

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. IPR-2024-00711

**PATENT OWNER'S RESPONSE IN OPPOSITION TO
PETITIONER'S MOTION TO EXCLUDE EVIDENCE
SUBMITTED WITH PATENT OWNER'S SUR REPLY**

RESPONSE IN OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE EVIDENCE

I. STATEMENT OF FACTS

On July 8, 2025, Patent Owner submitted its sur-reply to Petitioner's reply (Paper 13). Submitted concurrently with its sur-reply were the following exhibits:

- Exhibit 2003 - Declaration of Ashok Wahj;
- Exhibit 2004 - Representative NasalGuard[®] Products;
- Exhibit 2005 - How to Use NasalGuard[®];
- Exhibit 2006 - A Clinical Study of the Efficacy of Products Protected By the '802 Patent; and
- Exhibit 2007 - A Listing of Websites Where NasalGuard[®] Products Are Sold.

On July 15, 2025, Petitioner submitted its "Objections To Patent Owner's Evidence," (Paper 15). Its objections comprised the following:

- Patent Owner submitted the exhibits in violation of 37 CFR §42.23(b);
- Each exhibit constituted inadmissible hearsay under Fed. R. Evid. 801 and 802;

- The probative value of each exhibit is substantially outweighed by "the danger of unfair prejudice" under Fed. R. Evid 403;
- The probative value of Exhibit 2003 is substantially outweighed by "the danger of unfair prejudice" under Fed. R. Evid. 403 because Petitioner did not have the opportunity to cross-examine the Declarant. and
- Exhibits 2004-2007 are objected to under Fed. R. Evid. 901 because there is no admissible evidence to substantiate them.

On July 21, 2025, Patent Owner submitted its "Response In Opposition To Petitioner's Objections To Patent Owner's Evidence," (Paper 16) in which all Petitioner's objections were addressed.

On July 30, 2025, Petitioner submitted its "Motion to Strike Evidence Submitted with Patent Owner's Sur-Reply," (Paper 19) to which Patent Owner submitted its "Response in Opposition to Petitioner's Motion to Strike," (Paper 20) on August 6, 2025. The Board's ruling on Petitioner's motion is still pending.

On August 7, 2025, Patent Owner submitted an email to the Board seeking permission to file a motion to file a Motion to Submit Supplemental Information under 37 CFR § 42.123(b). On the same day, Petitioner stated its objection to Patent Owner's request.

II. ARGUMENT

A significant issue in this matter is whether the asserted claims of the '802 Patent¹ are unpatentable under 35 U.S.C. § 103 as being obvious over the prior art. The United States Supreme Court held that commercial success should be considered as a mitigating factor against obviousness.² In its preliminary response, Patent Owner raised this issue, stating that Patent Owner (Trutek Corp.) achieved significant commercial success from sales of its products protected by its '802 Patent.³ Further, in Patent Owner's response to the Petition, the commercial success was once again asserted.⁴ On Page 21 of that brief, a photograph was shown of the front and rear of the packaging for NasalGuard[®] Airborne Particle Blocker. At the bottom of the package's rear side, the '802 Patent number is clearly marked.

On Page 23 of Petitioner's Reply brief, Petitioner stated that, "no evidence has been introduced to overcome obviousness with

¹ U.S. Patent No. 8,163,802 issued on April 14, 2012 is herein referred to as the '802 Patent.

² *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

³ "Respondent/Patent Owner's Preliminary Response To Petition For *Inter-Partes* Review of U.S. Patent No. 8,163,802," Paper 6, September 11, 2024, Page 22.

⁴ "Respondent/Patent Owner's Response to Petition For *Inter-Partes* Review of U.S. Patent No. 8,163,802," Paper 9, March 4, 2025, Page 21.

commercial success." Petitioner stated that neither the photograph nor Patent Owner's arguments were evidence.

Accompanying its sur-reply, Patent Owner submitted Exhibits 2003-2007 in order to comply with the Board's requirement for direct evidence and to correct its unintended error.

A. Exhibit 2003

This exhibit is a declaration of Ashok Wahi. Mr. Wahi is the president and chief science officer of Patent Owner, Trutek Corp. As such, he testifies as a representative of the Patent Owner. Mr. Wahi is also the sole inventor of the '802 Patent, which is assigned to Trutek.

Patent Owner previously responded⁵ to Petitioner's objections to this exhibit. First, Petitioner claims that Mr. Wahi's testimony is inadmissible hearsay without exception under Fed. R. Evid. 801 and 802. However, as Mr. Wahi testified as a representative of the adversary party, his testimony is non-hearsay as an admission under Fed. R. Evid. 801(d)(2). His declaration represents (A) his own statement in a representative capacity; (B) that Mr. Wahi asserted is true under oath; and (C) the statement is one by the adversary party's

⁵ Paper 16 - "Patent Owner's Response in Opposition to Petitioner's Objections to Patent Owner's Evidence," July 21, 2025, Pages 1-3.

agent or servant concerning a matter within the scope of his agency or employment made during the existence of his relationship.

