

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SALVACION USA, INC.,
Petitioner,

v.

TRUTEK CORP.,
Patent Owner

U.S. Patent No. 8,163,802
Issued: April 24, 2012

Title: ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL
APPLICATION, PRODUCT, AND METHOD

Inter Partes Review No. IPR2024-00711

**PETITIONERS' MOTION TO EXCLUDE
EVIDENCE SUBMITTED WITH
PATENT OWNER'S SUR-REPLY**

Pursuant to 37 C.F.R. § 42.64(c) and the Federal Rules of Evidence, Petitioner, Salvacion USA, Inc., hereby moves to exclude Exhibits 2003-2007 filed by Patent Owner, Trutek Corp., accompanying Patent Owner's Sur-Reply to Petitioner's Reply.

I. STATEMENT OF FACTS

As summarized in Petitioner's Motion to Strike (Paper 19), Patent Owner submitted new Exhibits 2003-2007 with its Sur-Reply (Paper 13) to support its contentions of commercial success, in violation of 37 C.F.R. § 42.23(b). These exhibits are as follows:

- Exhibit 2003, which is presented as a Declaration of Ashok Wahi.
- Exhibit 2004, which is presented as Representative NasalGuard Products.
- Exhibit 2005, which is presented as How to Use NasalGuard.
- Exhibit 2006, which is presented as a Clinical Study.
- Exhibit 2007, which is presented as a listing of website where products allegedly embodying U.S. Patent No. 8,163,802 ("the '802 Patent") can be bought.

In addition to filing its Motion to Strike, Petitioner also filed objections to this evidence (Paper 15).

II. ARGUMENT

In its Motion to Strike (Paper 19), which is pending, Petitioner has argued that Exhibits 2003-2007 should be stricken as submitted in violation of 37 C.F.R. § 42.23(b). In addition, Exhibits 2003-2007 contain inadmissible evidence and should be excluded from the record as violating the Federal Rules of Evidence (“F.R.E.”), which apply to this proceeding. *See* 37 C.F.R. § 42.62(a).

In accordance with 37 C.F.R. § 42.64(b)(1), Petitioner timely objected to Exhibits 2003-2007 as being inadmissible for the bases set forth below when Exhibits 2003-2007 were first introduced in Patent Owner’s Sur-Reply. *See* Petitioner’s Objections to Patent Owner’s Evidence (Paper 15).

A. Exhibit 2003 Should Be Excluded

Exhibit 2003 is a document containing the Declaration of Ashok Wahi, the named inventor of the ’802 Patent. The document contains various statements about the NasalGuard® brand and its alleged sales in various countries, including the United States.

1. Exhibit 2003 is inadmissible hearsay

The Board should exclude Exhibit 2003 from the record under F.R.E. 801 and 802 as hearsay, as it comprises out-of-court statements offered for the truth of the matters asserted without the opportunity for cross-examination and otherwise not falling within any exception or exclusion.

Patent Owner relies on the Declaration of Mr. Wahi as evidence of commercial success of the NasalGuard® product. See Paper 13 at 23. Specifically, Patent Owner’s Sur-Reply cites Mr. Wahi’s statement that “Trutek sold more than fifteen-million tubes of gel worldwide with brand names Crystal Veil, Chloraseptic, and NasalGuard®” (see Ex. 2003 at 2) as direct evidence that “the product embodying the claimed invention has achieved significant commercial success.” See Paper 13 at 22, 23. Patent Owner thus relies on Mr. Wahi’s Declaration for the truth of the statements offered therein.

A “guiding principle” of IPR rules mandates that, “if a party proffers a witness’s testimony, that party must make that witness available for cross-examination by the other party. See 37 C.F.R. § 42.51-42.53.” *Vudu v. Ideahub*, IPR2020-01688, Paper 47, 7 (Mar. 16, 2022) (excluding direct testimony not subject to cross-examination as hearsay). See also Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48761 (Aug. 14, 2012) (explaining that the party presenting a witness bears the burden of making the witness available for cross-examination).

