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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SABRINA KUTTRUFF-COQUI, TONI WEINSCHENK, JENS FRITSCHE, STEFFEN WALTER, NORBERT HILF, OLIVER SCHOOR, COLETTE SONG, and HARPREET SINGH

Appeal 2020-000384
Application[1] 14/531,472
Technology Center 1600

Before RICHARD M. LEBOVITZ, RYAN H. FLAX, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a pharmaceutically acceptable salt of a particular peptide sequence, and a fusion protein, which have been rejected as directed to patent-ineligible subject matter, and/or as being indefinite and obvious. Oral argument was held on September 14, 2020. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm in part.

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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 Immatics Biotechnologies GmbH. (Appeal Br. 1.)

STATEMENT OF THE CASE

Claims 1, 5, 9, 16, 17, and 34 are on appeal. Claims 1 and 34 are representative and read as follows:

> 1. A peptide consisting of the amino acid sequence of SEQ ID NO: 28 wherein said peptide is in the form of a pharmaceutically acceptable salt.
>
> 34. A fusion protein, comprising
>
> (a) a peptide consisting of the amino acid sequence of SEQ ID NO: 28; and
>
> (b) N-terminal amino acids 1-80 of HLA-DR antigen-associated invariant chain (Ii) according to SEQ ID No. 133.

(Appeal Br. 43, 48.)

The prior art relied upon by the Examiner is:

Name	Reference	Date
Singh et al.	US 2009/0136528 A1	May 28, 2009
Grifantini et al.	WO 2011/051278 A1	May 5, 2011

The following grounds of rejection by the Examiner are before us on review:

Claims 1, 5, 9, 16, and 17 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter.

Claim 34 under 35 U.S.C. §112(b) as being indefinite.[2]

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[2] We cite to the post-AIA version of §§ 112 and 103, because the Application on Appeal was filed on November 3, 2014, based on an Application filed November 4, 2013, both of which are dates after the AIA amendments to § 112 took effect on September 16, 2012 and the amendments to § 103 took effect on March 16, 2013. *See, e.g.*, Leahy-Smith America Invents Act ("the AIA"), Pub. L. No. 112-29, §§ 3(n), 4(e), 125

Claim 34 under 35 U.S. C. § 103 as unpatentable over Singh and Grifantini.

DISCUSSION

I. Patent Eligible Subject Matter

The Dispute

The Examiner finds that claim 1 involves a product of nature, namely "the COL20A1 protein (collagen, Type XX, alpha 1)." (Final Action 4.) The Examiner states: "A peptide consisting of the amino acid sequence of SEQ ID NO: 28 (FLVDGSWSI) . . . is produced by cells expressing human COL20A1, collagen XX, the protein from which it is derived." (Ans. 13–14.) The Examiner notes that "a peptide consisting of the amino acid sequence of SEQ ID NO: 28 is the same as the peptide that was originally isolated from the COL20A1 protein, which has this same amino acid sequence and this same primary structure." (*Id.* at 15.)

The Examiner recognizes that "claim 1 calls for a peptide that consists of SEQ ID NO: 28 wherein the peptide is in the form of pharmaceutically acceptable salt," but finds that "the pharmaceutically acceptable salt recited in instant claim 1 is generic because the claims recite a 'wherein clause' limitation that does not change the final structure of the peptide." (Final Action 5; *see also* Ans. 14.) The Examiner finds

> [t]he fact that the peptide is in the form of a pharmaceutically acceptable salt simply means one or more of the amino acid residues of which the peptide is composed has been ionized and has formed an ionic bond with whatever cation (e.g., Na^+) or

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Stat. 284, 293, 297 (2011). However, the current law and respective pre-AIA law are, in all aspects relevant to this Decision, the same.

> anion (e.g., Cl^-) might be present, as exemplified in the instant specification, page 91.

(Ans. 15.) However, the Examiner finds that the ionized peptide structure is the same amino acid sequence and primary structure as that peptide in the naturally occurring protein. (*Id.* at 17–18.) The Examiner further finds that "[t]he pharmacological[ly] acceptable salt also reads on a natural product because it is still a naturally occurring peptide that is not markedly different from the naturally protein . . . [and] peptides (composed of amino acids) will naturally produce a salt." (Final Action 5–6 (citing Berge[3]).) The Examiner thus concludes that "claim 1 reads on naturally occurring polypeptide salts and thus, this composition reads on a natural product as well." (*Id.* at 6.)