Next, Petitioner objects to the fact that he was not provided the opportunity to cross-examine Mr. Wahi concerning the subject matter of his declaration. However, on Pages 2 and 3 of Paper 16, Patent Owner stated that "Mr. Wahi is available to be cross-examined by the Petitioner should it wish to do so." This offer was made on July 21, 2025, and Mr. Wahi would have been immediately available for deposition. However, Petitioner did not subsequently attempt to depose Mr. Wahi. More than one month remained for Petitioner to take Mr. Wahi's deposition had Petitioner decided to do it.

Then, Petitioner asserted that Exhibit 2003 is irrelevant. Yet, Mr. Wahi's testimony is directed toward commercial success as a mitigating factor against a determination of obviousness, which is at issue in this matter. Mr. Wahi testified that since 2012, Trutek sold more than fifteen-million units of the NasalGuard[®] product protected by the '802 Patent. The patent number was marked on all units sold in the United States. This is evidence of commercial success, which should be considered when determining whether the patent's claims are obvious over the prior art. It should be apparent from the papers

filed in this IPR that Patent Owner had no intention of waiving this issue.

In the alternative, Petitioner claims that the probative value of Mr. Wahi's testimony is substantially outweighed by its prejudicial effect under Fed. R. Evid. 403. Indeed, any evidence proffered by one litigant will have some prejudicial effect on its adversary litigant. Clearly, Petitioner does not want evidence of commercial success to be admitted because it will mitigate Petitioner's assertions of obviousness. But *Graham v. John Deere*, 383 U.S. 1 (1966), held that commercial success should be considered. Consideration of this factor would not create undue prejudice. On the other hand, failure to consider this factor would create undue prejudice upon Patent Owner. Consideration of this issue by the Board would be in the interest of Justice because doing so would promote an objective view of whether the claims of the issued '802 Patent are unpatentable under 35 U.S.C. § 103.

For the reasons stated above, Exhibit 2003 should not be excluded.

B. Exhibit 2004

Petitioner objects to Exhibit 2004, stating that "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." Exhibit 2004 was submitted to merely illustrate Paragraphs 6, 7, and 8 of Exhibit 2003. The primary evidence derives from Exhibit 2003. Exhibit number 2004 was not assigned to the document until after Mr. Wahi executed his declaration. Thus, Mr. Wahi had no knowledge of the exhibit numbers. Had Mr. Wahi been able to testify in-person, Exhibit 2004 would have been pre-marked and authenticated by the witness. However, under Fed. R. Evid. 901(b)(4), the exhibit has distinctive characteristics such as, "appearance, contents, substance, internal patterns, and other distinctive characteristics taken in conjunction with circumstances." Thus, Exhibit 2004 does not require further authentication. Further, under Fed. R. Evid. 902(7), the exhibit is self authenticating because it comprises trade inscriptions and labels purporting to have been affixed in the course of business and indicating ownership, control, or origin.

Next, Petitioner objects to Exhibit 2004 under Fed. R. Evid 801 and 802 as inadmissible hearsay asserted "without the opportunity for

cross-examination and otherwise not fitting within any exception or exclusion." First, Exhibit 2004 is not a statement. The statements are made only in Exhibit 2003. Second, as discussed *supra*, Patent Owner offered to make Mr. Wahi available for cross-examination on July 21, but Petitioner has not accepted the offer.

C. Exhibit 2005

Exhibit 2005 is a set of photographs that illustrate how to use the NasalGuard[®] gel product. On page 3 of Paper 7, Judge Franklin wrote:

The '802 patent recognizes that other patents have "describe[d] electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled." Id. at 2:42–45.

Then on Page 10, Judge Franklin wrote further:

Petitioner refers to a passage in the '802 patent describing the "object of the invention" as composition applied to "the exterior region around the nostril and/or slightly inside the edge of the nostril." Id. (quoting Ex. 1001, 2:62–65). Petitioner contends that "[l]ogically, the formulations applied in a thin film must be on the exterior region around the nostril (i.e., skin) and/or slightly inside the edge of the nostril which is the tissue of nasal passages in order to prevent nasal inhalation." Id. (citing Ex. 1002 ¶ 71).

Patent Owner does not address Petitioner's proposed construction of this claim phrase or provide one of its own. See Prelim. Resp. 6–12.

Exhibit 2005 was presented merely to illustrate that the NasalGuard[®] gel is applied to the exterior of the nostrils. This series of photographs reinforces Petitioner's claim construction as well as Judge Franklin's understanding.

First, Petitioner objects to Exhibit 2005, stating that it "is an unauthenticated document" under Fed. R. Evid. 901, and that "it is not a document subject to self authentication." However, the exhibit is clearly a screen captured from Patent Owner's website.⁶ According to Fed. R. Evid. 902(d)(7), the exhibit is self-authenticating because it comprises trade inscriptions purporting to have been affixed in the course of business and indicating ownership, control, or origin.

Next, Petitioner objects to the exhibit under Fed. R. Evid. 403 stating that its probative value is substantially outweighed by its prejudicial effect. On the contrary, this exhibit can be used to reinforce Petitioner's claim construction of the claim term, "skin or tissue of the nasal passages." This exhibit is harmless, and Petitioner failed to show that it creates any prejudicial effect.

