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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LAWRENCE D. MAYER, ROBERT K. PRUD'HOMME, CHRISTINE J. ALLEN, and WALID S. SAAD

Appeal 2019-006848
Application 13/905,015[1]
Technology Center 1600

Before FRANCISCO C. PRATS, TAWEN CHANG, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 relating to particulate constructs stabilized by an amphiphilic compound and comprising at least one active agent coupled through a linker to a hydrophobic moiety. Spec. ¶ 2. The Examiner rejected the claims on appeal as obvious under 35 U.S.C. § 103(a) and under 35 U.S.C. § 112 as indefinite, as failing to comply with

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. According to Appellant, the real party in interest is Celator Pharmaceuticals, Inc., which is wholly owned by Jazz Pharmaceuticals, PLC. Appeal Br. 2.

the written description requirement, and as introducing new matter. A hearing was held on May 11, 2020.[2] We affirm-in-part.

STATEMENT OF THE CASE

The Specification discloses that "[t]he present invention provides particulate constructs that can be adapted to the release of active agents of various types useful in both pharmaceutical and non-pharmaceutical applications." Spec. ¶ 24. According to the Specification, "[t]hese delivery systems provide high loading capacity for active compounds as well as provide a means for controlled release of the active, reduction in toxicity where relevant, and, if desired, selective delivery to a target site." *Id.*

Claims 1, 3, 4, 7–9, 13, and 16–24 are on appeal. Claim 1 is representative and reads as follows:

1. A composition comprising particles obtained by mixing

a) an amphiphilic stabilizer,

b) a conjugate of the formula

$$(\text{active} - \text{linker})_n - \text{hydrophobic moiety} \quad (1)$$

wherein n is an integer of 1–100;

"active" refers to a first therapeutic agent;

"linker" is a divalent residue of an organic molecule which comprises a bond that is selectively cleavable by reduction or hydrolysis to control the rate of release of said active from the particle free of said hydrophobic moiety or portion thereof; and

[2] A transcript from the hearing has been entered into the record ("Tr.").

> "hydrophobic moiety" refers to the residue of an organic molecule that is insoluble in aqueous solution; and
>
> c) a second therapeutic agent different from the first therapeutic agent,
>
> wherein said first and second therapeutic agents are present in the composition at a nonantagonistic ratio
>
> said conjugate and particles constructed so that the release of the first therapeutic agent from the particles is coordinated with the release of the second therapeutic agent so that the administered ratio of said first therapeutic agent to said second therapeutic agent in said composition is maintained when said composition is administered parenterally to a subject, as measured in the plasma of the subject, and
>
> wherein the hydrophobic moiety is a polymer having a molecular weight between 800 and 200,000 g/mole or is a natural product, and
>
> the amphiphilic stabilizer is a copolymer having a hydrophilic region and a hydrophobic region wherein said copolymer is a graft, block or random copolymer and has a molecular weight between 1,000 g/mole and 50,000 g/mole.

App. Br. 31.

The Examiner rejected the claims as follows:

Claims 1, 3, 4, 7–9, 13, and 16–24 were rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement.

Claims 1, 3, 4, 7–9, 13, and 16–24 were rejected under 35 U.S.C. § 112 as indefinite.

Claims 17–24 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Oh,[3] Soppimath,[4] McLeod,[5] and Muggia.[6]

Claims 17–24 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Oh, Soppimath, McLeod, Muggia, and Johnson.[7]

Claims 1, 3, 4, 7–9, and 16–24 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Oh, Soppimath, McLeod, Muggia, and Tardi.[8]

OBVIOUSNESS

The same issue is dispositive with respect to all three obviousness rejections. Accordingly, we address all three rejections together.

Oh discloses "a molecular sustained controlled release system constructed by the conjugation of molecules to be released with biodegradable polyester polymer via covalent bond." Oh Abstract. The "drug release rate" from Oh's controlled release system is taught to be "proportional to [the] mass erosion rate of the biodegradable microspheres, nanoparticles, and films." *Id.* at 7:35–41. The Examiner nonetheless finds that Oh discloses linkers that "control the rate of release," as recited in the

