UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PROLLENIUM US INC.,
Petitioner,

v.

ALLERGAN INDUSTRIE, SAS,
Patent Owner.

IPR2019-01505 (Patent 8,450,475 B2)
IPR2019-01506 (Patent 8,357,795 B2)
IPR2019-01508 (Patent 9,238,013 B2)
IPR2019-01509 (Patent 9,358,322 B2)
IPR2019-01617 (Patent 8,822,676 B2)
IPR2019-01632 (Patent 8,357,795 B2)
IPR2020-00084 (Patent 9,089,519 B2)

PATENT OWNER'S IDENTIFICATION OF IMPROPER NEW ARGUMENTS AND EVIDENCE[1]

[1] Authorization for the use of a joint caption page was received on April 27, 2020. Neither party opposes the use of a joint caption page. An identical paper has been filed in each case recited in the joint caption.

Patent Owner identifies improper arguments and evidence in Petitioner's Reply (Paper 43) and Prestwich Declaration (EX1105) under 37 C.F.R. § 42.23(b). *See* EX3003. Unless otherwise noted, all citations refer to papers and exhibits filed in IPR2019-01617 as representative of all related IPRs.

Citation	Explanation and Identification of Improper Evidence
Reply and EX1105 in their entirety	The Board "is not required to attempt to sort proper from improper portions of the reply" and should thus disregard the Reply and EX1105 entirely (Nov. 2019 TPG at 74); inadmissible under Fed. R. Evid. 402, 403, 702, and 703.
Reply 23:1-3	Improper incorporation by reference of 16 pages of EX1105 ¶¶ 46–69.
Reply 24 n.7	Improper incorporation by reference of EX1105 ¶¶ 71-75.
Reply 25:7–28:4; EX1105 ¶¶ 73, 163	Advancing new obviousness grounds based on evidence not cited in the Petition—"Prollenium's Ground is that a POSITA would simply add lidocaine to Lebreton's gels" (citing EX2067) (*Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1367 (Fed. Cir. 2015) (striking a reply that relied on "previously unidentified portions of a prior-art reference to make a meaningfully distinct contention")).
Reply 29:12-13	Improper incorporation by reference of EX1105 ¶¶ 46-51.
Reply 30:1-31:6; EX1105 ¶¶ 52-56	Asserting for the first time that the increase in ionic strength caused by addition of 0.3% lidocaine HCl would not discourage a POSA from making the claimed composition.
Reply 19:3-10, 26 n.9, 32:8-9	Citing non-public emails of inventor Lebreton to argue POSA was aware of successful addition of lidocaine to HA fillers.
Reply 31:2-3	Improper incorporation by reference of EX1105 ¶¶ 53-55.
Reply 31:7-20; EX1105 ¶¶ 39, 63, 159	Providing new evidence for argument of reasonable expectation of success and newly arguing that a POSA would have known Elevess used a pBCDI crosslinker (citing EX1216).
Reply 33:3-4, 7-9, 14-17	Improper incorporation by reference of EX1105 ¶¶ 52-59, 68-69, 74-75, 80-81; 71-75, 76-83, 84, 88-89.
Reply 35:2-18; EX1105 ¶¶ 78-79	Altering obviousness grounds by arguing Sadozai's "controlled release" of lidocaine inherently meets the "freely released" claim limitation.

