

Filed on behalf of: COLUMBIA

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILLUMINA, INC.
Petitioner,
v.
Patent of THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF
NEW YORK
Patent Owner.

Case IPR2012-00007
U.S. Patent 7,790,869

SUBSTITUTE COLUMBIA MOTION TO AMEND UNDER 37 C.F.R. §42.121
(FILING AUTHORIZED TO REPLACE PAPER NO. 66)

Illumina Ex. 1137 Illumina v. Columbia IPR2018-00291, -00318, -00322, -00385, and -00797

SUBSTITUTE COLUMBIA MOTION TO AMEND UNDER 37 C.F.R. §42.121 (FILING AUTHORIZED TO REPLACE PAPER NO. 66)

Pursuant to 37 C.F.R. §42.121 and the Board’s April 18, 2013 Order (Paper 45 at 5, 6), Patent Owner The Trustees of Columbia University in the City of New York (“Columbia”) hereby moves to amend the claims of U.S. Patent No. 7,790,869 (“‘869 Patent”).

35 U.S.C. §316 (d), as amended by the Leahy-Smith America Invents Act (Pub. L. 112-29, 125 Stat. 284 (2011)) (“AIA”), provides to the patent owner a right to amend claims in an inter partes review and states:

(d) AMENDMENT OF THE PATENT.—

(1) IN GENERAL.— During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

(A) Cancel any challenged patent claim.

(B) For each challenged claim, propose a reasonable number of substitute claims.

...

(3) SCOPE OF CLAIMS.— An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

37 C.F.R. §42.121 provides: “[a] motion to amend may be denied where: (i) The amendment does not respond to a ground of unpatentability involved in the trial; or (ii) The amendment seeks to enlarge the scope of the claims of the patent or introduce new subject matter.”

The amended claims proposed in this motion respond to grounds of unpatentability I and III set forth in the Decision on Petition for Inter Partes Review (Paper 38) as modified by the Decision on Request for Rehearing (Paper 54) and do not enlarge the scope of the claims of the '869 Patent or introduce new matter. Further, the filing of this motion was authorized by the Board, which stated: “The amendment, which is to be a listing of substitute claims, is to be filed as either an appendix to the motion or as an exhibit so that it will not count towards the page limits set for the motions to amend.” (Paper 45 at 5). A listing of the claim amendments and proposed substitute claims is attached hereto as Appendix A.

Therefore, this motion should be granted.

I. INTRODUCTION

On September 16, 2012, Illumina filed a petition for *inter partes* review (“IPR”) of Columbia’s ‘869 Patent.

On March 12, 2013 the PTAB authorized a trial on certain of the grounds for challenge asserted by Illumina in its Petition (Paper 38 at 33). Subsequently, on May 10, 2013, the Board modified the grounds for challenge to be tried, replacing

Stemple II with Stemple III (Paper 54 at 18). As a result, an Inter Partes Review is being conducted on the basis of the following grounds:

Challenge I. claims 12, 13, 17, 20-26, 28, 29, 31 and 33 under 35 U.S.C. § 102(b) as anticipated by Tsien, WO 91/06678 (Exhibit 1002) (“Tsien”);

Challenge II. claims 15 and 16 under 35 U.S.C. § 103(a) as obvious in view of Tsien and Prober et al., *Science* 238, 336-341 (Exhibit 1003) (“Prober I”);

Challenge III. claims 12, 13, 17, 20-23, 25, 26, 28, 29, and 31 under 35 U.S.C. § 102(a) as anticipated by Stemple, U.S. Patent No. 7,270,951 (Exhibit 1008) (“Stemple III”);

Challenge IV. claims 15 and 16 under 35 U.S.C. § 103(a) as obvious in view of Stemple III and Anazawa, WO 98/33939 (Exhibit 1011) (“Anazawa”).

II. STATEMENT OF RELIEF REQUESTED

Pursuant to 37 C.F.R. §42.121, Columbia requests that the Board grant this motion; cancel original claims 12-33 and replace these cancelled claims with proposed substitute claims 34-54 listed in attached Appendix A¹.

III. DISCUSSION OF AMENDMENTS MADE TO DERIVE PROPOSED SUBSTITUTE CLAIMS

The proposed amendment replaces original claims 12-33 with substitute claims 34-54. Thus 22 claims are being replaced by 21 claims. At most one substitute claim is being proposed for each cancelled claim as required by the Board. (Paper 45 at 5).

The relationship between the proposed substitute claims and the original claims is as follows:

A. Proposed claim 34

Proposed claim 34 is identical to original claim 15, rewritten in independent form and reciting all of the features of original claim 12. The only difference is

¹ There is no challenge in this Inter Partes Review of Claims 1-11, 14, 18-19, 27, 30 or 32. Therefore, amendments to claims 1-11 are not proposed in this motion. However, since claims 14, 18-19, 27, 30 and 32 depend from challenged claim 12, and claim 12 is proposed to be cancelled, these claims are also proposed to be cancelled and replaced by corresponding proposed substitutes.

that the word “light” has been deleted from two Markush groups as an alternative cleaving means.

B. Proposed substitute claims 35-54

Proposed claims 35-54 are identical to original claims 13-14 and 16-33, respectively, except that they depend directly or indirectly from proposed claim 34 and therefore incorporate the features of original claim 15.

Proposed claim 35 is identical to original claim 13 except that it depends from proposed claim 34 and therefore also incorporates the feature of original claim 15.

Proposed claim 36 is identical to original claim 14 except that it depends from proposed claim 34 and therefore also incorporates the feature of original claim 15.

Proposed claim 37 is identical to original claim 16 except that it depends from proposed claim 34 instead of original claim 15. Since proposed claim 34 amounts to re-writing claim 15 in independent form, proposed claim 37 is identical in substance to original claim 16.

Proposed claims 38-42 are identical to original claims 17-21, respectively, except that they depend from proposed claim 34 and therefore all incorporate the element of original claim 15.

Proposed claims 43-48 are identical to original claims 22-27, respectively, except that they depend either directly or indirectly from proposed claim 42. Since proposed claim 42 is dependent from proposed claim 34, proposed claims 43-48 include the additional feature of original claim 15.

Proposed claims 49 and 52 are identical to original claims 28 and 31, respectively, except that they depend from proposed claim 34 and therefore incorporate the feature of original claim 15.

Proposed claim 50 and 51 are identical to original claims 29 and 30, respectively, except that they depend from proposed claim 44 instead of original claim 23. Proposed claim 44 is dependent from proposed claim 43 which is in turn dependent from claim 42. Proposed claim 42 is identical to original claim 21 except that it is dependent from proposed claim 34. Since proposed claim 34 incorporates the feature of original claim 15, proposed claims 50 and 51 also incorporate the feature of original claim 15.

Proposed claim 53 is identical to original claim 32 except that it depends from proposed claim 52. Proposed claim 52 is identical to original claim 31 except that it depends from claim 34. Since proposed claim 34 incorporates the limitation of original claim 15, proposed claim 53 also incorporates the feature of original claim 15.

Proposed claim 54 is identical to original claim 33 except that it depends from proposed claim 45. Proposed claim 45 depends from proposed claim 44 which in turn depends from proposed claim 43 which in turn depends from proposed claim 42. Proposed claim 42 is identical to original claim 21 except that it depends from claim 34. Since proposed claim 34 incorporates the feature of original claim 15, proposed claim 54 also incorporates the feature of original claim 15.

IV. SUPPORT FOR CLAIMED SUBJECT MATTER

As required by 37 C.F.R. §42.121(b)(1) and (b)(2), support for each amended claim in the original disclosure of the patent and in earlier-filed disclosures “for which benefit of the filing date of the earlier filed disclosure is sought” is as follows:

A. Proposed claim 34

Original claim 15 depends from claim 12 and, incorporated the features of claim 15 into claim 12. New claim 34 therefore is identical in scope to original claim 15. Proposed claim 34 is supported by original claim 12 and 15. In addition, proposed claim 34 finds support in the ‘869 Patent and in earlier applications, benefit of which is claimed, as follows:

- a) U.S. Patent 7,790,869: col. 5 ll. 12-23; col. 7 ll. 44-47; col. 7 ll. 58-66; col. 10 ll. 36-54; col. 10 ll. 57-63; col. 12 ll. 35-46; col. 13 ll. 5-13; col. 14 ll. 1-4; col. 14 ll. 7-11;
- b) U.S. Patent No. 7,345,159: col. 5 ll. 17-28; col. 7 ll. 52-56; col. 7 l. 67 – col. 8 l. 8; col. 10 ll. 49-67; col. 11 ll. 4-10; col. 12 ll. 52-63; col. 13 l. 23 – col. 14 l. 7; col. 14 ll. 9-13; col. 14 ll. 16-21;
- c) U.S. Patent No. 6,664,079: col. 5 ll. 12-23; col. 7 ll. 53-57; col. 8 ll. 1-9; col. 10 ll. 53 – col. 11 l. 4; col. 11 ll. 8-14; col. 12 ll. 55-67; col. 14 ll. 3-11; col. 14 ll. 12-18; col. 14 ll. 19-22;
- d) U.S. Serial No. 09/684,670: p. 10 ll. 14-31; p. 14 ll. 28-32; p. 14 ll. 13-21; p. 25 l. 32 – p. 26 l. 14; p. 26 ll. 19-24;
- e) U.S. Serial No. 60/300,894: p. 10 ll. 14-31; p. 14 ll. 28-32; p. 14 ll. 13-21; p. 25 l. 32 – p. 26 l. 14; p. 26 ll. 19-24.

B. Proposed substitute claims 35-54

Proposed substitute claims 35-54 are identical to the original claims which they are proposed to replace except that these claims have been amended to depend, directly or indirectly, from proposed claim 34 instead of original claim 12. Specifically, proposed claim 34 incorporates the feature of original claim 15, “wherein the base is a deazapurine,” and consequently all claims which depend, directly or indirectly, from claim 34, i.e. proposed claims 35-54, do so as well.

The specification of the '869 Patent expressly states that "[t]he invention provides for the use any of the nucleotide analogues disclosed herein" '869 patent col. 19 ll. 17-18. Thus, support for proposed claims 35-54 may be found in the Summary of Invention and in the passages cited above as support for proposed substitute claim 34.

V. THE PROPOSED SUBSTITUTE CLAIMS ARE PATENTABLY DISTINCT FROM THE PRIOR ART

This amendment responds to two grounds of unpatentability, satisfying the requirement of rule 37 C.F.R. §42.121. Proposed claim 34 now includes all limitations of claim 15. Because grounds I and III did not include claim 15, proposed claim 34, and all the claims which depend from it, are free of grounds I and III.

A. Ground I

1. Proposed claim 34

The Board has twice previously held that Tsien does not disclose the features of original dependent claim 15. (Paper 38 at 11-14 and Paper 54 at 3-6). Since proposed claim 34 is claim 15 rewritten in independent form, it is not anticipated by Tsien.

2. Proposed dependent claims 35-54

Since proposed claim 34 has been shown to be novel over Tsien, proposed claims 35-54 are also novel over Tsien since they depend, either directly or indirectly, from proposed claim 34.

B. Ground II

1. Proposed claim 34

The Board has twice previously held that Stemple II does not disclose the features of claim 15. (Paper 38 at 19-20 and Paper 54 at 6-9). Since the Board also previously ruled that Stemple III is no more complete than Stemple II in describing the subject matter and since proposed claim 34 incorporates the limitations of original claim 15 it is patentably distinct from Stemple III. (Paper 38 at 22).

2. Proposed dependent claims 35-54

Since proposed claim 34 has been shown to be novel over Stemple III, proposed claims 35-54 are also patentable since they depend, either directly or indirectly, from proposed claim 34.

The facts which support that proposed substitute claims 34-54 are patentable are set forth in the Declaration of George L. Trainor, Ph.D. (Exhibit 2033, ¶¶48-140). The argument why those facts render substitute claims 34-54 patentably distinct from the prior art are set forth in the Response filed concurrently. Patent Owner is also not aware of any other prior art of which substitute claims 34-54 are not patentable.

VI. COLUMBIA REQUESTS THAT THE BOARD MAKE A DETERMINATION THAT SUBSTITUTE CLAIM 34 IS SUBSTANTIALLY IDENTICAL TO ORIGINAL CLAIMS 12 AND 15

Proposed claim 34 is substantially identical to original claims 12 and 15. No one's rights could be abridged or affected so there are no intervening rights under 35 U.S.C. §§252 and 328(c).

Upon showing that the scope of the amended patent claims is substantially identical to that of the original patent claims, a patent owner may request that the Board make a determination that the scope of the claims are substantially identical to the original claims, as they would have been interpreted by a district court (see Office Patent Trial Practice Guide II.6.1, claim construction 77 Fed. Reg. 48766 (August 14, 2012)). This precludes the application of any intervening rights.