According to the Examiner, "[t]he instant claims do not recite any elements in addition to the natural products that impose meaningful limits on the claim scope and would substantially foreclose others from using these natural products." (*Id.*)

Appellant argues that "the proper analysis for step 2A is to look at what is claimed and determine whether it has an identical natural counterpart. If an identical counterpart to what is claimed does not exist, that is the end of the analysis." (Appeal Br. 11. (emphasis omitted)). Appellant points out that the claimed invention is to a pharmaceutically acceptable salt of the peptide having SEQ ID No: 28 and that it is an improper analysis under § 101 to "parse[] [the claim] into i) the 9-amino acid and ii) a salt." (*Id.* at 13–14.)

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[3] Berge et al., *Pharmaeutical Salts*, 66 (1) J. Pharmaceutical Sciences, 1–19 (1977).

Appellant argues that the Examiner's rejection is in error because "there is no naturally occurring peptide of SEQ ID NO: 28 either in free form or in the form of a pharmaceutically acceptable salt." (*Id.* at 12.) As a consequence, Appellant argues, "it is impossible for the claims to be 'directed' to a judicial exception." (*Id.*) Appellant explains that

> [i]t is also impossible for the claimed subject matter to "monopolize" what occurs in nature, because what occurs in nature is either a whole 1284 amino acid 3-D protein, or the peptide complexed with other molecules (where it is never, at any time, in the form of a pharmaceutically acceptable salt).

(*Id.*) Undergirding Appellant's argument is the testimony of Dr. Lawrence Stern. (*Id.* at 16–20 (citing Stern Declaration[4]).)

Appellant further explains, with support from the testimony of Dr. Stern, that "[t]hese naturally-occurring complexes are both structurally and functionally different, i.e., 'markedly different,' from the peptide salt claimed." (*Id.* at 21–24.) Appellant further notes that "the salt form of the peptide enables the peptide to be used *in vitro* where it would otherwise not be able to be used because of degradation or insolubility." (*Id.* at 12–13, 25–27 (citing Stern Declaration).) Consequently, Appellant points out that "even if there were a naturally-occurring counterpart, the claimed physical salt form represents a practical application," having both structural and functional differences. (*Id.* at 13, 25.)

Analysis

35 U.S.C. § 101 defines patent-eligible subject matter. An invention is patent-eligible if it claims a "new and useful process, machine,

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[4] Declaration of Dr. Lawrence Stern, dated Dec. 19, 2017 ("Stern Declaration").)

manufacture, or composition of matter." 35 U.S.C. § 101. The Supreme Court, however, has carved out exceptions to what would otherwise appear to be within the literal scope of § 101, e.g., "[l]aws of nature [and] natural phenomena" such as products of nature that are considered "buildin[g] block[s] of human ingenuity." *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (citing *Ass'n for Molecular Pathology v. Myriad*, 569 U.S. 576 (2013) and *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 89 (2012)). "The 'manifestations of laws of nature' are 'part of the storehouse of knowledge,' 'free to all men and reserved exclusively to none.'" Manual of Patent Examiner Procedure ("MPEP") § 2106.04 (b) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Col*, 33 U.S. 127, 130 (1948)). "When a law of nature or natural phenomenon is claimed as a physical product, the courts have often referred to the exception as a 'product of nature.'" MPEP § 2106.04(b)(II).

The Supreme Court has established a two-step framework for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 573 U.S. at 216. "First, we determine whether the claims at issue are directed to" a patent-ineligible concept. *Id.* If so, "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 78–79).

The United States Patent and Trademark Office ("PTO") issued the *2019 Revised Patent Subject Matter Eligibility Guidance* ("Guidance"),

indicating how the PTO would analyze patent eligibility under the Supreme Court's two-step framework. 84 Fed. Reg. 50–57 (January 7, 2019).[5]

Under the Guidance, in determining what concept the claim is "directed to," we first look to whether the claim recites any judicial exceptions, including laws of nature, natural phenomena, and/or abstract ideas. (Guidance, 84 Fed. Reg. at 53–54.) ("Step 2A, Prong One"). If it does, then we look to whether the claim recites additional elements that integrate the recited judicial exception into a practical application. (*Id.* at 54–55 (citing MPEP § 2106.05(a)–(c), (e)–(h)).) ("Step 2A, Prong Two").