[3] Oh et al., US Patent No. 6,589,548 B1, issued July 8, 2003 ("Oh").
[4] Soppimath et al., *Biodegradable Polymeric Nanoparticles as Drug Delivery Devices,* 70 Journal of Controlled Release 1–20 (2001) ("Soppimath").
[5] McLeod et al., *Synthesis and Chemical Stability of Glucocorticoid-Dextran Esters: Potential Prodrugs for Colon-Specific Delivery,* 92 International Journal of Pharmaceutics, 105–114 (1993) ("McLeod").
[6] Muggia et al., *Phase III Randomized Study of Cisplatin Versus Paclitaxel Versus Cisplatin and Paclitaxel in Patients with Suboptimal Stage III or IV Ovarian Cancer: A Gynecologic Oncology Group Study,* 18(1) Journal of Oncology 106–115 (2000) ("Muggia").
[7] Johnson et al., WO 02/078674 A1, published Oct. 10, 2002 ("Johnson").
[8] Tardi et al., WO 03/028696 A2, published April 10, 2003 ("Tardi").

claims, because "there is a significant overlap between the types of linkers disclosed by Oh and those included in the definition of linker in the instant specification." Ans. 28. According to the Examiner "[b]onds such as the carbamate bond in examples 6 and 7 of Oh and other exemplified bonds such as esters, amides, anhydrides, ureas, urethanes, carbonates, imines, thioesters, disulfides, and carbamates include bonds that are cleaved by hydrolysis as required by the instant claims." *Id.* (internal citation omitted). The Examiner finds that the claims encompass biodegradation and states that she was "unable to locate any evidence either in Oh itself or in the prosecution history that all drug release from the particles occurs in a form in which the carbamate bond between the active and the polymer remains intact." *Id.* We are not persuaded.

As Appellant points out, in order for the "linker" to "control the rate of release of said active," as recited in the claims, the "rate of cleavage of the bond contained in the linker must be faster than the rate of disintegration of the hydrophobic moiety and the amphiphilic stabilizer." Reply Br. 5; *see also,* Torchilin Decl.[9] ¶ 6. Otherwise the rate of release would be controlled by the rate of disintegration of the hydrophobic moiety and the amphiphilic stabilizer.

The Examiner appears to contend that the linkers used in Oh would inherently have this property because the types of bonds disclosed in Oh are the same types of bonds as disclosed in the Specification. Ans. 28. However, Oh itself suggests that this is not the case. Oh describes a study in which the release profiles of two nanoparticles was compared. Oh, 16:14–

[9] Declaration of Dr. Vladimir P. Torchilin submitted under 37 C.F.R. § 1.132, dated June 5, 2015 ("Torchilin Decl.").

15. One of the nanoparticles studied was a doxorubicin-PLGA conjugate in which the doxorubicin was linked to the PLGA by a carbamate bond. *Id.* at 16:15–24. Oh teaches that "the carbamate linkage between doxorubicin and PLGA was not easily cleaved in the aqueous medium." *Id.* at 16:24–25. As a result, and as Oh explains, the release of doxorubicin was controlled by the degradation of the polymer rather than the cleavage of the linker:

> The sustained release action was caused by the gradual chemical degradation of conjugated PLGA backbone and subsequent controlled liberation of water soluble doxorubicin-PLGA oligomer conjugates in the incubation medium. ***Their release rate was solely dependent on how fast the conjugated PLGA chains were hydrolyzed*** to reach the critical MW.

Id. at 16:25–30 (emphasis added).

We acknowledge that certain of the linkers disclosed by Oh overlap with those disclosed in the specification. *Compare* Spec. ¶ 40 (identifying "esters, carbonates, carbamates, disulfides and hydrazones" as linkers forming "hydrolysable or enzymatically cleavable bonds") *with* Oh, 3:66–4:3 ("This invention provides the system employing the ester bond, amide bond, anhydride bond, urea bond, urethane bond, carbonate bond, imine bond, thioester bond, disulfide bond or carbamate bond for conjugation of molecules with biodegradable polyester polymers."). However, the Examiner has not identified persuasive evidence that any of the types of linkers disclose in Oh would necessarily cleave faster than the polymer degrades, as required in order for the linker to control the rate of release of the active. In contrast, Appellant directs us to evidence that "the same type of bond, such as a carbamate[,] will have a cleavage rate depending on its surroundings not simply on its own nature." Reply 5 (citing Torchilin Decl. ¶ 7).

In sum, the evidence does not support that Oh discloses the conjugates inherently having the claimed property that the linker controls the release rate because: 1) Oh teaches that the release rate in one of its nanoparticles was controlled *solely* by the hydrolyzation of its biodegradable polymer, 2) the Examiner has not identified persuasive evidence that the cleavage rate of the linkers disclosed in Oh is inherently faster than the degradation of the polymers to which they linked, and 3) Appellant has provided evidence that the release rate of a linker depends on more than just the constitution of the linker. As the Examiner has not persuasively articulated a reason why it would have been obvious to use a linker that controls the release rate, as claimed, we reverse the Examiner's three obviousness rejections.

