Filed: December 4, 2020

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

PETITIONER'S RESPONSE TO PATENT OWNER'S IDENTIFICATION OF ALLEGED NEW IMPROPER 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 consolidated caption.

Petitioner responds to Patent Owner Allergan's table of identified arguments and evidence as follows. Like Allergan's submission, all citations refer to papers and exhibits filed in IPR2019-01617. Allergan also cites alleged improper incorporation by reference, which was not raised in its request for authorization or authorized by the Board. *See* EX3003, 2 (citing only Rule § 42.23(b) as basis of relief). In any case, Prollenium contends its citations are proper (and in accord with Allergan's similar citations, *e.g.*, Patent Owner Response (POR) 6 (citing EX2013 Sections IV.C-F), 8 (citing EX2013 ¶¶ 64-78), 41 (citing EX2013 ¶¶ 229-41)).

Citation	**Responsive To Citation and/or Explanation**
Reply and EX1105 in their entirety	Both respond to Allergan's Response as supported by Berkland declaration. The Board denied Allergan's request to move to strike the Reply and EX1105 in their entirety, EX3003, and doing so is an "exceptional remedy." Nov. 2019 Trial Practice Guide, 80.
Reply 25:7–28:4; EX1105 ¶¶ 73, 163	*Cf.* POR 38-46 (arguing, *inter alia*, lidocaine had not been incorporated into crosslinked HA before; crosslinkers and processes are not interchangeable; that Petitioner "provides no rationale" for why "POSA would have ignored numerous pain-management techniques;" that Sadozai discourages use of BDDE, and "fundamental differences" between the references make them "incompatible"); EX2013 ¶¶ 218-236. *See also* Pet. 28-30, 39-40 (arguing obviousness of "adding lidocaine to Lebreton" and "the prior art suggests" that "simply adding lidocaine to a BDDE-crosslinked filler with pH control" is only thing "necessary to obtain the claimed fillers").
Reply 30:1-31:6; EX1105 ¶¶ 52-56	*Cf.* POR 14-15 (arguing lidocaine raises concerns with rheology not remedied by neutralization); EX2013 ¶¶ 84, 109-10, 180, 190, 234, 237-40, 264
Reply 19:3-10, 26 n.9, 32:8-9	The inventor's emails reflect his knowledge and access to *publicly available* information and belie Allergan's arguments (1) about the POSA's purported lack of knowledge of competitive product

Citation	Responsive To Citation and/or Explanation
	information, POR 17-18, 36, (2) that Dr. Lebreton's "concerns had merit," *id.* at 34-35, and (3) that Petitioner's positions rely on hindsight or a "fiction" of products including lidocaine, *id.* at 41-43; see also EX2013 ¶¶ 28-30; EX1200 112:14-119:2.
Reply 31:7-20; EX1105 ¶¶ 39, 63, 159	*Cf.* POR 41 (arguing "Petitioner has not established" POSA knew crosslinker identities and arguing Petitioner relied only on DeVore's "personal knowledge"). *See also* EX1002 ¶¶ 115-16, 152 (opinion testimony about what POSA would have known about crosslinkers); EX2100, 26:11-22 (DeVore testifying his "assessment of the art" was from the POSA's perspective); EX1035 (document submitted with Petition expressly describing DVS crosslinker in Prevelle).
Reply 35:2-18; EX1105 ¶¶ 78-79	*Cf.* POR 16, 48-52, 64; EX2013 ¶¶ 19, 211, 243-45. Argument does not *alter* the ground but merely elaborates why lidocaine is freely released in Sadozai and in the Ground. Pet. 31-32. *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 706 (Fed. Cir. 2020); *Chamberlain Grp., Inc. v. One World Techs., Inc.*, 944 F.3d 919, 925 (Fed. Cir. 2019) ("Parties are not barred from elaborating on their arguments on issues previously raised."); *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1381 (Fed. Cir. 2018).
Reply 37:1-7; EX1105 ¶ 44	The argument and evidence show methods of adding free HA were "well known," rebutting Allergan's contention that Monheit gives no "guidance" as to amount or method of incorporating free HA or its effect on a so-called "monophasic" gel. *Cf.* POR 22, 58-59; EX2013 ¶¶ 260-61 (adding free HA was unpredictable).
Reply 37:8-19; EX1105 ¶ 94	*Cf.* POR 53-54; EX2013 ¶¶ 269-272. Not new; Petition and cited evidence argued obviousness of overlapping ranges and no criticality or unexpected results. Pet. 22, 35-36, 46-47 & n.11.
Reply 38:9–40:8; EX1105 ¶¶ 107-10	*Cf.* POR 60-63; EX2013 ¶¶ 279-280). Also, Allergan alleges Prollenium provides "new evidence/argument on BDDE/DEO interchangeability." But this is the theory originally relied upon (Pet. 40-42); Reply elaborates based on Allergan's arguments.
EX1105 ¶¶ 36-37	*Cf.* EX2013 ¶¶ 208-12; EX1002 ¶¶ 134-137. Prestwich's testimony responds to Berkland and harmonizes the experts' views.
EX1105 ¶¶ 75, 179	*Cf.* EX2013 ¶¶ 250-52. Prestwich's testimony is about expectation of success, not motivation, and responds to Berkland's opinions that lidocaine would degrade HA gels.

Citation	Responsive To Citation and/or Explanation
EX1105 ¶ 96	*Cf.* EX2013 ¶¶ 277 (pointing to Kinney's "limited" disclosure and lack of process information); 279 (suggesting lack of interest in a double crosslinked filler). *See also* EX2200, 421:16-24.
EX1105 ¶¶ 28, 38-39, 70, 72-75, 97-113, 117-18, 122, 138-163, 178-79	These paragraphs are plainly responsive to arguments Allergan and Berkland raised about lack of motivation and expectation of success, *e.g.*, different pain relief methods, differences between the chemistry of the compositions and processes in respective Grounds, and often *expressly* cite responded-to material. Citations in the "Detailed Discussion" section (¶ 122 onward) merely provide "complete context" (EX1105 ¶¶ 120, 32) and background foundation for the specific testimony and opinions expressed above. *See also* EX2200, 466:22-477:6, 220:10-221:7.
EX1105 ¶¶ 44, 153-56	Allergan raised ¶ 44 in connection with Reply 37:1-7 (see above in this table). EX1210 is relied on as evidence of the "conventional" step of adding free HA to fillers and not as "disclosing the claimed amounts" of free HA as Allergan's Paper suggests (though it does, as Allergan concedes).
EX1105 ¶¶ 58-61, 64-69, 78-90	*Cf.* POR 14-15, 40, 48-52; EX2013 ¶¶ 85-87, 125, 237, 243-47. Allergan and Berkland argued "significant non-covalent interactions" between lidocaine and the HA polymer suggest lidocaine would not freely release.
EX1105 ¶¶ 64-69, 76-90	*Cf.* POR Section VII.E.1; EX2013 ¶¶ 87, 243-46, 288.
EX1105 ¶¶ 75, 138-52, 157-163, 166-68	*Cf.* EX2013 ¶¶ 250-52, 67-72, 192-94, 195-97, 105-112. The citations here span multiple topics, but generally cite to the "background" section of Prestwich's testimony, which provides foundation for his more substantive opinions actually cited in Reply. As to the sterilization topic specifically noted by Allergan, this testimony responds to Berkland suggesting autoclaving led to "unpredictable effects." EX2013 ¶¶ 93-95, 250-52, 293-96.
EX1105 ¶¶ 94	*Cf.* EX2013 ¶¶ 270-72 (suggesting no expectation of "specific" crosslinking degrees). *See also* Pet. 35 (citing specific crosslinking degrees, including the specific examples in Lebreton).
EXHIBITS: 1103, 1107, 1114, 1115, 1210	Each exhibit is cited in response to some argument or evidence presented in the POR, and Allergan has no prejudice because (1) by its admission, it made those arguments knowing of their existence, and (2) it can address in its sur-reply.

Respectfully submitted,

/Warren Thomas/
Warren J. Thomas (Reg. No. 70,581)

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