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, i.e., it is found to be "directed to" a judicial exception, do we then look to whether the claim contains an "'inventive concept' sufficient to 'transform'" the claimed judicial exception into a patent-eligible application of the judicial exception. Guidance, 84 Fed. Reg. at 56; *see also Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 82).

Claims alleged to be patent-ineligible because they recite products of nature are properly analyzed under the framework of the Guidance. *See* Guidance, 84 Fed. Reg. at 54 n.20 ("This notice does not change the type of claim limitations that are considered to recite a law of nature or natural

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[5] "All USPTO personnel are, as a matter of internal agency management, expected to follow the guidance." *Id.* at 51; *see also* USPTO, *October 2019 Update: Subject Matter Eligibility* 1 (the "October 2019 Update") (available at https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf).

phenomenon. For more information about laws of nature and natural phenomena, including products of nature, see MPEP 2106.04(b) and (c).").

Applying the Guidance and binding legal precedent, we disagree with the Examiner's conclusion that the claims are directed to patent-ineligible subject matter. We address independent claim 1 as the representative claim for our analysis. There is no dispute that claim 1, which recites a peptide in the form of a pharmaceutically acceptable salt, is a composition and, thus, falls squarely within the "composition of matter" statutory category. Consequently, we proceed to the next steps of the analysis.

STEP 2A, Prong One:

In Step 2A, Prong One of the Guidance, we evaluate whether claim 1 recites a judicial exception, i.e., whether it sets forth or describes a product of nature in accordance with the guidance in MPEP 2106.04 (b) and (c). Guidance, 84 Fed. Reg. at 54; October 2019 Update.

a. Product of Nature Analysis

Claim 1 includes recitation of a peptide sequence that is undisputedly found in nature as part of a larger sequence. SEQ ID No: 28 is a peptide sequence from a protein encoded by the COL20A1 gene, a collagen gene mapped to the human chromosome 20q13.33. (Spec. 5 (Table 1a), 33.) However, as Appellant points out, the claim does not recite a free peptide, but rather a pharmaceutically acceptable salt of that peptide.

According to Examiner, because the claim does not specify a particular "anionic or cationic constituent[] of the salt, apart from the peptide itself, *it is the peptide, not the salt, that is the invention*; and therefore the anion or cation (i.e., the 'counterion') that forms a salt with the ionized

peptide is unrelated to the invention." (Ans. 14 n.3 (emphasis added).) We disagree with the Examiner's claim interpretation.

The claim requires a peptide "consisting of the amino acid sequence of SEQ ID NO: 28" where that peptide is a pharmaceutically acceptable salt. In other words, the amino acid sequence of the peptide salt cannot be anything other than SEQ ID NO: 28, but that sequence must be in ionic combination with another ion to form a pharmaceutically acceptable salt. The claimed salt is a structurally different chemical composition than a free peptide, as even the Examiner recognizes. (*See* Ans. 15 ("The fact that the peptide is in the form of a pharmaceutically acceptable salt simply means one or more of the amino acid residues of which the peptide is composed has been ionized and has formed an ionic bond with whatever cation (e.g., Na^+) or anion (e.g., Cl^-) might be present." (footnote omitted)); *see also* Stern Declaration ¶ 20 ("Salts are formed when a compound that is ionized in solution forms a strong ionic interaction with an oppositely charged counterion, leading to neutralization of the charges. . . ."), *id.* ¶¶ 23–24 ("[P]eptides of any length . . . will therefore have a one free amino group (NH_2,) referred to as the amino terminus or N-terminus and one free carboxyl group (COOH) referred to as the carboxyl or C-terminus . . . . [T]here can also be ionizable groups in the side chains ('R') of the amino acid residues within the peptide.").)

