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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KRISTIAN STRØMGAARD,
ANDERS BACH, and KLAUS BERTRAM NISSEN
(APPLICANT: UNIVERSITY OF COPENHAGEN)

Appeal 2018-007255
Application 15/100,687
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and RYAN H. FLAX, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 3, 4, 25, 26, 28–31, and 34–37.[2] We have jurisdiction under 35 U.S.C. § 6(b).

This Appeal under 35 U.S.C. § 134(a) involves claims (Appeal Br. 4). Examiner entered rejections under the written description provision of

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as University of Copenhagen (Appellant's April 3, 2018 Appeal Brief (Appeal Br.) 2).
[2] Pending claims 27, 32, 38, 42, 43, 47, and 53–56 stand withdrawn from consideration (*see* Appeal Br. 4).

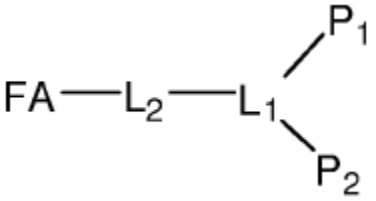
35 U.S.C. § 112(a), 35 U.S.C. § 103, and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellant's disclosure "relates to compounds capable of binding to the PDZ domains of PSD-95 and their medical use as inhibitors of protein-protein interaction mediated by PSD-95" (Spec.[3] 1: 6–8). Appellant's only independent claim, claim 1, is representative and reproduced below:

> 1. A dimeric ligand of PDZI-2 of PSD-95 comprising a first peptide (P_1) and a second peptide (P_2), wherein
>
> P_1 and P_2 individually comprise at least two proteinogenic or non-proteinogenic amino acid residues,
>
> both P_1 and P_2 are conjugated to a first linker L_1 via their N-termini,
>
> L_1 comprises polyethylene glycol (PEG) wherein at least one oxygen atom of said PEG is substituted with a nitrogen atom to give *N*PEG,
>
> an albumin binding moiety is linked to the nitrogen atom of the *N*PEG by an amide bond, or via second linker L_2,
>
> the albumin binding moiety is a fatty acid (FA),
>
> and wherein said dimeric ligand has the generic structure of formula (II), wherein L_2 is a nullity or comprises a nitrogen atom:



Formula (II)

(Appeal Br. 19.)

[3] Appellant's June 1, 2016 Specification.

Grounds of rejection before this Panel for review:

Claims 1, 3, 4, 25, 26, 34, 35, and 37 stand rejected under the written description provision of 35 U.S.C. § 112(a).

Claims 1, 3, 4, 25, 26, 28–31, and 34–37 stand rejected under 35 U.S.C. § 103 as unpatentable over the combination of Bach,[4] Kabanov,[5] Sjong,[6] Dragulescu-Andrasi,[7] and Gorris.[8]

Claims 1, 3, 4, 25, 26, 28–31, and 34–37 stand rejected under 35 U.S.C. § 103 as unpatentable over the combination of Bach '615,[9] Kabanov, Sjong, Dragulescu-Andrasi, and Gorris.

Claims 1, 3, 4, 25, 26, 28–31, and 34–37 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of Bach '615, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris.

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[4] Bach et al., *A high-affinity, dimeric inhibitor of PSD-95 bivalently interacts with PDZ1-2 and protects against ischemic brain damage*, 109 PNAS 3317–22 (2012).
[5] Kabanov et al., *New Technologies for Drug Delivery across the Blood Brain Barrier*, 10 Curr. Pharm. Des. 1355–63 (2004).
[6] Sjong et al., US 2013/0260404 A1, published Oct. 3, 2013.
[7] Dragulescu-Andrasi et al., *Cell-permeable GPNA with appropriate backbone stereochemistry and spacing binds sequence-specifically to RNA*, Chem. Commun. 244–46 (2005).
[8] Gorris et al., *Pushing Antibody-Based Labeling Systems to Higher Sensitivity by Linker-Assisted Affinity Enhancement*, 22 Bioconjugate Chem. 1619–24 (2011).
[9] Bach et al., US 9,139,615 B2, issued Sept. 22, 2015.

Written Description:

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention?

FACTUAL FINDINGS (FF)

FF 1. "Postsynaptic density protein-95 (PSD-95) . . . is a member of the membrane-associated guanylate kinase (MAGUK) family and is together with PSD-93 recruited into the same NMDA receptor and potassium channel clusters" (Spec. 1: 12–15).