WRITTEN DESCRIPTION

The Examiner rejected claims 1, 3, 4, 7– 9, 13, and 16–24 for failure to comply with the written description requirement. In doing so, the Examiner articulated three rationales, each applying to a different group of claims. We reverse the only one of the Examiner's rationales that applies to all of the pending claims. We also reverse the rationale that applies only to claims 17–24. We affirm the rationale that applies only to claims 1, 3, 4, 7–9, 13, and 16. In addition, we find that the Examiner has not established that all of the pending claims include new matter. Our analysis of all three of the Examiner's rationales, as well as the Examiner's finding that all of the pending claims recite new matter, is set forth below.

Rationale 1: "selectively cleavable bond"

All of the pending claims require a bond that is "selectively cleavable by reduction or hydrolysis to control the rate of release of said active from the particle free of said hydrophobic moiety or portion thereof."[10] The Examiner found that the claims fail to comply with the written description requirement because the Specification does not describe "the bonds that are suitable for this function." Ans. 6–7. We are not persuaded.

The Specification teaches that "the invention concerns particulate constructs stabilized by an amphiphilic compound and comprising at least one active agent coupled through a linker to a hydrophobic moiety, which agent can be released from the construct by cleavage of the linker." Spec. ¶ 2. The Specification also discloses linkers that it asserts can perform this function. *Id.* ¶ 52; *see also, generally, id.* ¶¶ 49–63. The Examiner does not provide reason to doubt these assertions. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) ("If. . . the specification contains a description of the claimed invention, albeit not *in ipsis verbis* (in the identical words), then the examiner . . . , in order to meet the burden of proof, must provide reasons why one of ordinary skill in the art would not consider the description sufficient."). Accordingly, the Examiner has not carried its burden to establish that claims 1, 3, 4, 7–9, 13, and 16–24 fail to comply with the written description requirement on the basis that they do not describe bonds suitable as linkers.

[10] The quoted language is from claim 1. Claim 17 uses the plural "particles" rather than the singular "particle" recited in claim 1. This difference does not substantively impact our analysis.

Rationale 2: "Nano Precipitation"

Claim 17, and the claims depending therefrom, require that the claimed composition be obtained using a "Nano Precipitation process." The Examiner rejected these claims for failing to comply with the written description requirement on the basis that the Specification does not describe the "particular method steps" relating to this term. Ans. 6–7. We are not persuaded.

The Specification teaches that "Nano Precipitation" is term of art that describes a known method for forming particulate constructs. It states:

> A number of methods can be used to form the particulate constructs of the invention. One particularly useful method is a process termed "Nano Precipitation" as described by Johnson, B. K., *et al., AIChE Journal* (2003) 49:2264-2282 and U.S. 2004/0091546 incorporated herein by reference.

Spec. ¶ 75. The Examiner does not direct us to persuasive evidence that the ordinary artisan would not have known what the method steps of Nano Precipitation were, or would not have understood Appellant to be in possession of a composition comprising particles obtained using Nano Precipitation. Accordingly, the Examiner has not carried its burden to establish that claims 17–24 fail to comply with the written description requirement on the basis that they do not describe the "Nano Precipitation process."

Rationale 3: "the administered ratio . . . is maintained"

Appellant argues the rejection of claims 1, 3, 4, 7–9, 13, and 16 under rational 3 (i.e., the rationale that the Specification does not disclose "maintain[ing]" the "administered ratio" as claimed) together. We designate claim 1 as representative.

Claim 1 requires that two therapeutic agents be "present in the [claimed] composition in a non-antagonistic ratio," and that "the release of the first therapeutic agent from the particles is coordinated with the release of the second therapeutic agent so that the administered ratio of said first therapeutic agent to said second therapeutic agent in said composition is maintained when said composition is administered parenterally." The Examiner finds that the Specification does not provide written description support for this limitation because the components of the composition are "broad in scope," and "[t]he specification does not provide any examples of particles that contain a non-antagonistic ratio maintained for any length of time with the structures that provide such a function." Ans. 5–6. The Examiner points to Example 16 as describing nanoparticles containing cisplatin and paclitaxel (two therapeutic agents) that were administered to mice but notes that no results were provided and that the example concludes with the statement that "[t]he experiment is repeated at various paclitaxel:cisplatin ratios for various polymer compositions until the synergistic ratio is maintained after i.v. injection." *Id.* at 6. From this, the Examiner concludes that, "whatever the initial formulation was in this example, maintenance of the synergistic ration was not present and . . . further experimentation was required to provide particles in which a synergistic ratio was maintained." *Id.* The Examiner thus concluded that the Specification provided "no indication as to the structure and/or composition of the nanoparticles that resulted in maintenance of the synergistic ratio of the drug." *Id.*

