UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GENOME & COMPANY,
Petitioner,

v.

THE UNIVERSITY OF CHICAGO,
Patent Owner.

_____

PGR2019-00002
Patent 9,855,302 B2

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**PATENT OWNER'S REPLY IN SUPPORT OF
MOTION TO EXCLUDE EVIDENCE
UNDER 37 C.F.R. § 42.64(c)**

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I.   INTRODUCTION

Patent Owner maintains all motions to exclude and comments further on only selected motions.

II.   ARGUMENT

A.   Exhibits 1002 and 1043 (Declarations of Dr. Braun): exclusion of selected paragraphs as party-supplied hearsay

Patent Owner's suggestion that Dr. Braun's testimony is largely Petitioner's transmitted hearsay is not "reckless" (Opp. 2), because it is based on the undeniable near-identity of large swaths of Dr. Braun's declaration to Petitioner's Petition and Reply, as well as on Dr. Braun's freely-given testimony that Petitioner's counsel prepared the first draft. This evidence indicates that Petitioner's counsel prepared Dr. Braun's declarations for him. It refutes the alternative that Dr. Braun arrived at his testimony through the "independent investigation or analysis" required of him, an issue Patent Owner discussed extensively in its motion but which Petitioner ignores in its opposition.

B.   Exhibit 1017 (O'Mahony): exclusion of patent application data offered for the truth

Petitioner's assertion that it offered O'Mahony's data merely as evidence of what how one of ordinary skill would have understood it (Opp. 6) mischaracterizes the Petition. Petitioner relied on O'Mahony at pages 31 and

44, both times stating that O'Mahony "showed" certain facts to be true,

namely, that certain bacterial strains possess particular properties:

> O'Mahony ***showed*** that *Bifidobacterium longum* subspecies
> infantis strain UCC356624 was immunostimulatory whereas
> *Bifidobacterium longum* strain 1714 was immnosuppressive
> or anti-inflammatory. *Bifidobacterium longum* strain
> UCC356624 had "quite a different pattern" for
> immunostimulatory cytokines IL-12, IFNγ and IL-6 than
> *Bifidobacterium longum* strain 1714. Consistent with those
> results, O'Mahony states that "the in vivo protection observed
> was strain specific". *See* Ex. 1017 at [0103-0109], [0108].

Pet. 31; and

> Additional research ***showed*** while a strains had anti-tumor
> activity and immunostimulatory (s*ee* Ex. 1005, 1007), other
> strains were anti-inflammatory (Ex. 1017).

Id. at 44.

Whether O'Mahony's data is true of the facts Petitioner ascribes to it

depends utterly on whether and how O'Mahony's experiments were carried

out. It therefore requires the testimony of a person having first-hand

knowledge of how the data was generated. *See* 37 CFR § 42.61(c). Thus the

manner in which Petitioner relies on O'Mahony's data— that it "showed" the

truth of supposed scientific facts— triggers the requirement for a supporting declaration. Petitioner has not provided the declaration, so O'Mahony should be excluded.

C.   Exhibits 1023, 1028, 1032, 1033, 1041, 1044, 1057, and 2005: exclusion for failure to show prior publication

Petitioner does not dispute that it has failed to show that any of these exhibits was published before the June 1, 2015 priority date. Petitioner instead relies on *Yeda Research* as blanket authority to rely on post-dated publications as evidence of the state of the art. But *Yeda Research* was a narrow decision on distinguishable facts.

In *Yeda Research*, the challenged patent claimed a dosing regimen. *Yeda Research v. Mylan Pharm. Inc.*, 906 F.3d 1031, 1035–36 (Fed. Cir. 2018).   A post-dated reference ("Khan 2009") was deemed admissible because it reported on a dosing regimen study that was designed before the challenged patent's filing date.   *Id.* at 1037. The Court ruled that the dosing regimens the authors designed for the Khan 2009 study were direct evidence of how the POSITA thought about dosing regimens at that time. *Id.* at 1041.

Here, Petitioner instead argues that it is reasonable to infer that the POSITA's state of mind as portrayed in the challenged references reflects the

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