Paper No. ___
Filed: April 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

ARBUTUS BIOPHARMA CORPORATION,
Patent Owner.

Case IPR2019-00554
Patent No. 8,058,069

PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE PURSUANT TO 37. C.F.R. § 42.64(c)

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

I. STATEMENT OF PRECISE RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c) and the Federal Rules of Evidence, Patent Owner respectfully moves to exclude exhibit 1020, as well as portions of exhibit 2033, pursuant to 37 C.F.R. § 42.64(c).

Patent Owner timely objected to exhibits 1020 and 2033 and reliance thereon. Paper 22, EX2033.

II. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Exhibit 1020 should be excluded

Exhibit 1020 is the declaration of Petitioner's proffered new expert, Dr. Anchordoquy, and it should be excluded in its entirety under at least F.R.E. 401, 402 (Irrelevant Evidence Inadmissible), 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons), F.R.E. 702, 703 (Expert Foundation and Opinions).

First, Dr. Anchordoquy is a zoologist, not a lipid chemist with formal training in the subject matter at hand. EX1020, ¶9. As such, Dr. Anchordoquy fails to qualify as a person of ordinary skill as defined by Petitioner and the Board. That is, Petitioner and Dr. Anchordoquy define the ordinary artisan as someone who "would have specific experience with lipid particle formation ***and use in the context of delivering therapeutic nucleic acid payloads***." EX1020, ¶25; *see also*

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Decision on Institution, 11-12 (discussing the level of ordinary skill in the art). Dr. Anchordoquy lacks the qualifications necessary to meet this minimal threshold.

Dr. Anchordoquy, as support for his expertise in the field, specifically discusses his first issued patent, U.S. Patent No. 7,914,714, which he asserts "described a process by which lipid bilayers could be formed around a solution of nucleic acids, effectively surrounding the nucleic acids to achieve complete encapsulation within a lipid vesicle." EX1020, ¶14. That patent, however, claims a "method for making an encapsulated droplet … of an agent to be encapsulated…through electrostatic atomization…." This technology is neither the same nor similar to the technology at issue. Indeed, it does not seem that Dr. Anchordoquy has any relevant patents or patent applications at all. Petitioner does not demonstrate that Dr. Anchordoquy has any significant expertise in the technology at issue through his publications or academic studies.

Clearly concerned by this new witness' thin resume, Petitioner staged an unprompted and rehearsed questioning on redirect during Dr. Anchordoquy's recent deposition. EX2043, 77:4-79:25. But that testimony is hardly reassuring. Dr. Anchordoquy attempted to spin his zoology training as broadly encompassing "everything related to animals." *Id.*, 77:22-23. He testified that while his graduate school offered a program in biophysics and the zoology department offered an emphasis in biophysics, he was not in either program. *Id.*, 78:6-14. He testified he

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

was aware of other individuals ("we had a guy down the hall who did muscle contraction") and lab equipment ("we had a calorimeter, a differential scanning calorimeter. Oh boy.") fitting under the broad umbrella of "biophysics," but unrelated to the technology at hand in this proceeding. *Id.*, 78:13-21; 79:10-11. His prepared remarks during redirect may shed further light on his lack of qualifications but offer no reassurance that his declaration testimony is relevant or otherwise admissible in this proceeding.

Accordingly, Dr. Anchordoquy does not have the requisite experience with delivering therapeutic nucleic acids as required by Petitioner's definition of the ordinary artisan and as adopted by Dr. Anchordoquy. His testimony should be excluded at least on this basis.

Second, even if the Board does not exclude the testimony of Dr. Anchordoquy on the basis that he lacks the requisite qualifications to serve as an expert in this case, his declaration is irrelevant for the purposes proffered by Petitioner. Dr. Anchordoquy's declaration is used as a means to belatedly introduce argument that should have been presented with the petition, but was not.

As is appreciated by the Board, bare notice pleading tactics—where critical evidence is missing from the petition materials and belatedly sought entry for the first time in Reply—is strictly prohibited in *inter partes* review proceedings. Consolidated Trial Practice Guide, 73 ("Petitioner may not submit new evidence in

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability."); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) ("Unlike district court litigation — where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material — the expedited nature of IPRs bring with it an obligation for petitioners to make their case ***in their petition*** to institute.") (emphasis added); 35 U.S.C. §312(a)(3) (requiring particularity in the petition materials).

Belated entry of evidence critically required of the petition materials is precisely what Petitioner now attempts at the reply stage of the proceeding. The petition cited caselaw and a legal theory which required a showing of routine optimization, but the petition materials critically lacked evidence to support such an obviousness charge. The Patent Owner Response (*e.g.*, POR, 11-24) explains in detail the disconnect between the invoked legal theory and the utter lack of evidence or argument in the petition to support this theory.

In fact, up until the Reply, Petitioner and its expert, Dr. Janoff, agreed on the inapplicability of routine optimization. The petition materials embraced the complexity of the technology and argued wild unpredictability. During cross-examination, Petitioner's expert witness repeatedly testified the prior art lipid ranges are "immense" and "would require undue experimentation, not simple

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | sales@docketalarm.com | 1-866-77-FASTCASE

fastcase®
Smarter legal research.