Finally, Petitioner objects to this exhibit under Fed. R. Evid. 801 and 802 as inadmissible hearsay. First, the exhibit is not a

⁶ Patent Owner's website is www.nasalguard.com.

statement. It is not offered to prove the truth of the matter asserted. It is not offered as evidence but as an illustration. It is not offered to prove the truth of any matter. It is merely an illustration of a fact that has been already accepted by both the Petitioner and the Board. Further, it is not hearsay because it is presented by the Patent Owner, an adversary party, and it is non-hearsay as an admission under Fed. R. Evid. 801(d)(2).

D. Exhibit 2006

Exhibit 2006 is a report on the safety and efficacy of the NasalGuard[®] product⁷ dated March 7, 2012, just prior to the issue date of the '802 Patent. It is thirteen years old, but not yet old enough to be considered ancient. Based on its age, the document is impossible to authenticate. However, the study was conducted at Trutek's request to establish the safety and efficacy of the product for public consumption. Thus, the document cannot be presented here to show that the product was effective against cold and flu viruses under Fed. R. Evid. 801 or 802.

That being said, Exhibit 2006 is neither essential nor relevant to Patent Owner's asserted issue of commercial success as a mitigating

⁷ Before the '802 Patent Issued, Trutek personnel referred to this prospective product as "MAPB" to designate it as a **M**ulti-**A**cting **P**article **B**locker.

factor against obviousness. Patent Owner has no objection to the exclusion of this exhibit.

E. Exhibit 2007

Exhibit 2007 is titled, " '802 Patent Commercialization Links," It is a list of websites where NasalGuard[®] products are sold online. The websites are listed in a PDF file as hyperlinks that when activated bring the reader to the associated websites. As such, Exhibit 2007 represents a summary (or table of contents), which are admissible under Fed. R. Evid. 1006. Its contents are also admissible under Rule 1007 as an admission by Patent Owner evidencing sales outlets for its products protected by the '802 Patent. The document is submitted to provide backup for Paragraph 9 of Exhibit 2003, where Mr. Wahi stated that, "[a]mong other online stores, NasalGuard[®] is sold on the Amazon, Shopify, and Walmart marketplaces in many countries, including the United States."

Petitioner objects to admission of Exhibit 2007, claiming that it has not been authenticated under Fed. R. Evid. 901. Further, under Fed. R. Evid. 902(7), the websites themselves are self-authenticating because they comprise trade inscriptions and labels purporting to have been affixed in the course of business and indicating ownership,

control, or origin. Under Rule 1006, such a summary does not require authentication as long as the items themselves are available to Petitioner. As a written admission by the Patent Owner, the document is admissible under Rule 1007.

Petitioner further objects to the exhibit as hearsay under Rule 801. But it is not hearsay because it is not a statement presented to prove the truth of the matter asserted. In addition, it is an admission by Patent Owner, which is non-hearsay under Rule 801(d)(2). Finally, the danger of unfair prejudice is not outweighed by the probative value of the exhibit because the Supreme Court held in *Graham v. John Deere Co.* that commercial success should be considered in a determination of obviousness of a claimed invention.

F. Additional Argument Opposing Exclusion of Evidence

It should be apparent from the pleadings that Patent Owner did not intend to waive the issue of commercial success as a mitigating factor against a determination of obviousness. That issue was raised as an argument in Patent Owner's preliminary response (Paper 6), response to petition (Paper 9), sur-reply (Paper 13), and every submission thereafter by Patent Owner. However, the issue was presented in Papers 6 and 9 as argument as opposed to direct

testimony. Patent Owner tried to correct this inadvertent mistake in its sur-reply by submitting Exhibits 2003 - 2007. This led to Petitioner's submission of objections, motion to strike, and the current motion to exclude the exhibits. As early as July 21, Patent Owner offered to present Ashok Wahi for cross-examination, but Petitioner did not accept the offer.

Patent Owner's commercial success of its NasalGuard[®] product since 2012 is a matter of fact. The '802 Patent number was marked and continues to be marked on every package sold in the United States and in countries around the world. Obviousness is at issue in this proceeding. Excluding evidence of this fact would not be in the interest of justice. When evaluating whether issued claims are invalid or unpatentable, the question of whether they are obvious should be evaluated objectively. The claims are either obvious or they are not. Thus, Patent Owner respectfully requests that, except for Exhibit 2006, the Board should not exclude the instant exhibits.

III. CONCLUSION

Based upon the arguments submitted *supra*, Patent Owner respectfully requests that the Board deny Petitioner's motion to exclude Exhibits 2003-2005 and 2007.

CERTIFICATION OF SERVICE

The undersigned hereby certifies that the above-captioned "Patent Owner's Response in Opposition to Petitioner's Motion to Exclude Evidence Submitted With Patent Owner's Sur-Reply," regarding IPR2024-00711 was served on August 26, 2025, upon the following via email:

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As well as a courtesy copy to the patent owner's litigation counsel, by email:

Jonathan Barnes	< jbarnes@bradley.com >
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/s/ Stanley H. Kremen

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*Lead Counsel for Patent
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Trutek Corp..*