Appellant's expert explained, with reference to numerous articles, that the amino acid sequence of SEQ ID NO: 28 would not exist in the body as a salt. (Stern Declaration ¶¶ 32–34.) Dr. Stern explained that peptide fragments, such as amino acid sequence SEQ ID NO: 28, that arise when proteins are degradedare themselves degraded within a few seconds if not

associated with other proteins involved in degradation, ER transport and loading of the peptide onto MHC-1 molecules. (Stern Declaration ¶ 32.) Dr. Stern notes that "[i]n the absence of peptide binding, neither the peptide nor the MHC molecule by itself is stable, or persists." (*Id.* ¶ 33.)

Dr. Stern further explains that even if the free peptide existed in the cell, "there is no acid-base reaction that could occur in the cytoplasm or ER of a cell . . . that would result in formation of a peptide salt." (*Id.* ¶ 34.) That is because "[t]he formation of salts requires specific combinations of acids or bases in specific concentrations, at a defined ratio (stoichiometry), so that there is a set number of moles of acid and moles of base in a controlled environment[, and] [t]he cytoplasm of a cell is not such an environment." (*Id.*) Dr. Stern notes that the cytoplasm "would not contain either the peptides or the acid or base counterpart in sufficient quantities in sufficient proximity to each other to form a peptide salt." (*Id.*) Furthermore, Dr. Stern explains that "[e]ven if all the water in cell were removed, specific salts would not form, because of the highly complex mixtures of anions and cations present." (*Id.*)

The Examiner has not provided any evidence in contravention of the foregoing testimony by Dr. Stern. Rather, the Examiner asserts that peptides will form salts because (1) "Amino acids will naturally produce a salt. Berge et al., 1977 (IDS, 2/22/2017) teaches that salt formation is an acid-base reaction involving a proton-transfer or neutralization reaction (see page 1, 1st column) and amino acids are also used as salt forming agents (see page 2, 2nd column, 3rd paragraph)" (Final Action 6); and because (2)"The human cell cytosol comprises ions of pharmaceutically acceptable salts, *e.g.* Na^+, Cl^-, K^+, HCO_3^-. One of ordinary skill is aware that at physiological pH, both

the amino and carboxy groups of a peptide are ionized" (Final Action 9). Relying on general principles of chemistry, the Examiner posits that because the peptide is present in an aqueous solution *in vivo* within the cytosol, the endoplasmic reticulum, and at the surface of cells in complex with an HLA class I molecule, it will be ionized and because there are "counterions of the appropriate charge" naturally present in each situation in the body, a salt will form. (Ans. 16–21.)

The Examiner does not assert that Berge describes *in vivo* salt formation of peptides. Berge is a review article concerned with providing information about salts to those in the pharmaceutical industry to have a rational basis for selecting a suitable salt form of a drug for administration. In particular, Berge states

> [t]his review surveys literature of the last 25 years, emphasizing comparisons between the properties of different salt forms of the same compound. Included also is a discussion of potentially useful salt forms. Our purpose is twofold: to present an overview of the many different salts from which new drug candidates can be chosen and to assemble data that will provide, for the student and practitioner alike, a rational basis for selecting a suitable salt form.

(Berge 1–2.)

Moreover, the Examiner's assertion that the peptide fragments of the collagen protein degraded by a proteasome will naturally form a salt in the cytosol, the ER, or the MHC because there are counterions such as sodium, chloride and potassium present around lacks any evidentiary foundation. And, it is contradicted by the testimony of Dr. Stern that salt formation requires specific combinations of acids or bases in specific concentrations, at a defined ratio (stoichiometry), so that there is a set number of moles of acid and moles of base in a controlled environment. It cannot be disputed that the

cytosol, the ER and the MHC *in vivo* is not such a controlled environment with respect to peptide fragments of the collagen protein degraded by a proteasome.

In addition, the Examiner's position that the free peptide is extant in the first place for long enough to form a salt is contradicted by Dr. Stern's testimony that any free peptide of the collagen protein degraded by a proteasome would be rapidly degraded if it is not associated with certain other proteins in the cytosol or in transport to the endoplasmic reticulum or when bound in the MHC.