We agree with the Examiner that Appellant's disclosure does not show that Appellant was in possession of compositions having the claimed

function of maintaining a non-antagonistic ratio between therapeutic agents when administered parenterally. This function is, according to Appellant's counsel, novel to the claimed composition. Tr. 6:22–7:3. ("Prior to the current invention, it was impossible to deliver two drugs to the correct ratio and maintain that ratio since different drugs had different solubility profiles.").

We begin by considering the scope of the claim. The structural components of claim 1 are very broadly defined. *See e.g.,* Spec. ¶¶ 45–48 (stating that "[a] wide variety of therapeutic agents can be included" and providing a long list of exemplary therapeutic agents); 50–62 (describing and providing examples of linkers), 66–69 (stating that "[t]he hydrophobic moiety may include polymers or natural products" and providing a long list of exemplary moieties), 70–74 (describing and providing a long list of exemplary amphiphilic stabilizers). Indeed, in its Reply Brief, Appellant states that the claims encompass "thousands of combinations of hydrophobic components, linkers and amphiphilic stabilizers that would achieve the intended result." Reply Br. 2; *see also,* Purd'homme Decl.[11] ¶ 3 (testifying that "the skilled artisan would have a wide variety of choices too numerous to be listed with any completeness . . . in order to construct . . . particles containing the conjugate"); Mayer Decl.[12] ¶ 3 (testifying that "there is a vast number of possible combinations that will result in particulate constructs meeting the requirements of the claims").

[11] Declaration of Robert K. Prud'homme submitted under 37 U.S.C. § 1.132, signed February 26, 2017 ("Prud'homme Decl.").
[12] Declaration of Lawrence D. Mayer submitted under 37 U.S.C. § 1.132, signed February 27, 2017 ("Mayer Decl.").

In support of this broad genus of functionally defined compositions, Appellant does not identify, and we do not find in the Specification, a single composition that has this functional characteristic. Nor do we find evidence in the Specification that the genus is identified by structural features common to members of the genus. This supports the Examiner's determination that the Specification does not provide written description support for claim 1. *See, Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1350. ("Sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.").

We recognize that the portions of the Specification cited above provide descriptions of each of the individual components of the claimed composition. What is missing is a disclosure of a correlation between inclusion of each of the recited components in the claimed composition and the claimed function of maintaining the ratio of therapeutic agents. *See Enzo Biochem Inc. v. Gen-Probe Inc.,* 323 F.3d 956, 964 (Fed. Cir. 2002) (holding that the written description requirement is met for a functional claim limitation where the function is "coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed"). Here, rather than provide a correlation between structure and function, the Specification suggests arriving at the claimed structure by trial and error experimentation.

In particular, Example 16, which Appellant cites as providing support for the claimed function (Appeal Br. 16), describes investigating

"[n]anoparticles containing both cisplatin and paclitaxel . . . for *in vivo* release rates" by injecting a composition comprising the nanoparticles into mice. Spec. ¶¶ 162–163. It concludes with the statement: "[t]he experiment is repeated at various paclitaxel:cisplatin ratios for various polymer compositions until the synergistic ratio is maintained after i.v. injection." *Id.* ¶ 163.[13] We agree with the Examiner that this statement suggests that Appellant did not have possession of a composition having the claimed functional characteristic at the time Experiment 16 was described in the application.[14] Ans. 6. In addition, this statement suggests identifying polymers that perform the claimed function (when used in combination with the other components of the composition) not by relying on a correlation between the structure of the polymer and the claimed function, but by brute force repetition with "various . . . polymer compositions until the synergistic ratio is maintained." *Id.*

Appellant argues that the claims themselves provide the structure required to satisfy the written description requirement. Appeal Br. 8. More specifically, Appellant contends that the claim structurally and functionally defines "the sizes of the conjugate, the linker, the hydrophobic moiety, the amphipathic stabilizer, as well as the function of the linker, the ratio of the two drugs and the timing of drug release." *Id.* We are not persuaded.

Although Appellant is correct that claim 1 defines certain structural aspects of the claimed composition, including, e.g., a range of molecular

[13] We understand the "polymer composition" referenced in Exhibit 16 to correspond to the "hydrophobic moiety" component of claim 1. *See* Spec. ¶ 66 (teaching that the hydrophobic moiety "may include polymers").
[14] We note that Example 16 describes the experiment in present tense and is therefore a prophetic, rather than a working, example.

weights for the hydrophobic moiety and the amphiphilic stabilizer, we are not persuaded that the recited structure provides written description support for the recited function. As discussed above, Appellant does not direct us to persuasive evidence that these structural features correlate with maintaining the claimed release profile. *See Enzo Biochem Inc.,* 323 F.3d at 964. Indeed, at least with respect to the ratio of agents and the identity of the hydrophobic moiety, Example 16 (discussed above) suggests using trial and error rather than structural correlation to identify appropriate components. Further, Example 16 makes clear Appellant's expectation that compositions having the claimed components may lack the recited function of maintaining the ratio of therapeutic agents.

In addition, the evidence supports that obtaining a particular release rate for the first therapeutic agent – one aspect of maintaining the claimed ratio of therapeutic agents – depends on more than just the identity of the linker. *See* Prud'homme Decl. ¶¶ 6–7 ("the rate of hydrolysis of the linkage depends not only on the nature of the cleavable bond itself but other factors such as its distance from the polymer backbone, the hydrophilicity of the surrounding groups and steric crowding around the center of reaction"). Accordingly, we are not persuaded that the broad recitation of structure in the claims is sufficient to show possession of a composition having the claimed function.

Appellant argues that the Specification teaches "how to form the nanoparticles, how to attach the linkers to the drug and hydrophobic moieties, how to determine non-antagonistic ratios, and how to test for effective drug combination[s]." Appeal Br. 9 (internal citations omitted). According to Appellant, the Specification also provides examples showing

"conjugation with active drugs and polymers/hydrophobic moieties, formation of conjugates into nanoparticles, combination therapies, and controlled delivery, among other things." *Id.* (internal citations omitted). Finally, Appellant points to the Specification, certain references, and two Declarations as showing that "the science has matured to a degree that it is predictable and can be relied on to show Written Description of the present invention." *Id.* at 10. We are not persuaded.

The evidence cited by Appellant goes to whether the ordinary artisan would be able to make and use the claimed composition, not whether the Appellant has provided a written description of the invention. *See e.g.,* Prud'Homme Decl. ¶ 8 ("In summary, the skilled artisan would readily be able to construct particles with the requirements of the claims without further description from that in the specification"); Meyer Decl. ¶ 5 ("Thus, it [(i.e., the information provided in the Specification)] is in fact sufficient to inform the skilled artisan that the nature of the hydrophobic moiety and the nature of the cleavable bond should be such that the cleavable bond controls the release of the coupled agent free of the hydrophobic moiety or portions thereof to enable the skilled artisan to construct the claimed particles."); *see also,* Appeal Br. 11 ("There is ample evidence of record that the skilled artisan, once advised of the inventive concept, could, without further instruction[,] combine the known elements that lead to the claimed function."). Appellant does not direct us to persuasive evidence that the ordinary artisan would have understood Appellant to *possess* any particular composition having the claimed function.

Even crediting that the evidence submitted by Appellant does, in fact, teach the ordinary artisan how to make and use the claimed composition,

that alone does not satisfy the written description requirement. *Ariad,* 598 F.3d at 1344 (holding that 35 U.S.C. § 112 "contains two separate description requirements: a 'written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention']." (alterations in original)); *Goeddel v. Sugano,* 617 F.3d 1350, 1356 (Fed. Cir. 2010) ("The question is not whether one skilled in this field of science might have been able to produce mature hFIF by building upon the teachings of the Japanese Application, but rather whether that application 'convey[ed] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'"). As our reviewing court explained, "[o]ne shows that one is 'in possession' of *the invention* by describing *the invention,* with all its claimed limitations, not that which makes it obvious." *Lockwood v. American Airline, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997).

Accordingly, we affirm the Examiner's rejection of claims 1, 3, 4, 7–19, 13, and 16 under 35 U.S.C. § 112 as failing to comply with the written description requirement.

New Matter

The Examiner found that claims 1, 3, 4, 7–9, 13, and 16–24 contain new matter because they require a linker that is "selectively cleavable by reduction or hydrolysis to control the rate of release of said active from the particle free of said hydrophobic moiety or portion thereof." Ans. 3. According to the Examiner, while the linker is taught to control the rate of release from the hydrophobic moiety, it is not taught that the linker controls "the rate of release of the drug from the particle." *Id.* at 4. As discussed above, the Specification teaches that "the invention concerns particulate constructs stabilized by an amphiphilic compound and comprising at least

one active agent coupled through a linker to a hydrophobic moiety, which agent can be released from *the construct* by cleavage of the linker." Spec. ¶ 2 (emphasis added). The Specification also discloses linkers that it asserts can perform this function. *Id.* ¶ 52; *see also, generally, id.* ¶¶ 49–63. Accordingly, we do not agree with the Examiner's conclusion that claims 1, 3, 4, 7–9, 13, and 16–24 comprise new matter.

INDEFINITENESS

Claims 1, 3, 4, 7–9, 13, and 16

Claims 1, 3, 4, 7–9, 13, and 16 require that the conjugate and particles be "constructed so that the release of the first therapeutic agent from the particles is coordinated with the release of the second therapeutic agent so that the administered ratio of said first therapeutic agent to said second therapeutic agent in said composition is maintained when said composition is administered parenterally." The Examiner found that these claims were indefinite because neither the claims nor the Specification "provide a link between the structure(s) that provide the claimed function of coordinated release of the first and second therapeutic agents such that the non-antagonistic ratio of the two drug is maintained following parenteral administration." Ans. 8. The Examiner notes that the claims encompass "all means or methods of resolving the problem" but contends that because "[t]he specification fails to provide examples of the structures that provide this function, . . . one of ordinary skill in the art would not be able to draw a clear boundary between what is and is not covered by the claims." *Id.* We are not persuaded.

The Examiner does not provide persuasive evidence or argument to support that the ordinary artisan would not have been able to determine what

was meant by the requirement that the ratio of the first therapeutic agent to the second therapeutic agent be maintained when the composition administered parenterally. Put another way, the current record does not support that, for any given composition, the ordinary artisan would be unable to ascertain whether that composition met the requirement for coordinating the release of therapeutic agents. Thus, although we agree with the Examiner that claims 1, 3, 4, 7–9, 13, and 16 are potentially quite broad in encompassing a wide range of compositions that provide the claimed function, and that the Specification does not provide examples of compositions that provide the claimed function, we do not agree with the Examiner that the ordinary artisan would "not be able to draw a clear boundary between what is and is not covered by the claims." *Id.*; *In re Miller*, 441 F.2d 689, 693 (CCPA 1971) ("[B]readth is not to be equated with indefiniteness."). Accordingly, we reverse the Examiner's rejection of claims 1, 3, 4, 7–9, 13, and 16 as indefinite.

Claims 17–24

Claim 17 requires a composition comprising particles that are "obtained from fast mixing according to the Nano Precipitation process." The Examiner rejected claim 17, and the claims depending therefrom, as indefinite on the basis that the term "Nano Precipitation process" lacked antecedent basis. Ans. 9. According to the Examiner, "[n]o particular method steps are recited in the body of the claim to further define the process referenced in the preamble of the claim and . . . [t]herefore the scope of the process that is used to prepare the nanoparticles in claim 17 is unclear." We are not persuaded.

As discussed above with respect to written description, the Specification teaches that "Nano Precipitation" is term of art describing a known method for forming particulate constructs. Spec. ¶ 75. The Examiner does not direct us to persuasive evidence that the ordinary artisan would not have known what the method steps of Nano Precipitation were, or would otherwise not have understood what was meant by the term "Nano Precipitation." Accordingly, we reverse the Examiner's rejection of claims 17–24 as indefinite.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Basis/Reference	Affirmed	Reversed
1, 3, 4, 7–9, 13, 16–24	112	Written description	1, 3, 4, 7–9, 13, 16	17–24
1, 3, 4, 7–9, 13, 16–24	112	Indefiniteness		1, 3, 4, 7–9, 13, 16–24
1, 3, 4, 7–9, 16–24	103	Oh, Soppimath, McLeod, Muggia, Tardi		1, 3, 4, 7–9, 16–24
17–24	103	Oh, Soppimath, McLeod, Muggia		17–24
17–24	103	Oh, Soppimath, McLeod, Muggia, Johnson		17–24
Overall Outcome			1, 3, 4, 7–9, 13, 16	17–24

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). *See*, 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART