Paper No. _ Filed: April 2, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILLUMINA, INC., Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK Patent Owner.

> IPR2018-00291 (Patent 9,718,852) IPR2018-00318 (Patent 9,719,139) IPR2018-00322 (Patent 9,708,358) IPR2018-00385 (Patent 9,725,480) IPR2018-00797 (Patent 9,868,985)¹

PATENT OWNER'S REPLY TO PETITIONER'S SUPPLEMENTAL BRIEF

¹ An identical Paper is being entered into each listed proceeding. Citations to papers and exhibits are from IPR2018-00291 except where indicated otherwise.

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Cases

Columbia submits this reply in response to Illumina's brief (Paper 63).

Questions 1 & 2: Collateral Estoppel Is Inapplicable

The PTO's position is that collateral estoppel cannot apply in IPRs, and the cases that Illumina cites when arguing otherwise fail to address that position. Patent Owner ("PO") Br., 7-9. Even if collateral estoppel could apply, it does not apply here. In making its "[t]rivial variations" argument, Illumina *ignores the negative limitations* (*i.e.*, not ketone, methoxy or ester), which make the present claims materially different from prior claims and raise new patentability questions. PO Br., 2-7; Petitioner ("Pet.") Br. 4-5. Indeed, Illumina's challenges here rely on entirely new arguments and issues, *e.g.*, the -CH₂-CH=CH₂ group ("allyl").

Question 3: Rule 42.73(d)(3) Is Inapplicable

Facing the weakness of its collateral estoppel position, Illumina reargues the applicability of § 42.73(d)(3). The Board previously rejected Illumina's same arguments and questioned if the rule applies to IPRs—it does not. Institution Dec., 35-36; *Gen. Elec. Co. v. United Techs. Corp.*, IPR2017-00428, Paper 38 at 8-9 (June 22, 2018) ("42.73(d)(3)(i) does not apply" to IPRs because "Patent Owner is not 'obtaining' claims ... as set forth in the rule."). Indeed, the statute only authorizes cancellation of claims in an IPR based on §§ 102/103. 35 U.S.C. § 311.

Illumina asserts that the Examiner found the present claims patentably indistinct from *canceled* claims. Pet. Br., 2. That is wrong. The double patenting

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rejection referenced a combined 17 claims, *15* of which remain valid. Response, 65. And, the Examiner allowed the claims after full disclosure of the prior proceedings. Ex. 2005, 123, 131, 139; *Freshpoint Qual. Assur. Ltd. v. JP Labs.*, IPR2017-00538,

Paper 11 at 3 (Nov. 3, 2017) (leaving the question of § 42.73(d)(3) to the Examiner).

Indeed, Illumina could not, and did not, prove a lack of patentable distinction. *Gen. Elec.*, Paper 38 at 8; 35 U.S.C. § 316(e) (petitioner's burden to prove unpatentability); MPEP 2144.08 (sub-genus analysis requires full consideration of the Graham factors, *e.g.*, differences between genus and sub-genus and the prior art's scope and content). Because Illumina relied only on the allyl to address the negative limitations, any question of patentable distinction turns on whether a POSA would have been motivated to use the allyl for SBS, an issue not previously adjudicated.

Question 4: The Present Claims Raise New Issues And Patentability Questions

Illumina asserts that "Columbia used <u>underlining</u> to identify" new features but failed to "argue that any of its 'narrowed' claim elements convey patentability." Pet. Br., 4, 6. That is wrong. During prosecution, Columbia overcame a § 103 rejection based on Tsien by establishing that it was "the inventors' insight and conception that [the capping group] must not be either a methoxy group or an ester group," and that Tsien taught using "such groups." Ex. 1068, 114-115, 112-113, 109; Ex. 1038, 4-5. Thus, Illumina is wrong that "[d]uring prosecution, Columbia's sole argument for nonobviousness was that it invented a nucleotide with a 'small' 3'-O-group." Pet. Br., 3. Illumina's position is also inconsistent with its concession that the negative limitations "*are carve-outs that Columbia added to avoid prior art*." Pet., 41 (emphases added throughout). And, Illumina's cases are inapposite, because in them the new claim elements were not "in any way important." Pet. Br., 9 (citing *Bourns*).