While an amino acid sequence consisting of SEQ ID NO: 28 is unquestionably identical to a peptide sequence found in COL20A1, which Appellant does not dispute, we conclude that the preponderance of the evidence favors finding that the claimed pharmaceutically acceptable salt of the peptide consisting of the amino acid sequence of SEQ ID NO: 28 is not a compound that occurs in nature.

Thus, we disagree with the Examiner's conclusion that the claimed invention is not markedly different from a naturally occurring peptide consisting of an amino acid sequence of SEQ ID NO: 28.[6] The Examiner's analysis does not properly address the claimed structure, as discussed above. It cannot be said that the pharmaceutically acceptable salt of amino acid peptide of SEQ ID NO: 28 is merely an isolated component of a larger structure known to be present in nature, similar to DNA isolated from the

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[6] We note, but do not find it necessary to respond to, Appellant's arguments concerning any alleged misapplication of law in the MPEP. (Appeal Br. 9.) We need not address this argument because we conclude that the Examiner erred in evaluating the claimed invention as a whole.

human genome. *Cf. Myriad*, 569 U.S. at 593 ("Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule."); *see also Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018) (finding similar to the claimed DNA at issue in Myriad, that the claimed primers were necessarily present in the natural genome of Mtb).

The markedly different characteristic for the claimed invention here is not merely due to the breaking of chemical bonds, but is rather based on chemical differences attributable to the fact that the peptide of SEQ ID NO: 28 is in strong ionic interaction with an oppositely charged counterion. In *Myriad*, the Supreme Court determined that naturally occurring, but isolated, DNA fell within the product of nature exception because "Myriad's claims . . . do [not] rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Myriad*, 569 U.S. at 593 (emphasis added). The Court in *Myriad*, however, also noted that "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring" and determined that such a chemical construct is patent-eligible. *Id.* at 594. We conclude that, like the cDNA in *Myriad*, the pharmaceutically acceptable salt of the peptide consisting of amino acid SEQ ID NO: 28 is markedly different from the peptide consisting of amino acid SEQ ID NO: 28 because the claimed pharmaceutically acceptable salt is a chemical construct that does not exist in nature. *Accord* MPEP 2106.04(c)(II) ("Markedly different characteristics can be expressed as the

product's structure, function, and/or other properties, and are evaluated based on what is recited in the claim on a case-by-case basis.").[7]

Accordingly, under Guidance Step 2A, Prong 1, we conclude that the composition of claim 1 does not recite a product of nature, and thus is not directed to a patent ineligible judicial exception. Our analysis of the issue need not proceed further.

Thus, we do not affirm the Examiner's rejection of claims 1, 5, 9, 16 and 17 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter.

II. Rejection of Claim 34 as Indefinite

The Examiner finds that the claim language of claim 34, the fusion protein claim, is "confusing and unclear" because "there are multiple interpretation[s] of the instant claim" because it uses both "comprising" and "consisting of" language. (Final Action 3.) The Examiner indicates that the following two interpretations are possible.

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[7] In addition to this structural difference, Dr. Stern contends that the free peptide would be poorly soluble in aqueous solution (Stern Declaration ¶ 38) whereas "[s]alts of hydrophobic peptides have been shown improve their solubility in aqueous solutions, just as salts of other compounds improve their solubility" (*Id.* ¶ 40). He also contends that "[p]eptides are not very stable in free form, without modifications" (*Id.* ¶ 41) and that "the peptide claimed in the Immatics application can undergo hydrolysis in aqueous solution in free form" (*Id.* ¶ 42), whereas "[f]ormation of peptide salts stabilizes the peptides from physical degradation, discussed above, to some extent" (*Id.* ¶ 45). In light of our conclusion regarding the marked structural difference, we need not address Appellant's additional argument and testimony of Dr. Stern that the physical properties of the pharmaceutically acceptable salt of the claimed peptide fragment is markedly different than a free peptide fragment if it existed in nature.