A. Substitute claim 34 is substantially identical in scope to original claims 12 and 15 because the original claims simply have been rewritten in independent form.

There is little question that substitute claim 34 is substantially identical to original claims 12 and 15. Columbia simply proposes writing claims 12 and 15 in independent form in substitute claim 34. This, by itself, does not change the scope of the claims. The term "identical" in section 252 has been interpreted by the courts to allow for amendment in claim language that is "without substantive change." *Kaufman Co., Inc. v. Lantech, Inc.* 807 F.2d 970,977 (Fed. Cir. 1986).

B. Deleting the word “light” from the Markush groups does not broaden the scope of the claims

One element in proposed claim 34 has been deleted from rewritten original claims 12 and 15, that is, that “light” can be used as one alternative cleaving means specified in two Markush groupings. Deletion of a member of a Markush group is a narrowing amendment so that the patent owner can no longer seek to enforce the patent against that alternative method. *See Merck & Co. Inc. v. Mylan Pharmaceuticals, Inc.* 190 F.3d 1335, 1341 (Fed. Cir. 1999).

The deletion of “light” from the Markush groups does not add scope to the claim. Rather, the claim is limited in what could be an infringement. The present change means that fewer cleaving means than before are encompassed within the claim. This change does not broaden the scope and does not result in any intervening rights.

VII. CONCLUSION

The proposed amendments represent a reasonable number of substitute claims, are fully supported by the specification of the '869 Patent, do not broaden the scope of the '869 Patent, and obviate two grounds on which trial was instituted. Accordingly, the motion should be granted, the proposed substitute claims should be entered, and a finding should be made that intervening rights do not apply to substitute claim 34.

Case IPR2012-00007
U.S. Patent 7,790,869

Respectfully submitted,

Dated: August 30, 2013

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APPENDIX A

PROPOSED CLAIM AMENDMENTS

In accordance with 37 C.F.R. §42.121(b), the following claim listing shows the proposed changes, with markings indicating changes incorporated into each proposed substitute claim relative to the corresponding original claim. Congruent with the Patent Trial and Appeal Board's guidance, the amendments are presented following the example format provided in the Official Trial Practice Guide, Section II.G.

I. CLAIM LISTING

Claim 1 (original): A nucleotide having a base that is attached to a detectable label through a cleavable linker, wherein the nucleotide has a deoxyribose comprising a cleavable chemical group capping the 3' OH group of the deoxyribose and wherein both the cleavable linker and the capping cleavable chemical group are cleavable by light.

Claim 2 (original): The nucleotide of claim 1, wherein the base is a purine or a pyrimidine.

Claim 3 (original): The nucleotide of claim 2, wherein the base is a deazapurine.

Claim 4 (original): The nucleotide of claim 1, wherein the nucleotide is a deoxyribonucleotide triphosphate.

Claim 5 (original): The nucleotide of claim 1, wherein the detectable label is a fluorophore.

Claim 6 (original): A nucleotide having a base that is linked to a detectable label via a cleavable linker, wherein the nucleotide has a deoxyribose sugar moiety comprising a protecting or capping group attached via the 3' oxygen and the cleavable linker and the protecting or capping group are cleavable by light.

Claim 7 (original): The nucleotide of claim 6, wherein the base is a purine or a pyrimidine.

Claim 8 (original): The nucleotide of claim 7, wherein the base is a deazapurine.

Claim 9 (original): The nucleotide of claim 6, that is a deoxyribonucleotide triphosphate.

Claim 10 (original): The molecule of claim 6, wherein the detectable label is a fluorophore.

Claim 11 (original): The molecule of claim 6, wherein the linker is photolabile or photocleavable.

Claims 12 (cancelled)

Claims 13-14 (replaced by proposed substitute Claims 35-36)

Claims 15-16 (replaced by proposed substitute Claims 34-35)

Claim 17-33 (replaced by proposed substitute Claims 38-54)

Claim 34 (proposed substitute for original Claim 15 rewritten in independent form to include features of independent Claim 12 and amended to delete member of Markush group): A nucleotide of claim 12 having a base that is attached to a detectable label through a cleavable linker, wherein the base is a deazapurine, wherein the nucleotide has a deoxyribose comprising a cleavable chemical group capping the 3' OH group, wherein the cleavable linker is cleaved by a means selected from the group consisting of one or more of a physical means, a chemical means, a physical chemical means, and heat, and light and wherein the cleavable chemical group capping the 3' OH group is cleaved by a means selected from the group consisting of one or more of a physical means, a chemical means, a physical chemical means, and heat, and light.

Claim 35 (proposed substitute for Claim 13): The nucleotide of claim [[12]] 34, wherein the cleavable linker is cleaved by chemical means, and wherein the cleavable chemical group capping the 3'OH group is cleaved by chemical means.

Claim 36 (proposed substitute for Claim 14): The nucleotide of claim [[12]] 34, wherein the cleavable linker is cleaved by light, and wherein the cleavable chemical group capping the 3'OH group is cleaved by light.

Claim 37 (proposed substitute for Claim 16): The nucleotide of claim [[15]] 34, wherein said deazapurine is selected from the group consisting of deaza-adenine and deaza-guanine, each comprising a unique label attached through a cleavable linker to a 7-position of deaza-adenine or deaza-guanine.

Claim 38 (proposed substitute for Claim 17): The nucleotide of claim [[12]] 34, wherein the detectable label is a fluorophore.

Claim 39 (proposed substitute for Claim 18): The nucleotide of claim [[12]] 34, wherein said cleavable chemical group comprises $\text{—CH}_2\text{—OCH}_3$

Claim 40 (proposed substitute for Claim 19): The nucleotide of claim [[12]] 34, wherein said cleavable chemical group comprises $\text{—CH}_2\text{CH=CH}_2$.

Claim 41 (proposed substitute for Claim 20): The nucleotide of claim [[12]] 34, wherein said cleavable chemical group has a molecular weight of 300 Daltons or less.

Claim 42 (proposed substitute for Claim 21): The nucleotide of claim [[12]] 34 wherein said nucleotide is an analog of adenosine, guanosine, cytosine, or thymidine.

Claim 43 (proposed substitute for Claim 22): The nucleotide of claim [[21]] 42, wherein said nucleotide analog is incorporated in a primer.

Claim 44 (proposed substitute for Claim 23): The nucleotide of claim [[22]] 43, wherein said primer is in a complex with a nucleic acid template.

Claim 45 (proposed substitute for Claim 24): The nucleotide of claim [[23]] 44, wherein said template is immobilized on a solid surface.

Claim 46 (proposed substitute for Claim 25): The nucleotide of claim [[23]] 44, wherein said template is part of array.

Claim 47 (proposed substitute for Claim 26): The nucleotide of claim [[23]] 44, wherein said nucleic acid template is derived from genomic nucleic acid.

Claim 48 (proposed substitute for Claim 27): The nucleotide of claim [[24]] 45, wherein said solid surface is a bead.

Claim 49 (proposed substitute for Claim 28): The nucleotide of claim ~~[[12]]~~ 34, wherein said cleavable chemical group does not interfere with the recognition of the nucleotide by a polymerase.

Claim 50 (proposed substitute for Claim 29): The nucleotide of claim ~~[[23]]~~ 44, wherein said complex further comprises a polymerase.

Claim 51 (proposed substitute for Claim 30): The nucleotide of claim ~~[[23]]~~ 44, wherein the nucleic acid template is labeled with an azido-group via a polymerase chain reaction.

Claim 52 (proposed substitute for Claim 31): The nucleotide of claim ~~[[12]]~~ 34, wherein the cleavable chemical group capping the 3' OH group is a small chemical moiety.

Claim 53 (proposed substitute for Claim 32): The nucleotide of claim ~~[[31]]~~ 52, wherein the cleavable chemical group capping the 3' OH group comprises two carbon atoms or three carbon atoms.

Claim 54 (proposed substitute for Claim 33): The nucleotide of claim ~~[[24]]~~ 45, wherein the template is attached to the solid surface via an attachment group.

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U.S. Patent 7,790,869

CERTIFICATE OF SERVICE

I hereby certify that SUBSTITUTE COLUMBIA MOTION TO AMEND UNDER
37 C.F.R. §42.121 (FILING AUTHORIZED TO REPLACE PAPER NO. 66)
INCLUDING APPENDIX A in connection with *Inter Partes* Review Case
IPR2012-00007 was served on this 30th day of August 2013 by electronic mail to
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Dated: August 30, 2013

/Aaron P. Selikson/

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