FF 2. PSD-95 comprises "three PDZ domains . . . PDZ1-3, [which] bind peptide ligands with similar consensus sequence such as Ser/Thr-X-Val/Ile/Leu-COOH" (*id.* at 2: 3–4).

FF 3. Appellant discloses a compound having the structure of Formula (II), wherein:

> P_1 comprises the amino acid sequence $X_4X_3X_2X_1$ (SEQ ID NO: 1), and
>
> P_2 comprises the amino acid sequence $Z_4Z_3Z_2Z_1$ (SEQ ID NO: 2),
>
> wherein
>
> a) X_1 and/or [Z_1] is an amino acid residue selected from I, L and V,
>
> b) X_2 and/or Z_2 is an amino acid residue selected from A, D, E, Q, N, S, V, *N*-Me-A, *N*-Me-D, *N*-Me-E, *N*-Me-Q, *N*-Me-*N*, *N*-Me-S and *N*-Me-V,
>
> c) X_3 and/or Z_3 is an amino acid residue selected from S and T,
>
> d) X_4 and/or Z_4 is an amino acid residue selected from E, Q, A, N and S,

> wherein X_1 and Z_1 both individually represent the ultimate C-terminal amino acid residue comprising a free carboxylic acid.

(*id.* at 22: 27 – 23: 7; *see also id.* at 42–43.)

FF 4. Appellant exemplifies two compounds within the scope of Formula (II), wherein P_1 and P_2 each have the sequence IE*TAV* (*see id.* at 34: 27 – 35: 4 and 37: 7 – 38: 3 (emphasis added to highlight Appellant's disclosed P_1 and P_2 consensus sequence (*see* FF 2))).

ANALYSIS

Appellant discloses a three amino acid P_1 and P_2 consensus sequence (FF 2). Appellant further discloses four amino acid P_1 and P_2 sequences that fulfill the requirements of the P_1 and P_2 consensus sequence (*see* FF 3–4; *cf.* FF 1). Thus, Appellant's Specification provides written descriptive support for a dimeric ligand of PDZ1-2 of PSD-95 comprising first (P_1) and second (P_2) sequences that are each at least three amino acids in length (FF 2–4).

Appellant's claim 1, however, requires that the claimed dimeric ligand comprising first peptide (P_1) and second (P_2) sequences that are each *at least two* amino acid residues in length (*see* Appeal Br. 19; *see also* Final Act.[10] 5 ("the only limitation on [Appellant's claimed ligand is that its] length is 'at least two' [amino acids]"); Ans.[11] 6). For the reasons set forth above, Appellant's Specification fails to provide written descriptive support for a dimeric ligand of PDZ1-2 of PSD-95 comprising first (P_1) and second (P_2) sequences that are each *at least two* amino acids in length.

We are not persuaded by Appellant's reference to their "Formulas III and IV," as well as, "[t]welve specific compounds along with physical

[10] Examiner's October 5, 2017 Final Office Action.
[11] Examiner's May 16, 2018 Answer.

characterization data . . . in Tables 1 and 2 of [their] [S]pecification" and "a large number of peptide species . . . described on pages 24, 42, and 43 of [Appellant's] [S]pecification" (Appeal Br. 6; *see also* Reply Br. 3). Appellant does not identify, nor do we find, a disclosure in Appellant's Specification of a dimeric ligand of PDZ1-2 of PSD-95 that is *two* amino acids in length, i.e., a length that is smaller than Appellant's disclosed consensus sequence. Thus, Appellant's Specification fails to provide written descriptive support for a dimeric ligand of PDZ1-2 of PSD-95 that is commensurate in scope with Appellant's claim 1.

CONCLUSION

The preponderance of evidence on this record supports Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention. The rejection of claim 1 under the written description provision of 35 U.S.C. § 112(a) is affirmed. Claims 3, 4, 25, 26, 34, 35, and 37 are not separately argued and fall with claim 1.

Obviousness:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 5. Bach discloses "[a] high-affinity, dimeric inhibitor of PSD-95 [that] bivalently interacts with PDZ1-2 and protects against ischemic brain damage" (Bach, Title; *see also* Final Act. 6; Ans. 9).

FF 6. Bach discloses a dimeric inhibitor that comprises two IETDV, or IETAV, moieties linked through a *N*PEG linker (Bach 3317; *see also* Final Act. 6; Ans. 9).