One interpretation is that the "the fusion protein is composed of only SEQ ID NO: 28, the N-terminal amino acids 1-80 of HLA-DR antigen-associated invariant chain and other components." (*Id.*) The second interpretation is that fusion protein is composed of any peptides/proteins including up to the full length of COL20A1 and the HLA-DR antigen-associated invariant chain as long as they include the specific peptides in SEQ ID NOs: 28 and 133. (*Id.*)

Appellant argues that the use of the phase "fusion protein comprising" "does not mean that the term applies to the individual elements within the claim that are further limited by the term 'consisting of.'" (Appeal Br. 40.) Appellant explains, therefore, that because clause (a) of the claim uses the term "consisting of," it "cannot include anything beyond the peptide of SEQ ID NO: 28 and certainly not the whole protein, which is not a peptide as would reasonably be understood." (Appeal Br. 40.)

We disagree with Appellant's claim construction. We find the claim language issue similar to that present in *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004). In that case, our reviewing Court explained that a claim to an "oligonucleotide *comprising* at least a portion of . . . SEQ ID NO:1, . . . wherein said portion *consists of* nucleotides 521 to 2473" reads on a plasmid that includes more than just the recited portion of SEQ ID NO:1. *In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004). "The reasonable interpretation of the claims containing both of the terms 'comprising' and 'consists' is that the term 'consists' limits the 'said portion' language to the subsequently recited numbered nucleotides, but the earlier term 'comprising' means that the claim can include that portion plus other nucleotides." *Id.*

Here the language "consisting of" limits clause (a) to the amino acid sequence specified in SEQ ID NO: 28 being present in the fusion protein without any variation to that sequence. It does not limit the other amino sequences that may be present in the claimed fusion protein. Nor is there other limiting language in the claim requiring the amino acid sequence of clause (a) to be directly fused to the amino acid sequence recited in clause (b). "'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). Thus, the use of the term fusion protein comprising means that the claim can include SEQ ID NO: 28 including up to the full length of COL20A1, as the Examiner recognized.

Nevertheless, we disagree with the Examiner that the claim is indefinite. Breadth is not equated with indefiniteness. *In re Miller*, 441 F.2d 689, 693 (CCPA 1971). That the claim can be read to encompass up to the full length of COL20A1 as a fusion protein with the "N-terminal amino acids 1–80 of HLA-DR antigen-associated invariant chain (Ii) according to SEQ ID No. 133" is an issue of claim breadth. The fact that the claim encompasses as much as an entire protein that includes a specifically recited peptide sequence where that protein is fused to another amino acid sequence or as little as just a specific peptide sequence fused to another amino acid sequence does not make it indefinite.

Consequently, we reverse the Examiner's rejection of claim 34 as being indefinite.

III. Rejection of Claim 34 as Obvious

Appellant contests the Examiner's rejection of claim 34 as being obvious on the grounds that "no reasonable interpretation of 'consisting of' encompasses the whole protein from which SEQ ID NO: 28 is derived" and the prior art does not teach or suggest a fusion protein of SEQ ID NO: 28. (Appeal Br. 41.) As explained above, we do not agree with Appellant's claim interpretation. So long as the amino acid sequence of SEQ ID NO: 28 is present in a fusion protein, the limitation in dispute would be met.

Furthermore, Appellant does not dispute the Examiner's findings that "[t]he sequences taught by Grifantini, COL20A1 in it[s] variant isoforms SEQ ID NOs: 32, 35-37 or with a sequence identity of at least 80-95% (see page 10) encompass the instantly claimed SEQ ID NO: 28" or that "Grifantini teaches a fusion protein of COL20A1 (see page 34, Figures 25-26 and page 41, lines 5-6)." (Final Action 16.) Nor does Appellant dispute the Examiner's findings regarding Singh as to fusion proteins "which comprises the 80 N-terminal amino acids of the HLA-DR antigen associated invariant chain (see paragraph 105)." (*Id.* at 15.) Appellant also does not challenge the Examiner's findings concerning the reason to combine the teachings of Grifantini and Singh to arrive at a fusion protein that would include the full length of COL20A1 in its variant isoforms and the 80 N-terminal amino acids of the HLA-DR antigen associated invariant chain. (*Id.* at 16–17.) Consequently, we affirm the Examiner's rejection of claim 34 as obvious over Singh and Grifantini.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 5, 9, 16, 17	101	Eligibility		1, 5, 9, 16, 17
34	112(b)	Indefinite		34
34	103	Singh, Grifantini	34	
Overall Outcome			34	1, 5, 9, 16, 17

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED IN PART