use."[45]

> Simply put: prior to Applicant's constructive priority date, Opposer had no medical devices intended for or suitable for sale in the medical device market. It had no products that were approved or cleared for use under the relevant regulatory regimes for use as medical devices on humans. It should not be allowed to rely on a limited distribution of prototypes in collaborative product testing and development to claim prior technical

[44] Applicant's Brief, pp. 30-33.
[45] Applicant's Brief, p. 31.

> trade mark use with respect to medical devices intended for use on humans.[46]

This argument is essentially the same as applicant's first argument. As indicated above, we do not agree with applicant's premise that the products sold by opposer to the military were required to be FDA approved before the sales of those products may constitute *bona fide* use of the mark in commerce. *See* the discussion *supra.*

5. Opposer's testimony regarding its April 2005 sale is not corroborated by any documentary evidence.[47] However, "oral testimony, if sufficiently probative, is normally satisfactory to establish priority of use in a trademark proceeding." *Powermatics, Inc. v. Globe Roofing Products Co., Inc.*, 341 F.2d 127, 144 USPQ 430, 432 (CCPA 1965). While oral testimony is strengthened by corroborative documentary evidence, oral testimony alone that is consistent, definite and without contradictions may be sufficiently probative. *B.R. Baker Co. v. Lebow Bros.*, 150 F.2d 580, 66 USPQ 232, 236 (CCPA 1945). The testimony of Mr. Evans was consistent, definite and without contradictions. Moreover, it remained consistent, definite and without contradictions throughout applicant's rigorous

[46] Applicant's Brief, p. 33.
[47] Applicant's Brief, pp. 11-12.

and lengthy cross-examination. Furthermore, Mr. Evans' testimony was corroborated by Dr. Wiesman, who was also cross-examined by applicant.

6. The April 2005 sale was made on behalf of Sekos, Inc., not opposer.[48] We disagree. After Sekos, Inc. contracted with the Air Force to deliver 5 prototypes of the portable ventilator, Dr. Wiesman incorporated opposer and transferred the assets of the ventilator program to opposer. Opposer fulfilled the obligations under the contract even though the operator's manual identified Sekos, Inc. and Sekos, Inc. never formally notified the Air Force that opposer was the owner of the portable ventilator being provided to the Air Force. The record clearly establishes that opposer is the successor-in-interest to Sekos, Inc. for the technology regarding SAVe portable generators and that the SAVe trademark was used only by opposer. It is further clear from the record that Dr. Wiesman has been the central figure of what can be characterized as a number of research and development projects that are ultimately marketed by separate entities. Even if the SAVe mark was used by Sekos, Inc. and then subsequently used by opposer, the mark points to a single source: that is, the use of the SAVe mark was for the benefit of and inured to the benefit of Dr. Wiesman through his conglomerate, including Sekos, Inc. and opposer.

[48] Applicant's Brief, pp. 12-17.

See Airport Canteen Services, Inv. v. Farmer's Daughter, Inc., 184 USPQ 622, 627 (TTAB 1974).

B. Whether opposer's sale of SAVe portable ventilators prior to the FDA's approval constitutes lawful use of the mark in commerce?

Determining whether the use of a mark is lawful under one or more of the myriad of regulatory acts involves two questions: (1) whether a court or government agency having competent jurisdiction under the statute involved has previously determined that party is not in compliance with the relevant statute; or (2) whether there is a *per se* violation of a statute regulating the sale of a party's goods. *General Mills Inc. v. Healthy Valley Foods*, 24 USPQ2d 1270, 1273 (TTAB 1992). In this case, there has been no final determination of noncompliance by a court or agency regarding opposer's initial shipments of its SAVe portable ventilators. Rather, applicant has attempted to show that opposer's April 2005 and August 2006 shipments of SAVe portable ventilators were *per se* violations of FDA regulations.[49]

> [I]t is incumbent upon the party charging that the use was unlawful to demonstrate by clear and convincing evidence more than that the use in question was not in compliance with applicable law. Such party must prove also that the non-compliance was material, that is, was of such gravity and significance that the usage must be considered unlawful – so tainted that,

[49] Applicant's Brief, pp. 30-33.

> as a matter of law, it could create no trademark rights -- warranting cancellation of the registration of the mark involved.

General Mills Inc. v. Healthy Valley Foods, 24 USPQ2d at 1274. Furthermore, "there must be some nexus between the use of the mark and the alleged violation before the unlawfulness of a shipment can be said to result in the invalidity of a registration." *Id. citing Satinine Societa v. P.A.B. Produits,* 209 USPQ 958, 967 (TTAB 1981).

Applicant argues that opposer's April 2005 and August 2006 transactions violate FDA regulations because they are sales of medical devices that have not been approved for human use.

> [t]he FDCA establishes an extensive regulatory regimen pertaining to medical devices. Central to that regimen is the requirement that any establishment involved in the manufacturing of medical devices should register with the FDA unless its activities are exempt, for example as a manufacturer of devices intended for veterinary use, or a manufacturer of devices used solely for testing or research purposes and not for sale. 21 U.S.C. § 360(b)(2), 21 U.S.C. § 360 (g)(3); *see also* 21 C.F.R. § 807.65(b) (veterinary exception), 21 C.F.R. § 807.65(f) (non-commercial testing exemption). Furthermore, before a medical device such as [opposer's] may be marketed for human use it must receive 510(k) clearance from the FDA.
>
> * * *
>
> Opposer's (sic) neglect the significant fact that FDA only exempts manufacturers

> from establishment registration when the manufacturer is engaged in *non-commercial* product testing and development. 21 U.S.C. § 360 (g)(3). Indeed, Opposer itself has admitted that it is not subject to this *non-commercial* exemption afforded under the FDCA. … In fact, a violation of the establishment registration requirement is a *prima facie* case of misbranding. 21 U.S.C. § 360(o).[50]

Furthermore, applicant contends that opposer may not argue that its initial prototype or demonstration units were not subject to FDA approval because they were only test products and at the same time assert that they were goods in trade. According to applicant, if the portable ventilators are goods in trade, which they must be in order for opposer to claim priority, then the sale of the portable ventilators must be approved for human use by the FDA to constitute lawful use in commerce.[51]

Despite applicant's vigorous argument, we find that applicant failed to show that there was a *per se* violation of any law or FDA regulations. As previously indicated, we disagree with applicant's premise that the products sold by opposer to the military were required to be FDA approved before the sales of those products may constitute *bona fide* use of the mark in commerce. Opposer sold its portable

[50] Applicant's Brief, pp. 31-32.
[51] Applicant's Brief, p. 32.

ventilators to the military in an arm's length transaction so the military could test the efficacy, ease of use, and portability of the units with the aim of refining the ventilator for future purchases. While they were not sold for human use, they were *bona fide* sales and there is no perceptible violation of any laws or regulations.

In view of the foregoing, we find that opposer's April 2005 and August 2006 sales of its SAVe portable ventilators were *bona fide* sales in the ordinary course of trade in lawful commerce and not merely to reserve a right in the mark.

Because we have found that opposer has made *bona fide* sales in the ordinary course of trade, we do not have to determine whether opposer's use constitutes use analogous to trademark use.

As indicated above, although applicant denied that there is a likelihood of confusion, it did not proffer any evidence or argument on the issue and, therefore, essentially conceded that there is a likelihood of confusion. Suffice it to say, the evidence shows that there is a likelihood of confusion between the opposer's mark SAVe and applicant's mark SAVE both for use in connection with ventilators.[52]

[52] Because the drawing of applicant's mark is depicted in standard character form, applicant is not claiming the right to depict is

Decision: The opposition is sustained and registration to applicant is refused.

mark in any special form and, in fact, may depict its mark in any reasonable manner, including SAVe.