Here, Mr. Wahi’s Declaration was signed on July 7, 2025, and offered into evidence on July 8, 2025—the same day Patent Owner filed its Sur-Reply (Paper 13)—in direct contravention of 37 C.F.R. § 42.23(b). Meanwhile, both 37 C.F.R. § 42.53(d) and the Scheduling Order in this proceeding state that cross-examination is

to take place no later than a week before the filing date for any paper in which the cross-examination testimony is expected to be used. (See Paper 8 at 4.)

The late filing of the Declaration, in violation of the rules and without any other dispensation from the Board, effectively renders these provisions inoperative. There are no remaining papers to be filed by Petitioner in the ordinary course with which any cross-examination testimony of Mr. Wahi would be used. Any attempt to notice and schedule a deposition, and obtain and file a transcript, outside the normal course, given the short time frame before oral argument, would have been futile. Petitioner has been effectively denied the opportunity to cross-examine the declarant on the statements contained in his Declaration.

Exhibit 2023 is therefore inadmissible hearsay under F.R.E. 801 and 802 and should be excluded from the record.

2. Exhibit 2003 is irrelevant, or its probative value is substantially outweighed by its prejudicial effect

The Board should also exclude Exhibit 2003 from evidence under F.R.E. 401, 402, and/or 403. Mr. Wahi's statements relating to the commercial success of Trutek's products have little, if any, relevance to the technology embodied by the '802 Patent. In other words, the Declaration does not demonstrate a nexus between the claims of the '802 Patent and the alleged sales of Trutek's products. Rather, Mr. Wahi states the '802 Patent is marked on all NasalGuard® tubes sold in the United States but does not indicate that the other brand names (Crystal Veil and

Chloraseptic) have similar markings, despite grouping the sales of these products with the sales of NasalGuard® branded products. Moreover, Mr. Wahi does not state that the “more than fifteen million tubes” sold worldwide have any relationship with or are derived from the claims of the ’802 Patent.

In the alternative, to the extent that Exhibit 2003 has any relevance, that relevance is substantially outweighed by the prejudice of allowing inventor testimony that has not been subject to cross-examination and which lacks any corroboration. Accordingly, Exhibit 2003 should be excluded under F.R.E. 401, 402 and/or 403.

B. Exhibit 2004 Should Be Excluded

Exhibit 2004 is a document containing a variety of images of product packaging, including packaging of the brand NasalGuard® and the brand Chloraseptic.

1. Exhibit 2004 is an unauthenticated document

The Board should exclude Exhibit 2004 from the record under F.R.E. 901 as there is no admissible evidence to authenticate it, and it is not a document subject to self-authentication under F.R.E. 902. Patent Owner cites to Exhibit 2004 in its Sur-Reply (see Paper 13 at 24) without providing any extrinsic evidence sufficient to support a finding that the exhibit is what Patent Owner claims it is, in violation of F.R.E. 901. Although testimony of a witness with knowledge may be sufficient to

authenticate an item under F.R.E. 901(b)(1), the Declaration of Mr. Wahi in Exhibit 2003 makes no reference to or attempt to authenticate Exhibit 2004. Accordingly, Exhibit 2004 is not an authenticated document, and should be excluded.

2. Exhibit 2004's probative value is substantially outweighed by its prejudicial effect

The Board should exclude Exhibit 2004 under F.R.E. 403 because the prejudicial effect of its admittance would substantially outweigh its limited, if existing, probative value.

Patent Owner relies on Exhibit 2004 as evidence that Trutek sells NasalGuard® gel products under several brand names. See Paper 13 at 24. This document, however, is unauthenticated and is therefore prejudicial. Moreover, nothing from the Chloraseptic packaging indicates a relationship with the NasalGuard® brand or the '802 Patent, and the remaining images show products described in a foreign language, necessitating at least a translation to ascertain their probative value. Therefore, Exhibit 2004 should be excluded under F.R.E. 403.