FF 7. Bach discloses that "[i]n order to improve permeability across the blood-brain barrier, [Bach] attached the cell-penetrating peptide sequences, Tat and its inverse D-amino acid-containing version Retroinverso-D-Tat . . ., to the linker nitrogen" of its dimeric inhibitor (Bach 3317; *see also* Final Act. 6–7; Ans. 9).

FF 8. Examiner finds that Bach's dimeric inhibitor differs from Appellant's claimed dimeric ligand by using "TAT instead of a fatty acid with an optional linker" (Final Act. 7; Ans. 10).

FF 9. Kabanov discloses that "*artificial hydrophobization of peptides* and proteins . . . *facilitates the delivery of these peptides* and proteins *across* [*the blood brain barrier (BBB)*]" (Kabanov, Abstract (emphasis added); *id.* at 8 (Kabanov discloses "a new promising strategy for the brain delivery of *peptides* and proteins is emerging, which involves *artificial hydrophobization* of the protein (*peptide*) *molecule with fatty acid residues*" (emphasis added)); *see generally* Final Act. 7, 10, and 13; Ans. 10, 16–17, and 20).

FF 10. Kabanov discloses that "artificial hydrophobization . . . technology involves [the *gentle* modification of protein or peptide molecules, wherein the] introduction of a very small number of residues of a fatty acid (e.g. stearic, palmitic, oleic) into the protein molecules, specifically, 1 to 2 residues per protein globule" (Kabanov 6; *see generally* Final Act. 7, 10, and 13; Ans. 10, 16–17, and 20; *cf.* Spec. 22 ("The fatty acid of [Appellant's]

invention may be . . . a fatty acid selected from the group consisting of [*inter alia*] . . . palmitic acid, stearic acid, [and] . . . oleic acid")).

FF 11. Sjong discloses linkers, such as "4-aminobutanoic acid, 5-aminopentanoic acid, 6-aminohexanoic acid, 7-aminoheptanoic acid, 8-aminooctanoic acid, or an N-protected derivative of any of the foregoing" (Sjong 37; Final Act. 7, 10, and 13; Ans. 10, 17, and 20).

FF 12. Dragulescu-Andrasi discloses an aminobutanoic acid linker (Dragulescu-Andrasi 245; Final Act. 7, 10, and 13; Ans. 10, 17, and 20–21).

FF 13. Gorris discloses an aminobutanoic acid linker (Gorris, Abstract; Final Act. 7, 10, and 13; Ans. 10, 17, and 21).

FF 14. Bach '615 discloses:

> A compound comprising a first peptide linked to a second peptide by a linker, wherein the first and the second peptide comprise at least four amide-bonded residues having a sequence YTXV (SEQ ID NO: 5) or YSXV (SEQ ID NO: 6), wherein
>
> a. Y is selected from among E, Q, and A, and
>
> b. X is selected from among A, Q, D, N, N-Me-A, N-Me-Q, N-Me-D, and N-Me-N, and
>
> wherein the linker comprises PEG and, wherein at least one oxygen atom of the PEG is substituted with a nitrogen atom to give NPEG,
>
> wherein a Cell Penetrating Peptide (CPP) is linked to the nitrogen atom of the linker by an amide bond, and
>
> wherein the CPP comprises at least 4 amino acid residues selected from arginine and/or lysine.

(Bach '615 45: 54–67 (Claim 1); *see id.* 47: 27–48: 55 (Claim 14); *see also* Final Act. 9–10 and 12–13; Ans. 16 and 19–20.)

FF 15. Bach '615 discloses "[a] pharmaceutical composition comprising a compound according to [Bach '615's] claim 1 [(*see* FF 14)]" and a "method

of treatment of an excitotoxic-related disease in a subject, . . . comprising administering to [the] subject a therapeutically effective amount of the pharmaceutical composition . . . wherein the disease is ischemic or traumatic injury of the CNS" (Bach '615 47: 11–20 (Claims 10–12); *see* Final Act. 9–10 and 12–13; Ans. 16).

ANALYSIS

The rejection over the combination of Bach, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris:

Based on the combination of Bach, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious "to substitute the TAT of Bach . . . with the stearic acid described by Kabanov . . . as a simple substitution of one known element for another yielding expected results" (Final Act. 7; *see also* Ans. 11). In this regard, Examiner reasons that because "the two compounds (TAT and stearic acid) are both known in the art for the same purpose, an artisan in this field would attempt this substitution with a reasonable expectation of success" (Final Act. 7; *see also* Ans. 11).

