

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ENCUBE ETHICALS PVT. LTD.,  
Petitioner

v.

DERMAVANT SCIENCES GMBH,  
Patent Owner

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Case IPR2024-00834  
U.S. Patent No. 11,590,088 B2

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE**

***Mail Stop "PATENT BOARD"***  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Patent Owner, Dermavant Sciences GmbH (“Dermavant”) objects under the Federal Rules of Evidence (FRE) and 37 C.F.R. § 42.64(b)(1) to the admissibility of Exhibits 1003, 1007, 1014, 1016–1026, 1031–1032, and 1034 (the “Challenged Evidence”), filed by Petitioner, Encube Ethicals Pvt. Ltd. (“Encube”), on April 23, 2024, with Encube’s Petition for *Inter Partes* Review. Dermavant’s Objections are timely filed under 37 C.F.R. § 42.64(b)(1), within ten business days of the Board’s November 8, 2024 Decision on Institution. Dermavant files these Objections to provide notice to Encube that Dermavant may move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

## **I. IDENTIFICATION OF GROUNDS FOR OBJECTIONS**

### **A. Exhibit 1003**

Exhibit 1003 (“EX1003”) purports to be the “Declaration of Wieke H. Liem, M.D.” Dermavant objects to paragraphs 25–38, 54–55, 57–62, 67–76, 105–108, 178, 238, 292, and 319 of EX1003 under FRE 401–403. Encube does not cite any of these paragraphs in its Petition for IPR, rendering the testimony in these paragraphs irrelevant under FRE 401. Dermavant therefore objects to these paragraphs under FRE 402. Dermavant also objects to these paragraphs under FRE 403 because they have no probative value, create unfair prejudice to Dermavant, and will only confuse issues and waste the Board’s time.

Dermavant also objects to the following paragraphs in EX1003 under FRE

702 and 703 because Dr. Liem relies on inadmissible evidence that experts in the field would not reasonably rely on in forming an opinion: *see* EX1003, paragraphs 40, 42–43, 45, 47–53, 57–58, 66, 77, 89–90, 96–97, 119, 122, 136, 147–150, 158, 190, 191, 194–195, 197–198, 208–209, 214, 219, 222–224, 233–234, 243, 246, 253–254, 261, 264, 273, 280, 285, 289, 302, 313, 326, 330, 334, 337–338, 347, 355, 362, 365–366, and 369–370. These paragraphs in EX1003 rely on inadmissible evidence (discussed below) such as EX1007, EX1016–1019, EX1026, and EX1032.

Dermavant further objects to the following paragraphs in EX1003 under FRE 702 because Dr. Liem’s testimony is not based on sufficient facts or data, nor is it the product of reliable principles and methods: *see* EX1003, paragraphs 23–26, 28–36, 39–40, 45–46, 48–49, 52, 65, 74, 76, 86, 89–90, 97, 99–101, 105–109, 111, 113, 115–125, 128, 131–133, 135–139, 141–144, 146–147, 149–151, 156–157, 160–180, 182–186, 188–195, 197–211, 214–217, 219–232, 237–242, 244–250, 252, 255–258, 261–267, 269–272, 274–278, 281, 283–286, 289, 291–297, 300–301, 303–328, 330–340, 342, 344–351, 353, 357–361, 363–365, 367–386, 388–394, and 396–400—which, *e.g.*, provide unsupported assertions and/or rely on the conclusions of Mr. Sudhakar, rather than the underlying facts or data. In particular, Dr. Liem relies *exclusively* on the testimony of Mr. Sudhakar to form her opinion with respect to claims 3 and 4: *see* EX1003, paragraphs 149–150 and 223–224; and as discussed herein and below, Mr. Sudhakar’s testimony with regard to claims 3 and 4 is

incomplete and thus not reliably supported. Claims 3 and 4 depend from, and therefore necessarily include, every element of claim 1, and Mr. Sudhakar does not analyze or even acknowledge claim 1 in his declaration. *See generally*, EX1032. Thus, Dr. Liem's testimony will not help the trier of fact understand the evidence or determine a fact in issue. *See* FRE 702; *see also*, 37 C.F.R. § 42.65.

**B. Exhibit 1007**

EX1007 purports to be “Spuls, et al., How Good Are Clinical Severity and Outcome Measures for Psoriasis?: Quantitative Evaluation in a Systematic Review, *Journal of Investigative Dermatology* 130:933-943 (2010).” Dermavant objects to EX1007 under FRE 403 and 1001–1003 because it is an incomplete document; *e.g.*, EX1007 does not include its supplementary material that was purportedly published with the document. *See, e.g.*, EX1007, p. 10. EX1007 is therefore not a “duplicate” as defined by FRE 1001(e) insofar as the exhibit is not “a copy . . . which accurately reproduces the original.” Dermavant accordingly objects to EX1007 under FRE 1002 for failure to comply with the best evidence rule. Dermavant further objects to EX1007 as lacking authentication under FRE 901 because Encube has not provided sufficient information regarding its authenticity.

