

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 REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE¹

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, consolidated Reply to the Motion to Exclude has been filed in each case recited in the consolidated caption, as authorized by the Board via e-mail on December 8, 2020.

IPR2019-01505, IPR2019-01506, IPR2019-01508, IPR2019-01509,
IPR2019-01617, IPR2019-01632, IPR2020-00084

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TABLE OF ABBREVIATIONS

Abbreviation	Term
BDDE	butanediol diglycidyl ether
HA	hyaluronic acid
POSITA	Person of Ordinary Skill in the Art
Response	Patent Owner Response, IPR2019-01617, Paper 40 (cited as exemplary of citations for the remaining proceedings)
Pet. MTE	Petitioner's Motion to Exclude, IPR2019-01617, Paper 54 (cited as exemplary of citations for the remaining proceedings)
PO Opp. MTE	Patent Owner's Opposition to Petitioner's Motion to Exclude, IPR2019-01617, Paper 57 (cited as exemplary of citations for the remaining proceedings)

Prollenium US Inc. (“Prollenium”) respectfully replies to its Motion to Exclude (MTE) certain information under the Federal Rules of Evidence (FRE).

I. EXHIBITS 2059 AND 2060 (THE MICHEELS ARTICLES)

The parties agree post-filing documents can be used as evidence of the state of the art at the relevant time. But those documents must relate to or show the knowledge or skill of the POSITA at the time; they cannot be used to contradict the POSITA’s knowledge at the relevant time. *See* PO Opp. MTE 4 (agreeing). The only way Allergan can paint its post-dated exhibits as representing the “state of the art” is by misconstruing what the documents actually say.

The two “Micheels” papers (EX2059, EX2060), published 8-10 years post-filing, do **not** show “unpredictability” in formulating HA fillers or “that creating crosslinked HA fillers was an *uncertain endeavor*” as Allergan argues. PO Opp. MTE 4. Rather, they show “[a]t least 7 *different types of crosslinking technology are used* in the production of current HA gels,” all of which are available with lidocaine introduced during manufacturing. EX2059, 601.

While Micheels 2016 contains one sentence speculating that added lidocaine “*may modify*” rheological properties, the authors explained that “differences in the behavior” of the tested gels came from the “different crosslinking technologies” used. EX2059, 604, 606. Indeed, Micheels noted that a **2008** test found that “cohesivity ... results were the same for all gels, *whether or not* they contained

added lidocaine.” EX2059, 604.² Micheels 2018 likewise found *some* rheological differences when comparing gels with and without lidocaine, but the differences were “to a variable extent.” EX2060, Abstract, 954. Specifically, both Restylane and Juvéderm gels were found to have “similar viscoelastic characteristics” between the tested versions. *Id.*

The Micheels articles thus show a variety of crosslinking technologies were successfully used in BDDE-crosslinked gels with lidocaine, and even where there are *some* rheological differences from their non-lidocaine iterations, the overall characteristics for Restylane and Juvéderm were “similar,” “comparable,” or “equivalent.” These articles *do not comment on*, and are thus irrelevant to, the POSITA’s expectations for *making* a gel with lidocaine as of the priority date.

II. EXHIBITS 2083 AND 2084 (THE VIVACY REPORTS)

Allergan asserts that the Vivacy Reports are offered to show “skepticism that a lidocaine-HA-gel could be heat-sterilized without degradation” and the fact that testing was performed at all shows “scientists were ‘concerned’ about lidocaine degradation and ‘in disbelief’ of Molliard’s alleged discovery.” PO Opp. MTE 6.

First, Allergan cannot sidestep the hearsay problems by arguing a non-

² Micheels 2016 also reports the CPM gel “remains perfectly cohesive with or without ... lidocaine.” *Id.*

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