

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ENCUBE ETHICALS PVT. LTD.
Petitioner

v.

DERMAVANT SCIENCES GMBH
Patent Owner

IPR2024-00834

U.S. Patent No. 11,590,088

PETITIONER'S MOTION TO SUBMIT SUPPLEMENTAL INFORMATION

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PETITIONER’S EXHIBIT LIST

Exhibit No.	Exhibit Description
1001	U.S. Patent No. 11,590,088 (“the ’088 patent”)
1002	File History of U.S. Patent No. 11,590,088
1003	Declaration of Wieke H. Liem, M.D.
1004	<i>Curriculum Vitae</i> of Wieke H. Liem, M.D.
1005	U.S. Patent Application Pub. No. 2016/0338973 (“Sonti”)
1006	Dogra, et al., Psoriasis: Epidemiology, Clinical Features, Co-morbidities, and Clinical Scoring, Indian Dermatology Online Journal 7(6):471-480 (2016)
1007	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)
1008	Bissonnette, et al., Efficacy and Safety of Topical WBI-1001 in Patients With Mild to Moderate Psoriasis: Results From a Randomized Double-Blind Placebo-Controlled, Phase II Trial, Journal of the European Academy of Dermatology & Venereology 26:1516-1521 (2012) (“Bissonnette”)
1009	Bolkote, et al., An Analysis of Psoriasis Skin Images, International Journal of Inventive Engineering and Sciences 2(12):17-22 (2014)
1010	Cappelleri, et al., Psychometric Validation of the Physician Global Assessment Scale For Assessing Severity of Psoriasis Disease Activity, Quality of Life Research 22:2489-2499 (2013)
1011	Patel, et al., Evaluating Psoriasis: A Review of the Assessments Most Commonly Used in Clinical Trials, Psoriasis Forum 17(4):259-266 (2011)
1012	WO 2001/042231
1013	U.S. Patent No. 7,868,047 (“Chen”)
1014	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 <i>Xenorhabdus</i> spp., <i>Journal of Chemical Ecology</i> 7(3):589-597 (1981)
1015	Smriti K. Raychaudhuri, Emanuel Maverakis, & Siba P. Raychaudhuri, <i>Diagnosis and Classification of Psoriasis</i> , 13 <i>Autoimmunity Reviews</i> 490 (2014)
1016	Chinese Clinical Trial Register Registration Number ChiCTR-TRC-10000995, Pharmacokinetics and Tolerability of Topically Applied Benvitimod Cream in Patients with Psoriasis
1017	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
1018	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
1019	Mark S. Butler, Avril A. B. Robertson, Matthew Cooper, <i>Natural product and natural product derived drugs in clinical trials</i> , <i>Natural Product Reports</i> (2014)
1020	USAP Dictionary of USAN and International Drug Names, 42nd ed., p. 212 (2006)
1021	Precision FDA, U.S. Food & Drug Administration, UNII Search, entry for UNII: L0Q8IK9E08 (“Steareth-20”)
1022	Precision FDA, U.S. Food & Drug Administration, UNII Search, entry for UNII: V56DFE46J5 (“Steareth-2”)
1023	Global Ingredient Archival System, GSRS database (https://gsrs.ncats.nih.gov/ginas/app/beta/browse-substance), entry for Steareth-2
1024	Global Ingredient Archival System, GSRS database (https://gsrs.ncats.nih.gov/ginas/app/beta/browse-substance), entry for Steareth-20
1025	FDA Prescribing Information, VTAMA® (tapinarof) topical cream, 1%
1026	Clinical Trials website (https://clinicaltrials.gov/), clinical trials

	for plaque psoriasis treatments prior to November 2018
1027	U.S. Patent Publication No. 2003/0171429 (“Chen 1”)
1028	U.S. Patent Publication No. 2010/0094041 (“Chen 2”)
1029	U.S. Patent Publication No. 2008/0255245 (“Chen 3”)
1030	McMullen et al., Emulsions and their Characterization by Texture Profile Analysis, Handbook of Formulating Dermal Applications, Section II, Chapter 6, 131-151 (2017)
1031	Excerpts from Handbook of Pharmaceutical Excipients , 8 th Edition
1032	Declaration of Paul T. Sudhakar, MS, MBA
1033	<i>Curriculum Vitae</i> of Paul T. Sudhakar
1034	Declaration of Sylvia D. Hall-Ellis, Ph.D.

Pursuant to 37 C.F.R. § 42.123, and as authorized by the Board on December 18, 2024, Petitioner Encube Ethicals Ptv. Ltd. (“Encube”) hereby moves to submit the below-identified evidence as supplemental information.

I. Legal Standard

A party may move to submit supplemental information once trial has been instituted if: “(1) A request for the authorization to file a motion to submit supplemental information is made within one month of the date the trial is instituted” and “(2) [t]he supplemental information must be relevant to a claim for which the trial has been instituted.” 37 C.F.R. § 42.123(a).

II. Argument

Encube’s request meets the requirements of 37 C.F.R. § 42.123(a). Encube’s request for authorization to file a motion to submit supplemental information under 37 C.F.R. § 42.123(a) was timely, and the Board subsequently authorized the motion. Ex. 3003; Paper 14. The documents Encube seeks to file are relevant to claims at issue in this trial. Encube seeks to file the following documents:¹

1) The webpage cited by ¶62 of the declaration of Paul Sudhakar
<https://openstax.org/books/organic-chemistry/pages/1-12-drawing-chemical->

¹ Encube also served these documents on Patent Owner on December 11, 2024, as Exhibits A-D to the supplemental declaration of Paul Sudhakar.

[structures](#)). This document is relevant to claims for which review was instituted, including claim 1 which recites a method that includes administering a topical composition “containing... about 1.0% tapinarof”. *See* Ex-1032 at ¶62. For example, the document is relevant to why a POSITA would understand the drawing of the chemical structure in the Sonti reference (the lead reference for Grounds 1 and 2 of the Petition) to be tapinarof.

2) The webpage cited by ¶73 of the declaration of Paul Sudhakar, (<https://pubchem.ncbi.nlm.nih.gov/compound/6439522#section=MeSH-EntryTerms>). This document is relevant to claims for which review was instituted, including claim 1 which recites a method that includes administering a topical composition “containing... about 1.0% tapinarof”. *See* Ex-1032 at ¶73. For example, the document recites various names used in the field for tapinarof (e.g., Benvitimod, WBI-1001). References the Petition relies on (e.g., Exs. 1016-1018, Bissonnette, Chen) also use various nomenclature to refer to tapinarof (e.g., Exs. 1016-1018 use Benvitimod, Bissonnette uses WBI-1001). This document is relevant to disclosure of administering tapinarof by such references. The document also identifies names the Chen references use for tapinarof.

3) The webpage cited by ¶73 of the declaration of Paul Sudhakar (<https://en.wikipedia.org/wiki/Tapinarof>). This document is relevant to claims for which review was instituted, including claim 1 which recites a method that

includes administering a topical composition “containing... about 1.0% tapinarof”.
See Ex-1032 at ¶73; *see also* Ex-1003 at ¶¶52, 89. For example, the document recites various names used in the field for tapinarof (e.g., “Benvitimod”).
References the Petition relies on also use various nomenclature to refer to tapinarof (e.g., Exs. 1016-1018, Chen). This document is relevant to disclosure of administering tapinarof by such references. The document also identifies names the Chen references use for tapinarof.

4) The webpage cited by ¶77 of the declaration of Paul Sudhakar
(<https://www.chemicals.co.uk/blog/what-do-vv-ww-wv-mean>). This webpage is relevant to claims for which review was instituted, including claim 1 which recites a method that includes administering a topical composition “containing... about 1.0% tapinarof”. *See* Ex-1032 at ¶77; *see also* Ex-1003 at ¶122. The webpage describes how a POSITA would understand a reference to a composition that is 1% “w/w” of an ingredient to refer to 1% by weight, and as such is relevant to discussion by references the Petition relies on (such as the Sonti reference) that discuss administering a composition of 1% “w/w” of tapinarof.

For at least the foregoing reasons, the documents Encube wishes to file as supplemental information are relevant to claims for which review was instituted, and Encube respectfully requests that the Board grant this motion.

Dated: December 24, 2024

Respectfully submitted,

/Gary J. Speier/

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CERTIFICATE OF SERVICE

I certify that on December 24, 2024, I caused a true and correct copy of the foregoing PETITIONER'S MOTION TO SUBMIT SUPPLEMENTAL INFORMATION to be served upon the following parties via electronic mail:

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