Dermavant also objects to EX1007 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Liem relies on EX1007 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh

its prejudicial effect. *See, e.g.*, EX1003, pp. 21–23, 25, 31, 34, 59, 68, 91–92, 97–98, 101, 103, 105, 113, 117, 128, 150, and 153–154; and (2) Encube relies on EX1007 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 4, 7, 41, 44, 50, and 63. EX1007 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**C. Exhibit 1014**

EX1014 purports to be “Valerie J. Paul, Sally Frautschy, William Fenical, and Kenneth H. Nealson, Antibiotics in Microbial Ecology, Isolation and Structure Assignment of Several New Antibacterial Compounds from the Insect-Symbiotic Bacteria *Xenorhabdus* spp., *Journal of Chemical Ecology* 7(3):589-597 (1981).” Dermavant objects to EX1014 under FRE 403 because EX1014 is not cited in any paper or in either of Petitioner’s expert declarations.

**D. Exhibit 1016**

EX1016 purports to be “Chinese Clinical Trial Register Registration Number ChiCTR-TRC-10000995, Pharmacokinetics and Tolerability of Topically Applied Benvitimod Cream in Patients with Psoriasis.” Dermavant objects to EX1016 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1016 is not a self-authenticating

document under FRE 902.

Dermavant also objects to EX1016 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Liem relies on EX1016 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1003, pp. 29, 89, 116, and 146; (2) Dr. Sudhakar relies on EX1016 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 28; and (3) Encube relies on EX1016 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 8 and 33. EX1016 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**E. Exhibit 1017**

EX1017 purports to be “Chinese Clinical Trial Register Registration Number ChiCTR-TRC-11001391, Multicentre, Randomised, Double-Blind, Placebo Controlled Trial on Topically Applied Benvitimod Cream in Patients with Psoriasis.” Dermavant objects to EX1017 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1017 is not a self-authenticating document under FRE 902.

Dermavant also objects to EX1017 under FRE 801–802 for containing

inadmissible hearsay because (1) Dr. Liem relies on EX1017 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1003, pp. 29–30, 89, 116, and 146; (2) Dr. Sudhakar relies on EX1017 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 28; and (3) Encube relies on EX1017 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 8 and 33. EX1017 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**F. Exhibit 1018**

EX1018 purports to be “Chinese Clinical Trial Register Registration Number ChiCTR-TRC-13003259, Multi-Centre, Randomised, Double-Blind, Placebo- and Comparator-Controlled Trial on Topically Applied Benvitimod Cream in Patients with Psoriasis.” Dermavant objects to EX1018 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1018 is not a self-authenticating document under FRE 902.

Dermavant also objects to EX1018 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Liem relies on EX1018 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh

its prejudicial effect. *See, e.g.*, EX1003, pp. 28–30, 89, 116, and 146; (2) Dr. Sudhakar relies on EX1018 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 28; and (3) Encube relies on EX1018 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 8 and 33. EX1018 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**G. Exhibit 1019**

EX1019 purports to be “Mark S. Butler, Avril A. B. Robertson, Matthew Cooper, Natural product and natural product derived drugs in clinical trials, Natural Product Reports (2014).” Dermavant objects to EX1019 under FRE 403 and 1001–1003 because it is an incomplete document; *e.g.*, EX1019 does not include its supplementary information. *See, e.g.*, EX1019, p. 2–3, 22, 32, and 35. EX1019 is therefore not a “duplicate” as defined by FRE 1001(e) insofar as the exhibit is not “a copy . . . which accurately reproduces the original.” Dermavant accordingly objects to EX1019 under FRE 1002 for failure to comply with the best evidence rule. Dermavant further objects to EX1019 as lacking authentication under FRE 901 because Encube has not provided sufficient information regarding its authenticity.

Dermavant also objects to EX1019 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Liem relies on EX1019 for the truth of the

matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1003, pp. 42 and 135; (2) Dr. Sudhakar relies on EX1019 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 26–29; and (3) Encube relies on EX1019 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 11. EX1019 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

#### **H. Exhibit 1020**

EX1020 purports to be “USAP Dictionary of USAN and International Drug Names, 42nd ed., p. 212 (2006).” Dermavant objects to EX1020 under FRE 403 because EX1020 is not cited in any paper or in either of Petitioner’s expert declarations. Dermavant also objects to EX1020 under FRE 403 and 1001–1003 because it is an incomplete document; *e.g.*, EX1020 does not include its table of contents and/or index, and the text on page 4 is not clearly displayed. *See, e.g.*, EX1020, p. 4. EX1020 is therefore not a “duplicate” as defined by FRE 1001(e) insofar as the exhibit is not “a copy . . . which accurately reproduces the original.” Dermavant accordingly objects to EX1020 under FRE 1002 for failure to comply with the best evidence rule. Dermavant further objects to EX1020 as lacking authentication under FRE 901 because Encube has not provided sufficient

information regarding its authenticity.