Examiner further concludes that, at the time Appellant's invention was made, it would have been prima facie "obvious to attach the fatty acid via an aminobutanoic acid linker, as a combination of known elements yielding expected results" (Final Act. 8; *see also* Ans. 11). In this regard, Examiner reasons that because aminobutanoic acid "is a common linker in the art, an artisan in this field would attempt this modification with a reasonable expectation of success" (Final Act. 8; *see also* Ans. 11).

We find no error in Examiner's prima facie case of obviousness.

Appellant contends that Egleton[12] discloses that "increased lipophilicity . . . [deters] BBB crossing by peptides" and, therefore, "modification of the peptide of Bach with the fatty acid of Kabanov would be expected to decrease the ability to cross the BBB in direct contrast with the goal of Bach, thus rendering the [modified Bach] peptide unsuitable for its intended purpose" (Appeal Br. 9–10 (citing Egleton 48: left column) (emphasis omitted); *see generally* Appeal Br. 8–9; Reply Br. 4–5). We are not persuaded.

Egleton discloses that "[h]ighly lipophilic drugs tend to be extensively plasma bound, may increase affinity for efflux transporters at the BBB, resulting in intraendothelial sequestration and are readily taken up in the periphery" (Egleton 48: left column). In contrast, Kabanov discloses the *gentle* modification of peptide molecules, wherein "a very small number of residues of a fatty acid (e.g. stearic, palmitic, oleic)," i.e. 1–2 fatty acid residues are introduced into the peptide molecule (*see* FF 9–10). Kabanov discloses that it is this *gentle* modification, as opposed to Egleton's extensive modification, of peptides with fatty acid residues that is "a new promising strategy for the brain delivery of *peptides*" (FF 9). Appellant failed to establish an evidentiary basis on this record to support a finding that Kabanov's gentle modification technique results in the creation of a highly lipophilic drug discussed by Egleton.

Bach discloses attaching a molecule that facilitates BBB permeation to the *N*PEG component of its dimeric inhibitor (FF 5–7). Therefore, we are

[12] Egleton et al., *Development of Neuropeptide Drugs that Cross the Blood-Brain Barrier*, 2 THE JOURNAL OF THE AMERICAN SOCIETY FOR EXPERIMENTAL NEUROTHERAPEUTICS, 44–53 (2005).

not persuaded by Appellant's contention that "[t]here is no teaching or suggestion that provides a motivation to connect a fatty acid[, as disclosed by Kabanov to facilitate BBB permeation,] to any other molecule, let alone to attach a fatty acid to a *N*PEG linker as claimed (Appeal Br. 10 (emphasis omitted)).

Because Kabanov discloses the use of a fatty acid as an alternative to Bach's TAT moiety, we find no error in Examiner's conclusion that a person of ordinary skill in this art would have found it prima facie obvious to substitute Kabanov's fatty acid for Bach's TAT moiety to achieve the same purpose (*see* Final Act. 7; *see also* Ans. 11; FF 5–10). Therefore, we are not persuaded by Appellant's contention that "there is nothing in the references that would lead one of ordinary skill in the art to replace the TAT of Bach with the fatty acid of Kabanov instead of merely adding the fatty acid of Kabanov" (Appeal Br. 10 (emphasis omitted); *see also id.* at 11). It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); *see also id.* at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

For the foregoing reasons, we are not persuaded by Appellant's contention that Examiner's conclusion is based on improper hindsight reconstruction (Appeal Br. 10–11; *see* Reply Br. 5).

On this record, we find that the preponderance of the evidence falls in favor of Examiner's conclusion that it would have been prima facie obvious to substitute Kabanov's fatty acid, i.e. stearic acid, for Bach's TAT to facilitate BBB permeation. In this regard, although Appellant's claim 1 does not require any degree of stability, we find that such a modification would

result in at least the same degree of stability as Appellant's claimed dimeric ligand. Therefore, to the extent that Appellant discovered that replacing Bach's TAT for Kabanov's fatty acid, as suggested by the combination of references relied upon by Examiner, will result in increased plasma concentration, we find that such a discovery does not distinguish over the prior art (*cf.* Appeal Br. 11). *See e.g.*, *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer). For the foregoing reasons, we are not persuaded by Appellant's contentions regarding unexpectedly improved properties (Reply Br. 5–6). "Evidence of secondary considerations, including evidence of unexpected results and commercial success, are but a part of the 'totality of the evidence' that is used to reach the ultimate conclusion of obviousness." *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997).