Citation	Explanation and Identification of Improper Evidence
Reply 35:12-14, 35:19-36:2	Improper incorporation by reference of EX1105 ¶¶ 37, 76-83.
Reply 37:1-7; EX1105 ¶ 44	Altering obviousness grounds with new evidence (EX1210) ("[P]rior art show[s] methods of including free (uncrosslinked) HA were well-known.")
Reply 37:8-19; EX1105 ¶ 94	Arguing for a new theory of obviousness, that the claimed degree of crosslinking is a result-effective variable.
Reply 38:9–40:8; EX1105 ¶¶ 107-10	Altering motivation to combine Kinney and Zhao with new evidence/argument on BDDE/DEO interchangeability, citing previously unidentified part of Zhao (Tables 1-3), new EX1112, and teaching of different crosslinker *in the challenged patents*.
Reply 39:16-18	Improper incorporation by reference of EX1105 ¶¶ 98-100.
Reply 40:2-3	Improper incorporation by reference of EX1105 ¶¶ 108-10.
Reply 41 n.17	Improper incorporation by reference of EX1105 ¶¶ 114-16.
EX1105 ¶¶ 36-37	Providing new claim construction for "freely released."
EX1105 ¶¶ 75, 179	Altering motivation to combine Kinney and Zhao, citing new EX1114 and EX1115 to claim that lidocaine stabilized HA.
EX1105 ¶ 96	Altering motivation to combine Kinney and Zhao, alleging POSA would have known of authors' professional connections.
EX1105 (paragraphs listed below) ¶¶ 28, 38-39, 70, 72-75, 97-113, 117-18, 122, 138-163, 178-79	Adding new testimony and evidence to fill gaps in Dr. DeVore's conclusory statements, "sandbag[ging] . . . by raising new matter in reply." (*Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, No. IPR2014-00309, Paper 83 at 13 (PTAB, Mar. 23, 2014) (citation omitted)) (illustrative examples of Dr. DeVore's testimony (EX1002) listed below): Citing new EX1083, EX1093, EX1102, EX1103, EX1114, EX1115, EX1210, and EX1216 and opining on motivation to "add 0.3% (w/w) lidocaine to the BDDE-crosslinked fillers," as BDDE, DEO, BCDI, and DVS are allegedly similar, BDDE-crosslinked HA had been approved, and lidocaine was used in other crosslinked HA fillers—*cf.* EX1002, ¶¶ 139-40 (0.3% lidocaine would be used as it was used in other products), ¶ 189 (BDDE and DEO have "high degree of similarity"); ¶ 188 (would choose BDDE as it was already approved); ¶¶ 153, 189 (BDDE similar to BCDI and DVS), ¶ 180 ("double crosslinking with either DEO or BDDE would be very similar");

Citation	Explanation and Identification of Improper Evidence
¶¶ 44, 153-56	Opining on new EX1210 allegedly disclosing the claimed amounts of free HA, *cf.* EX1002, ¶¶ 155–56 (POSA would have determined amount of free HA by routine optimization);
¶¶ 58-61, 64-69, 78-90	Citing new (and unsubmitted) "Karp" reference and EX1016 for the first time and arguing POSA would not have expected interactions between lidocaine and HA, *cf.* EX1002, ¶ 147 (same without citation), ¶ 169 (POSA would have expected lidocaine and BDDE-crosslinked HA to have shelf-life "comparable to other BDDE-crosslinked fillers");
¶¶ 64-69, 76-90	Citing Sadozai, and EX1041 and EX1053 for the first time, and arguing lidocaine freely releases from crosslinked HA without further steps—*cf.* EX1002, ¶ 143 ("[L]idocaine incorporated into a gel (whether crosslinked with BDDE or BDCI) would freely release . . . ."); ¶ 180 (POSA would not have expected BDDE to inhibit lidocaine free release);
¶¶ 75, 138-52, 157-163, 166-68	Citing new EX1083, EX1093, EX1107 and EX1114, EX1210, EX1216, and EX1041 and EX1048 for the first time, and alleging "autoclaving was used to sterilize virtually all types of HA compositions prior to 2008," and "BDDE-crosslinked HA was autoclave sterilized"—*cf.* EX1002, ¶ 97 (unsupported assertion that autoclaving was "[b]y far the most common method for sterilizing dermal fillers"), ¶ 169 ("no reason to expect BDDE-crosslinked HA would be more susceptible to degradation" than others);
¶ 94	Opining on Lebreton for the claimed degree of crosslinking—*cf.* EX1002, ¶ 165 (POSA could have and would have prepared a filler "having any of the [claimed] degrees of crosslinking").
EX1105 ¶¶ 42-45, 62-63, 70, 120-180	Incorporating dozens of pages from Dr. Prestwich's *Galderma* and *Teoxane* declarations attacking two of the same patents challenged here ('795 and '475 patents)—particularly egregious as Dr. Prestwich's declarations from those unsuccessful IPR petitions were known to Petitioner prior to Petitioner's original filings.
EXHIBITS: 1103, 1107, 1114, 1115, 1210	New exhibits cited in Reply, even though previously cited in the *Teoxane* or *Galderma* IPRs and thus known to Petitioner when it filed the Petitions. (Nov. 2019 TPG at 80 (Board may strike "belatedly presented evidence")).

Respectfully submitted,

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