**I. Exhibit 1021**

EX1021 purports to be “Precision FDA, U.S. Food & Drug Administration, UNII Search, entry for UNII: L0Q8IK9E08 (‘Steareth-20’).” Dermavant objects to EX1021 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1021 is not a self-authenticating document under FRE 902.

Dermavant also objects to EX1021 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Sudhakar relies on EX1021 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 43; and (2) Encube relies on EX1021 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 21. EX1021 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**J. Exhibit 1022**

EX1022 purports to be “Precision FDA, U.S. Food & Drug Administration, UNII Search, entry for UNII: V56DFE46J5 (‘Steareth-2’).” Dermavant objects to EX1022 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not

provided sufficient information regarding its authenticity. EX1022 is not a self-authenticating document under FRE 902.

Dermavant also objects to EX1022 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Sudhakar relies on EX1022 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 42; and (2) Encube relies on EX1022 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 21. EX1022 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**K. Exhibit 1023**

EX1023 purports to be “Global Ingredient Archival System, GSRS database (<https://gsrs.ncats.nih.gov/ginas/app/beta/browse-substance>), entry for Steareth-2.” Dermavant objects to EX1023 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1023 is not a self-authenticating document under FRE 902.

Dermavant also objects to EX1023 under FRE 801–802 for containing inadmissible hearsay because Dr. Sudhakar relies on EX1023 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 42. EX1023 does not fall under any of

the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**L. Exhibit 1024**

EX1024 purports to be “Global Ingredient Archival System, GSRS database (<https://gsrs.ncats.nih.gov/ginas/app/beta/browse-substance>), entry for Steareth-20.” Dermavant objects to EX1024 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1024 is not a self-authenticating document under FRE 902.

Dermavant also objects to EX1024 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Sudhakar relies on EX1024 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 43; and (3) Encube relies on EX1024 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 21. EX1024 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**M. Exhibit 1025**

EX1025 purports to be “FDA Prescribing Information, VTAMA® (tapinarof) topical cream, 1%.” Dermavant objects to EX1025 under FRE 401–403. Petitioner has not established that EX1025 is a prior-art publication to U.S. Patent No. 11,590,088 B2—rendering EX1025 irrelevant under FRE 401. *See, e.g.*, EX1025, p.

1 (providing a 5/2022 revision date). Dermavant therefore objects to EX1025 under FRE 402. Dermavant also objects to EX1025 under FRE 403 because it has no probative value, creates unfair prejudice to Dermavant, and will only confuse issues and waste the Board's time.

**N. Exhibit 1026**

EX1026 purports to be “Clinical Trials website (<https://clinicaltrials.gov/>), clinical trials for plaque psoriasis treatments prior to November 2018.” Dermavant objects to EX1026 as lacking authentication under FRE 901 because Encube has failed to provide sufficient evidence indicating the origin of the document and has not provided sufficient information regarding its authenticity. EX1026 is not a self-authenticating document under FRE 902. Dermavant also objects to EX1026 under FRE 401–403. Petitioner has not established that EX1026 is a prior-art publication to U.S. Patent No. 11,590,088 B2—rendering EX1026 irrelevant under FRE 401. *See, e.g.*, EX1026, Part 3, pp. 421, 333–334, and 343. Dermavant therefore objects to EX1026 under FRE 402. Dermavant also objects to EX1026 under FRE 403 because it has no probative value, creates unfair prejudice to Dermavant, and will only confuse issues and waste the Board's time.

Dermavant further objects to EX1026 under FRE 801–802 for containing inadmissible hearsay because (1) Dr. Liem relies on EX1026 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh

its prejudicial effect. *See, e.g.*, EX1003, pp. 26–28, 34, 89, 91–92, 101, 103, 105, 109, 114, 116–117, 123, 128, 146, 150, and 153–154; (2) Dr. Sudhakar relies on EX1026 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 63; and (3) Encube relies on EX1026 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 8, 33, 41–42, 44, 48, and 50. EX1026 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**O. Exhibit 1031**

EX1031 purports to be “Excerpts from Handbook of Pharmaceutical Excipients, 8th Edition.” Dermavant objects to EX1031 under FRE 403 and 1001–1003 because it is an incomplete document; *e.g.*, EX1031 is missing the first page of the section on “Citric Acid Monohydrate” and part of the section on “Coconut Oil.” *See, e.g.*, EX1031, pp. 17 and 19. EX1031 is therefore not a “duplicate” as defined by FRE 1001(e) insofar as the exhibit is not “a copy . . . which accurately reproduces the original.” Dermavant accordingly objects to EX1031 under FRE 1002 for failure to comply with the best evidence rule. Dermavant further objects to EX1031 as lacking authentication under FRE 901 because Encube has not provided sufficient information regarding its authenticity.

Dermavant also objects to EX1031 under FRE 801–802 for containing

inadmissible hearsay because (1) Dr. Sudhakar relies on EX1031 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, EX1032, p. 48 and 54–55; and (3) Encube relies on EX1031 for the truth of the matter asserted, and its probative value in helping the factfinder does not outweigh its prejudicial effect. *See, e.g.*, Petition at 23, 36, and 62. EX1031 does not fall under any of the hearsay exceptions, *e.g.*, FRE 803–805 and 807.

**P. Exhibit 1032**

EX1032 purports to be the “Declaration of Paul T. Sudhakar, MS, MBA.” Dermavant objects to paragraphs 16–41, 44, 51–55, 71–73, and 134–138 of EX1032 under FRE 401–403. Encube does not cite any of these paragraphs in its Petition for IPR, rendering the testimony in these paragraphs irrelevant under FRE 401. Dermavant therefore objects to these paragraphs under FRE 402. Dermavant also objects to these paragraphs under FRE 403 because they have no probative value, create unfair prejudice to Dermavant, and will only confuse issues and waste the Board’s time.

Dermavant also objects to paragraphs 65, 71–72, 101, 103, 110, 120–121, and 137 in EX1032 under FRE 702 and 703 because Mr. Sudhakar relies on inadmissible evidence (discussed above) such as EX1016–1019, EX1021–1024, EX1026, and EX1031, that experts in the field would not reasonably rely on in forming an opinion:

*see* EX1032, paragraphs 65, 71–72, 101, 103, 110, 120–121, and 137.

Dermavant further objects to the paragraphs 16–29, 32, 37, 41, 48, 50–53, 58, 62, 65–67, 69, 72–75, 77–84, 86–87, 89–92, 95–96, 107, 110–112, 114–133, and 137–138 in EX1032 under FRE 702 because Mr. Sudhakar’s testimony is not based on sufficient facts or data, nor is it the product of reliable principles and methods. The listed paragraphs, *e.g.*, provide unsupported assertions and/or include citations to unreliable sources, such as Wikipedia and a blog post pre-dating the earliest priority of the ’088 patent, neither of which, along with other URL citations included throughout, have been entered as exhibits on the record. Finally, Dermavant objects to Mr. Sudhakar’s testimony with regard to claims 3 and 4 because it is not supported by reliable evidence; claims 3 and 4 depend from, and therefore necessarily include, every element of claim 1, and Mr. Sudhakar does not analyze or even acknowledge claim 1 in his declaration. *See* EX1032. Thus, Mr. Sudhakar’s testimony regarding claims 3 and 4 is deficient, and will not help the trier of fact understand the evidence or determine a fact in issue. *See* FRE 702; *see also*, 37 C.F.R. § 42.65.

**Q. Exhibit 1034**

EX1034 purports to be the “Declaration of Sylvia D. Hall-Ellis, Ph.D.” Dermavant objects to the following paragraphs in EX1034 under FRE 702 because Dr. Hall-Ellis’s testimony is not based on sufficient facts or data, nor is it the product of reliable principles and methods: *see* EX1034, paragraphs 46–52, which contain

or rely on misstatements of fact regarding the completeness of EX1007. In particular, regarding EX1007, Dr. Hall-Ellis states that “the text of the article is complete” and “Exhibit 1007 is a true and correct copy in a condition that creates no suspicion about its authenticity”: *see* EX1034, paragraph 46; however, as described above, EX1007 is an incomplete document; *e.g.*, EX1007 does not include its supplementary material that was purportedly published with the document. *See, e.g.*, EX1007, p. 10. Thus, Dr. Hall-Ellis’s testimony will not help the trier of fact understand the evidence or determine a fact in issue. *See* FRE 702; *see also*, 37 C.F.R. § 42.65.

## II. CONCLUSION

Dermavant’s objections to the Challenged Evidence are timely. Dermavant therefore reserves the right to move to exclude the Challenged Evidence under 37 C.F.R. § 42.64(c).

Respectfully submitted,  
STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
/Deborah A. Sterling/  
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Date: November 25, 2024

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**CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))**

I certify that the above-captioned **PATENT OWNER'S OBJECTIONS TO EVIDENCE** was served in its entirety on November 25, 2024 upon the following parties via electronic mail:

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