3. Exhibit 2004 is inadmissible hearsay

The Board should exclude Exhibit 2004 from the record under F.R.E. 801 and 802 as hearsay, as it comprises out-of-court statements offered for the truth of the matters asserted without the opportunity for cross-examination and otherwise not falling within any exception or exclusion.

Patent Owner's Sur-Reply cites to Exhibit 2004 (*see* Paper 13 at 24) as evidence that NasalGuard® products are sold under "several brand names," supposedly embodied in the various images presented in Exhibit 2004. This Exhibit was similarly offered into the record on the same day Patent Owner filed its Sur-Reply, without any accompanying declaration or witness testimony authenticating its contents, thereby depriving Petitioner of the opportunity to evaluate its credibility. Petitioner would have had the opportunity to cross-examine a witness with knowledge of Exhibit 2004's contents (*e.g.*, Mr. Wahi) had the witness attested to Exhibit 2004's authenticity and if Petitioner had the opportunity to cross-examine the witness. However, neither of these conditions were met. Exhibit 2004 is therefore inadmissible hearsay under F.R.E. 801 and 802 and should be excluded from the record.

C. Exhibit 2005 Should Be Excluded

Exhibit 2005 is a document containing a sequence of images showing "How to Use NasalGuard[®]" and including a "Step 1," "Step 2," and "Step 3."

1. Exhibit 2005 is an unauthenticated document

The Board should exclude Exhibit 2005 from the record under F.R.E. 901 as there is no admissible evidence to authenticate it, and it is not a document subject to self-authentication under F.R.E. 902. Patent Owner cites to Exhibit 2005 in its Sur-Reply (*see* Paper 13 at 21) without providing any extrinsic evidence sufficient to

support a finding that the exhibit is what Patent Owner claims it is, in violation of F.R.E. 901. Mr. Wahi's testimony (Ex. 2003) makes no reference to or attempt to authenticate Exhibit 2005. Accordingly, Exhibit 2005 is not an authenticated document, and should be excluded.

2. Exhibit 2005's probative value is substantially outweighed by its prejudicial effect

The Board should exclude Exhibit 2004 under F.R.E. 403 because the prejudicial effect of its admittance would substantially outweigh its limited probative value.

Patent Owner relies on Exhibit 2005 as evidence that the '802 Patent, allegedly embodied by the NasalGuard® gel product, is "applied to the nose externally." See Paper 13 at 21. However, Exhibit 2005 is unauthenticated and is therefore prejudicial. Moreover, no admissible evidence connects the NasalGuard® brand to the claims of the '802 Patent, leaving the Exhibit with particularly little probative value. The prejudicial effect of Exhibit 2005 substantially outweighs its probative value, therefore Exhibit 2005 should be excluded under F.R.E. 403.

3. Exhibit 2005 is inadmissible hearsay

The Board should exclude Exhibit 2005 from the record under F.R.E. 801 and 802 as hearsay, as it comprises out-of-court statements offered for the truth of the matters asserted without the opportunity for cross-examination and otherwise not falling within any exception or exclusion.

Patent Owner's Sur-Reply cites Exhibit 2005 as evidence that NasalGuard® products are applied to the nose externally. See Paper 13 at 21. Step 3 of the Exhibit instructs, "[a]pply directly around the nostrils and above the upper lip," while depicting an individual demonstrating the same. Patent Owner relies upon this instruction as evidence of the truth of its statement in its Sur-Reply (*i.e.*, "a feature that is required by the '802 Patent"). *Id.* This Exhibit was similarly offered into the record on the same day Patent Owner filed its Sur-Reply. For the same reasons provided above with respect to Exhibit 2004, Exhibit 2005 is inadmissible hearsay under F.R.E. 801 and 802 and should be excluded from the record.

D. Exhibit 2006 Should Be Excluded

Exhibit 2006 is an excerpt of a report of a clinical study ("the Report") investigating the efficacy of Trutek's "Multi Acting Nasal Particle Blocker (MAPB)." See Ex. 2006 at 3. The Report was authored by three individuals, including Shekar Sunjoku, Priyanka Bhattacharya, and Dr. Shariq Anwar. See Ex. 2006 at 5.

1. Exhibit 2006 is an unauthenticated document

The Board should exclude Exhibit 2006 from the record under F.R.E. 901 as there is no admissible evidence to authenticate it, and it is not a document subject to self-authentication under F.R.E. 902. Patent Owner cites to Exhibit 2006 in its Sur-Reply (see Paper 13 at 24) without providing any extrinsic evidence sufficient to

support a finding that the exhibit is what Patent Owner claims it is, in violation of F.R.E. 901. Mr. Wahi's testimony (Ex. 2003) makes no reference to or attempt to authenticate Exhibit 2006, and Patent Owner has not provided authenticating testimony of any of the authors. Accordingly, Exhibit 2006 is not an authenticated document, and should be excluded.

2. Exhibit 2006's probative value is substantially outweighed by its prejudicial effect

The Board should exclude Exhibit 2006 under F.R.E. 403 because the prejudicial effect of its admittance would substantially outweigh its probative value. Patent Owner relies on Exhibit 2006 as evidence that "users of the NasalGuard® get fewer respiratory infections." See Paper 13 at 24. However, Exhibit 2006 is unauthenticated and is therefore prejudicial. Moreover, no admissible evidence connects the NasalGuard® brand or its alleged commercial success to the claims of the '802 Patent. The only nexus offered between the claims and the commercial success of NasalGuard® products is in the form of unsupported assertions made by Patent Owner in its Sur-Reply. See Paper 13 at 24 (speculating that the "specific features recited in the claims . . . are directly responsible for the product's market differentiation."). Attorney argument is insufficient to establish this nexus. See, e.g., *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1380 (Fed. Cir. 2009) ([U]nsworn attorney argument . . . is not evidence and cannot rebut . . . other admitted evidence . . .").

The clinical efficacy of MAPB, as suggested by the Report, thus has limited probative bearing on the alleged commercial contribution of the ‘802 Patent’s claims. The prejudicial effect of Exhibit 2006 therefore substantially outweighs its probative value, and Exhibit 2006 should be excluded under F.R.E. 403.

3. Exhibit 2006 is inadmissible hearsay

The Board should exclude Exhibit 2006 from the record under F.R.E. 801 and 802 as hearsay, as it comprises out-of-court statements offered for the truth of the matters asserted without the opportunity for cross-examination and otherwise not falling within any exception or exclusion.

Patent Owner relies on the Report’s findings (Ex. 2006) as evidence of consumer demand for NasalGuard® products. *See* Paper 13 at 24. The Report concludes, “[s]ubjects of [control] Group B had 3 times higher probability of getting a cold and/or flu than subjects of [active] Group A.” *See* Ex. 2006 at 5. Patent Owner relies upon this conclusion as evidence of the truth of its statement in its Sur-Reply (*i.e.*, that “users of the NasalGuard® get fewer respiratory infections”). *See* Paper 13 at 24. Exhibit 2006 was similarly offered into the record on the same day Patent Owner filed its Sur-Reply, thereby depriving Petitioner of the opportunity to cross-examine the authors. Exhibit 2006 is therefore inadmissible hearsay under F.R.E. 801 and 802 and should be excluded from the record.

4. Exhibit 2006 comprises expert testimony from witnesses not qualified as experts

Exhibit 2006 should further be excluded as comprising expert testimony from witnesses not qualified as expert under F.R.E. 701 and 702. The subject matter of the Report (Ex. 2006) comprises “scientific, technical, or other specialized knowledge within the scope of Rule 702” and therefore cannot constitute opinion testimony of a lay witness. *See* F.R.E. 701(c). Yet, Patent Owner has not demonstrated that the authors, either individually or collectively, are qualified as experts by knowledge, skill, experience, training, or education, as required by F.R.E. 702. Therefore, Exhibit 2006 should be excluded.

E. Exhibit 2007 Should Be Excluded

Exhibit 2007 is a document containing a variety of links to websites offering NasalGuard® products for sale, including Amazon.com and nasalguard.com.

1. Exhibit 2007 is an unauthenticated document

The Board should exclude Exhibit 2007 from the record under F.R.E. 901 as there is no admissible evidence to authenticate it, and it is not a document subject to self-authentication under F.R.E. 902. Patent Owner cites to Exhibit 2007 in its Sur-Reply (*see* Paper 13 at 25) without providing any extrinsic evidence sufficient to support a finding that the exhibit is what Patent Owner claims it is, in violation of F.R.E. 901. Specifically, Patent Owner has not proffered any extrinsic evidence that the websites linked in Exhibit 2007 contain the same product listings and consumer ratings referred to in the Sur-Reply. *Id.* Mr. Wahi’s testimony (Ex. 2003) makes no

reference to or attempt to authenticate Exhibit 2007. Accordingly, Exhibit 2007 is not an authenticated document, and should be excluded.

2. Exhibit 2007's probative value is substantially outweighed by its prejudicial effect

The Board should exclude Exhibit 2007 under F.R.E. 403 because the prejudicial effect of its admittance would substantially outweigh its probative value. Patent Owner relies on Exhibit 2007 as evidence that “NasalGuard® has received over 4,000 customer ratings and maintains a rating above 4 stars.” See Paper 13 at 25. However, Exhibit 2007 is unauthenticated and is therefore prejudicial. Moreover, no admissible evidence connects the NasalGuard® brand or its alleged commercial success to the claims of the '802 Patent. In fact, the unauthenticated links provided in Exhibit 2007 are active links to unauthenticated websites, which themselves are not self-authenticating under F.R.E. 902. The prejudicial effect of Exhibit 2007 therefore substantially outweighs its probative value, and Exhibit 2007 should be excluded under F.R.E. 403.

3. Exhibit 2007 is inadmissible hearsay

The Board should exclude Exhibit 2007 from the record under F.R.E. 801 and 802 as hearsay, as it comprises out-of-court statements offered for the truth of the matters asserted without the opportunity for cross-examination and otherwise not falling within any exception or exclusion.

Patent Owner relies on Exhibit 2007 as evidence of the commercial success of NasalGuard® products. See Paper 13 at 25. Specifically, Patent Owner cites to Exhibit 2007 to support its assertion that “NasalGuard® has received over 4,000 customer ratings and maintains a rating above 4 stars.” *Id.* Treating Exhibit 2007 as the websites themselves, Patent Owner relies on the Exhibit for the truths of the matters asserted therein and offered Exhibit 2007 into the record on the same day it filed its Sur-Reply. For the same reasons provided above with respect to Exhibit 2004, Exhibit 2007 is inadmissible hearsay under F.R.E. 801 and 802 and should be excluded from the record.

However, Exhibit 2007 is not simply a compilation of websites. Rather, Exhibit 2007 contains links to websites and customer reviews which are each independently susceptible to hearsay rules under F.R.E. 801 and 802. Patent Owner has not authenticated these websites nor has Petitioner had the opportunity to evaluate the credibility of the content contained therein, such as through authentication by a knowledgeable witness (e.g., Mr. Wahi) or cross-examination of a product reviewer. Exhibit 2007 therefore comprises double hearsay, is inadmissible under F.R.E. 801 and 802, and should be excluded from the record.

III. CONCLUSION

For the foregoing reasons, the Board should exclude Patent Owner's Exhibits 2003-2007 in Patent Owner's Sur-Reply from the record.

Respectfully submitted,

VORYS, SATER, SEYMOUR AND PEASE LLP

Dated: August 19, 2025

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that the above-captioned “Petitioner’s Motion to Exclude Evidence Submitted with Patent Owner’s Sur-Reply” was served on August 19, 2025, upon the following via email:

uspto@patentsgroup.com
shk@shk-dplc.com

As well as a courtesy copy to the Patent Owner’s litigation counsel, by email:

keithaltman@kaltmanlaw.com
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