Columbia also repeatedly explained the importance of the negative limitations during the present proceedings. Sur-reply, 3-4; Ex. 2141, slides 4-6; Paper 62, 33:21-35:1, 75:12-20; Prelim. Response, 1, 5-8, 11-12, 16, 19, 22, 39, 49; Response, 51, 64; PO Br., 2-4. Those limitations, with others, compelled Illumina to rely solely on the allyl as an allegedly-obvious choice, entirely changing the patentability questions and raising new issues regarding the disclosure of, motivation to select, and expectation of success using the allyl. PO Br., 2-5.

Illumina also wrongly asserts "estoppel attaches to the issues of smallness." Pet. Br., 7. Previously, in deciding an *anticipation* challenge, the Board found that Tsien *discloses* small capping groups. Ex. 1005, 11. That is irrelevant to the issue here that the prior art failed to appreciate "the *criticality* of using small capping groups." Sur-reply, 3. Tsien discloses both small *and* large capping groups, *i.e.*, it does not teach that the group *must* be small. Ex. 1013, 21. While one prior claim with the small limitation ('575 patent claim 6) was challenged for obviousness, the Board did not mention "small" in its analysis of claim 6, let alone find a motivation to select such a group. Ex. 1007, 17-18 (addressing only use of deazapurines in

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Tsien's methods); *Voter Verified, Inc. v. Election Sys. & Software*, 887 F.3d 1376, 1382-83 (Fed. Cir. 2018) (no estoppel where prior court did not evaluate and decide an issue). Also, the file wrapper here includes explicit evidence of small's meaning (<3.7Å) not in the prior record. Response, 9-10; *In re Herr*, 377 F.2d 610, 610-611 (CCPA 1967) (no estoppel where file wrapper of new and old claims differed).

Question 5: No Allyl Issues Were Previously Decided

Illumina offers generalities regarding *any* capping group and, for the allyl, attempts to manufacture prior findings where none exist. It claims that the allyl was mentioned once in a deposition (which is wrong, only "allyl ethers" were mentioned, Ex. 1098, 112:8-24), and once in Illumina's briefs, where Illumina said the allyl met the limitation of not interfering with polymerase recognition. But collateral estoppel applies to issues previously *decided* by the fact-finder and *essential* to the judgment; not to something merely mentioned in the record. PO Br., 2. Regardless, Columbia never disputed that the allyl does not interfere with certain polymerases, but a POSA had no such expectation prior to the Columbia invention (Response, 50-51), and the prior Board never found otherwise. Illumina has not, and cannot, identify any issue regarding the allyl that was previously decided, let alone essential to the judgment.

Illumina wrongly claims that the prior Board's denial of a motion to amend decided the obviousness of 3'-O-allyl nucleotides. As an initial matter, estoppel does not arise from that motion because the burden of proof was on Columbia, whereas it

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is on Illumina here. Freeman United Coal Min. Co. v. Office of Workers' Comp., 20 F.3d 289, 294 (7th Cir. 1994) (citing Restatement (Second) of Judgments § 28(4)) ("estoppel should not apply where the party against whom preclusion is sought faced a heavier burden ... in the first action"). Regardless, the motion did not relate to the allyl beyond updating the dependency of an unchallenged claim reciting that group. PO Br., 14-15. Contrary to Illumina's exaggerations, no findings were made on the allyl, let alone on efficient incorporation or SBS-compatible cleavability of the allyl. Id.; Mayer/Berkshire Corp. v. Berkshire Fashions, Inc., 424 F.3d 1229, 1234 (Fed. Cir. 2005) ("if ... anything is left to conjecture as to what was necessarily involved and decided, there is no estoppel"). In fact, Illumina argued the prior proposed claims "do not require incorporation by a polymerase." Ex. 1128, 2-3. The motion was denied for reasons that are irrelevant here, *i.e.*, another claim's amended requirement for cleavage by non-light means did not confer patentability. Ex. 1005, 46-47.

Illumina simply fails to address Question 5(b), *i.e.*, whether the prior Board decided there was an expectation that a nucleotide *with the properties listed in the question* would be incorporated. It made no such decision. PO Br., 13-14.

Despite the Board not requesting such briefing, Illumina says there is estoppel to "patentability over Dower." Pet. Br., 15. But prior challenges to Dower were based on § 102, not § 103, and the Board never decided whether Dower provides any motivation or expectation of success. Collateral estoppel does not apply.

Respectfully submitted,

Dated: <u>April 2, 2019</u>

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing PATENT

OWNER'S REPLY TO PETITIONER'S SUPPLEMENTAL BRIEF is being

served on April 2, 2019, via email to Counsel for Petitioner at the email addresses

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