Further, we limit our analysis to the arguments presented in Appellant's Brief. Therefore, additional arguments and new arguments in Appellant's Reply Brief that were not presented in Appellant's Brief, were not considered (*see generally* Reply Br. 5–6 (citing Example 3, Example 7, Table 1, and ¶¶ 137 and 156 of Appellant's Specification)). *See Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) (Appellant fails to "explain what 'good cause' there might be to consider the new argument. On this record, Appellant's new argument is belated.").

We recognize Appellant's arguments based on "the supplementary data attached [to Appellant's Appeal Brief] as Appendix B," but find that

this "data" is not in the form of a publication or declaration and, thus, is considered attorney argument (*see* Appeal Br. 12). *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

The rejection over the combination of Bach '615, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris:

Based on the combination of Bach '615, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious "to substitute [Bach '615's CPP] TAT . . . with the stearic acid described by Kabanov . . . as a simple substitution of one known element for another yielding expected results" (Final Act. 10–11; *see also* Ans. 17). In this regard, Examiner reasons that because "the two compounds ([CPP] TAT and stearic acid) are both known in the art for the same purpose, an artisan in this field would attempt this substitution with a reasonable expectation of success" (Final Act. 11; *see also* Ans. 17).

Examiner further concludes that, at the time Appellant's invention was made, it would have been prima facie "obvious to attach the fatty acid via an aminobutanoic acid linker, as a combination of known elements yielding expected results" (Final Act. 11; *see also* Ans. 18). In this regard, Examiner reasons that because aminobutanoic acid "is a common linker in the art, an artisan in this field would attempt this modification with a reasonable expectation of success" (Final Act. 11; *see also* Ans. 18).

We find no error in Examiner's prima facie case of obviousness.

Appellant contends that Egleton discloses that "increased lipophilicity . . . [deters] BBB crossing by peptides" and, therefore,

"modification of the peptide of Bach with the fatty acid of Kabanov would be expected to decrease the ability to cross the BBB in direct contrast with the goal of Bach '615, thus rendering the [modified Bach] peptide unsuitable for its intended purpose" (Appeal Br. 14 (citing Egleton 48: left column) (emphasis omitted); *see generally* Appeal Br. 13–14). We are not persuaded.

Egleton discloses that "[h]ighly lipophilic drugs tend to be extensively plasma bound, may increase affinity for efflux transporters at the BBB, resulting in intraendothelial sequestration and are readily taken up in the periphery" (Egleton 48: left column). In contrast, Kabanov discloses the *gentle* modification of peptide molecules, wherein "a very small number of residues of a fatty acid (e.g. stearic, palmitic, oleic)," i.e., 1–2 fatty acid residues are introduced into the peptide molecule (*see* FF 9–10). Kabanov discloses that it is this *gentle* modification, as opposed to Egleton's extensive modification, of peptides with fatty acid residues that is "a new promising strategy for the brain delivery of *peptides*" (FF 9). Appellant failed to establish an evidentiary basis on this record to support a finding that Kabanov's gentle modification technique results in the creation of a highly lipophilic drug discussed by Egleton.

Because Kabanov discloses the use of a fatty acid as an alternative to Bach's TAT moiety, we find no error in Examiner's conclusion that a person of ordinary skill in this art would have found it prima facie obvious to substitute Kabanov's fatty acid for Bach's TAT moiety to achieve the same purpose (*see* Final Act. 7; *see also* Ans. 11; FF 5–10). Therefore, we are not persuaded by Appellant's contention that "there is nothing in the references that would lead one of ordinary skill in the art to replace the TAT of Bach

’615 with the fatty acid of Kabanov instead of merely adding the fatty acid of Kabanov to the molecule of Bach ’615” (Appeal Br. 14 (emphasis omitted); *see also id.* at 15–16). It is proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *see also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

On this record, we find that the preponderance of the evidence falls in favor of Examiner’s conclusion that it would have been prima facie obvious to substitute Kabanov’s fatty acid, i.e. stearic acid, for Bach ’615’s CPP to facilitate BBB permeation. In this regard, although Appellant’s claim 1 does not require any degree of stability, we find that such a modification would result in at least the same degree of stability as Appellant’s claimed dimeric ligand. Therefore, we are not persuaded by Appellant’s contention that “absent impermissibly using hindsight reconstruction, one of ordinary skill in the art would not be led to remove the CPP of Bach ’615 and add the fatty acid of Kabanov, particularly when seeking to improve stability in plasma, as Appellant did” (Appeal Br. 15 (emphasis omitted)). Therefore, to the extent that Appellant discovered that replacing Bach ’615’s CPP for Kabanov’s fatty acid, as suggested by the combination of references relied upon by Examiner, will result in increased plasma concentration, we find that such a discovery does not distinguish over the prior art (*cf.* Appeal Br. 15–16). *See e.g.*, *Atlas Powder*, 190 F.3d at 1347 (“[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer). For the foregoing reasons, we are not persuaded by Appellant’s contentions regarding unexpectedly

improved properties (Reply Br. 5–6). "Evidence of secondary considerations, including evidence of unexpected results and commercial success, are but a part of the 'totality of the evidence' that is used to reach the ultimate conclusion of obviousness." *Richardson-Vicks*, 122 F.3d at 1483.

Further, we limit our analysis to the arguments presented in Appellant's Brief. Therefore, additional arguments and new arguments in Appellant's Reply Brief that were not presented in Appellant's Brief, were not considered (*see generally* Reply Br. 5–6 (citing Example 3, Example 7, Table 1, and ¶¶ 137 and 156 of Appellant's Specification)). *See Ex parte Borden*, 93 USPQ2d at 1474 (Appellant fails to "explain what 'good cause' there might be to consider the new argument. On this record, Appellant's new argument is belated.").

For all of the foregoing reasons we are not persuaded by Appellant's contention that Examiner's conclusion is based on improper hindsight reconstruction (Appeal Br. 14–15).

We again recognize Appellant's arguments based on the supplementary data attached to Appellant's Appeal Brief as Appendix B, but find that this "data" is not in the form of a publication or declaration and, thus, is considered attorney argument (*see* Appeal Br. 16). *See In re Pearson*, 494 F.2d at1405 ("Attorney's argument in a brief cannot take the place of evidence.").

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claim 1 under 35 U.S.C. § 103 as unpatentable over the combination of Bach, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris. Claims 3, 4, 25, 26, 28–31, and 34–37 are not separately argued and fall with claim 1.

The rejection of claim 1 under 35 U.S.C. § 103 as unpatentable over the combination of Bach ’615, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris. Claims 3, 4, 25, 26, 28–31, and 34–37 are not separately argued and fall with claim 1.

Obviousness-type Double Patenting:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness-type double patenting?

ANALYSIS

Having found no deficiency in the foregoing rejection of claim 1 under 35 U.S.C. § 103 as unpatentable over the combination of Bach ’615, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris, we are not persuaded by Appellant’s contention that the obviousness-type double patenting rejection on this record fails for reasons “[a]s per above and incorporated herein by reference and extendible to the subject rejection, there is no motivation or reasonable expectation of success to substitute a fatty acid for the CPP of Bach ’615” (Appeal Br. 17; *see* Reply Br. 6).

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness-type double patenting.

The rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of Bach '615, Kabanov, Sjong, Dragulescu-Andrasi, and Gorris. Claims 3, 4, 25, 26, 28–31, and 34–37 are not separately argued and fall with claim 1.

SUMMARY

In summary,

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 3, 4, 25, 26, 34, 35, 37	112(a)	Written Description	1, 3, 4, 25, 26, 34, 35, 37	
1, 3, 4, 25, 26, 28–31, 34–37	103	Bach, Kabanov, Sjong, Dragulescu-Andrasi, Gorris	1, 3, 4, 25, 26, 28–31, 34–37	
1, 3, 4, 25, 26, 28–31, 34–37	103	Bach '615, Kabanov, Sjong, Dragulescu-Andrasi, Gorris	1, 3, 4, 25, 26, 28–31, 34–37	
1, 3, 4, 25, 26, 28–31, 34–37	Judicially created doctrine of obviousness-type double patenting	Bach '615 claims 1, 11, 12, and 14, Kabanov, Sjong, Dragulescu-Andrasi, Gorris	1, 3, 4, 25, 26, 28–31, 34–37	
Overall Outcome			1, 3, 4, 25, 26, 28–31, 34–37	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED