

AQUESTIVE THERAPEUTICS, INC.,

Petitioner,

v.

NEURELIS, INC.,

Patent Owner.

Case IPR2019-00451 Patent 9,763,876

PATENT OWNER'S SURREPLY



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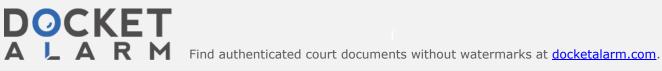
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CASES Dynamic Drinkware v. National Graphics, 800 F.3d 1375 (Fed. Cir. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002)12 Ex parte Maziere, 27 USPQ 1705 (BPAI 1993).....8 *In re Voss*, 557 F.2d 812 (CCPA 1977)......7 *In re Wertheim*, 541 F.2d 257 (CCPA 1976).....11 Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359 Koninklijke Philips N.V. v. Google LLC, 948 F.3d 1330 (Fed. Cir. 2020)......7 Motor Vehicle Mfrs. Ass'n v. State Farm, 463 U.S. 29 (1983)8 Purdue Pharma v. Faulding Inc., 230 F.3d 1320 (Fed. Cir. 2000)......11 SAS Inst. Inc. v. Iancu, 138 S.Ct. 1348 (2018)8 Sirona Dental v. Institut Straumann, 892 F.3d 1349 (Fed. Cir. 2018)......26 Sony Corp. v. Collabo Innovations, Inc., IPR2017-00938, Paper 23 (PTAB 2017)......23



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I. INTRODUCTION

Aquestive's new theories in its Reply underscore its Petition's deficiencies. As an initial matter, Aquestive's new theories fail to undo the damaging testimony from its Petition expert, Dr. Peppas, despite a 125-page declaration from a brandnew expert, Dr. Wermeling (which, remarkably, expressly ignores the original Petition). The Reply materials consistently disregard and misstate the evidence—including Dr. Wermeling's clear recognition of a "significant unmet medical need to serve the pharmacotherapeutic requirements of epilepsy patients through commercial development and marketing of intranasal antiepileptic products" in 2009. EX1151, 352; EX2031, 127:4-130:3. Aquestive's wholesale replacement of its initial theories cannot rescue the failed Petition, and fundamentally prejudices Neurelis because Neurelis cannot at this stage file its own rebuttal evidence.

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Because Aquestive cannot prevail without new theories and new evidence,

court. Neurelis, Inc. v. Aquestive Therapeutics, Inc., No. 37-2019-00064665

(Super. Ct. Cal., San Diego).



¹ Aquestive's Reply shenanigans are part of an ongoing harassment campaign against Neurelis—here, at the FDA, and in the press—to distract investors from Aquestive's failure to produce its buccal epilepsy therapy and has forced Neurelis to pursue a tort action against Aquestive in California superior

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