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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HOSSEIN OMIDIAN, YOGESH N. JOSHI, and RAND HUSNI MAHMOUD AHMAD

Appeal 2020-005200
Application 16/122,360
Technology Center 1600

Before ERIC B. GRIMES, RICHARD M. LEBOVITZ, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The Examiner rejected the claims under 35 U.S.C. § 112 as lacking written description and as indefinite and under 35 U.S.C. § 103 as obvious. Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject the claims. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

[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 MEC Device Pharma International LLC. Appeal Br. 3.

STATEMENT OF THE CASE

The claims stand rejected by the Examiner in the Final Office Action as follows:

1. Claims 1, 3, and 14–30 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph,[2] as failing to comply with the written description requirement. Final Act. 4.

2. Claims 1, 3, and 14–30 under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention. Final Act. 5.

3. Claims 1, 3, 16–19, 22, and 24–30 under 35 U.S.C. § 103 as obvious in view of Barnscheid et al. (US 2012/0065220 A1, published Mar. 15, 2012) ("Barnscheid"), Ghebre-Sellassie (US 2015/006425 A1, published Mar. 5, 2015) ("Ghebre-Sellassie"), Tracy ("Drug Absorption and Distribution"[3]) ("Tracy"), Mehta et al. (US 8,491,935 B2, issued July 23, 2013) ("Mehta"), Lubrizol (Pharmaceutical Bulletin, "Pharmaceutical Applications" May 31, 2011) ("Lubrizol"), and Florence et al. ("Physicochemical properties of drugs in solution"[4]) ("Florence"). Final Act. 6–7.

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[2] The earliest claimed priority date of the application is Aug. 10, 2017, which is after § 112(a) went into effect. It is therefore not clear why the Examiner has stated the rejection as alternatively under pre-AIA § 112, first paragraph, which was not in effect at the time the application was filed. The same applies to the rejection under § 112(b) and § 112, second paragraph.
[3] Craig, Charles R. & Stitzel, Robert E., *Modern Pharmacology with Clinical Applications* (6th ed.), pp. 20–32. Lippincott, Williams & Wilkins, Philadelphia (2004).
[4] *Physicochemical Principles of Pharmacy* (4th ed.), pp. 55–92. Pharmaceutical Press (2006).

4. Claims 1, 3, 14–19, and 22–30 under 35 U.S.C. § 103 as obvious in view of Barnscheid, Ghebre-Sellassie, Tracy, Lubrizol, Florence, and Chen et al. (US 2004/0013731 A1, published Jan. 22, 2004) ("Chen"). Final Act. 13.

5. Claims 1, 3, 16–22, and 24–30 under 35 U.S.C. § 103 as obvious in view of Barnscheid, Ghebre-Sellassie, Tracy, Lubrizol, Florence, Chang (US 2006/0083690 A1, published Apr. 20, 2006) ("Chang"), Neal (US 2011/0144409 A1, June 16, 2011) ("Neal), and EMS World ("Drug Abuse Update: Dextromethorphan")[5]. Final Act. 15,

Claim 1, the only independent claim on appeal, is reproduced below. The claim is annotated with bracketed numbers to reference the components of the tablet or capsule.

> 1. An abuse-resistant orally-administrable tablet or capsule comprising: [1] a cationic drug, [2] a poly(acrylic acid) interpolymer, and [3] at least one nonionic amphiphilic polymer; wherein
>
> the weight ratio of [1] the cationic drug to [2] poly(acrylic acid) interpolymer in the tablet or capsule is 1:1 to 1:10, about 1:10, or about 1:20;
>
> more than 50% of [1] the cationic drug in the tablet or capsule is ionically bound to [2] the poly(acrylic acid) interpolymer in [4] a solid drug-polymer complex such that the cationic drug is partially prevented from being extracted from the tablet or capsule in each of water, hydroalcohol solutions, pH 3 solutions, acetic acid solutions, and saline at solution temperatures of 20–90°C, while allowing release of [1] the cationic drug from the tablet or capsule in 0.1N HCl at 37°C;
>
> wherein [4] the solid drug-polymer complex is made by reacting [1] the cationic drug and [2] the poly(acrylic acid) interpolymer at a weight ratio of between 2:1 and 1:15 in an

[5] https://www.emsworld.com/article/10324941/drug-abuseupdate-Dextromethorphan (Feb. 1, 2004) (last accessed Mar. 4, 2019).

> aqueous solution at a pH range of greater than the pKa-1 of [2] the poly(acrylic acid) interpolymer and lower than the pKa+1 of [1] the cationic drug.

1., 2. REJECTIONS BASED ON § 112

The Examiner rejected the claims as lacking written description and as indefinite in the recitation of "partially prevented" in the phrase "the cationic drug is partially prevented from being extracted from the tablet or capsule." Final Act. 4.

We reverse the rejections. It is correct that the recited language does not literally appear in the Specification. However, in describing the claimed invention, there is no requirement that the wording in the claim be identical to that used in the specification as long as there is sufficient disclosure to show one of skill in the art that the inventor "invented what is claimed." *Union Oil Co. v. Atlantic Richfield Co*., 208 F.3d 989, 997 (Fed. Cir. 2000) (citation omitted). The written description requirement is met when a person "of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification." *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996).

Here, as explained by Appellant, the Specification discloses that a low- and high-loaded complex (the claimed "solid drug-polymer complex") did not completely prevent drug from being extracted from the tablet. For example, Table 28 of the Specification shows that the high-loaded drug-polymer complex retained 99%, 95%, 74%, 65%, etc. of drug under the different extraction procedures; thus, some drug (1%, 5%, 26%, 35%) was released into the extraction medium. Spec. ¶ 137. Fig. 32 in the Specification

further depicts the amount of drug bound after being subjected to the various extractions described in Table 28. The complex partially prevented the drug from being eluted from the tablet because some amount of drug was extracted under each condition. For this reason, one of ordinary skill in the art, upon reading the Specification would recognize that Appellant had possession of the claimed invention at the time of filing.

Based on the aforementioned disclosure in the Specification, one of ordinary skill would understand that the phrase "the cationic drug is partially prevented from being extracted from the tablet or capsule" reflects the actual data in the Specification that the claimed "solid drug-polymer complex" did not completely prevent at least some drug from being extracted under the recited conditions. Both rejections under § 112 are therefore reversed.

3. OBVIOUSNESS REJECTION BASED ON BARNSCHEID AND GHEBRE-SELLASSIE

Claim 1 is directed to an abuse-resistant orally-administrable tablet or capsule that comprises four components: [1] a cationic drug, [2] a poly(acrylic acid) interpolymer, [3] at least one nonionic amphiphilic polymer, and [4] a solid drug-polymer complex in which "more than 50% of [1] the cationic drug in the tablet or capsule is ionically bound to [2] the poly(acrylic acid) interpolymer."

The Examiner found that Barnscheid describes a tamper resistant dosage form comprising an active compound and an anionic polymer bearing anionic functional groups. Final Act. 7. The Examiner also found that Barnscheid discloses that a "controlled release may be based upon various concepts such as binding the active compound to an ion-exchange

resin forming a complex of the active compound (paragraph 0013)." *Id.* (emphasis omitted). The anionic polymer corresponds to the claimed [2] poly(acrylic acid) interpolymer and the active compound to the [1] cationic drug of claim 1.

The Examiner found that preferred anionic polymers described in Barnscheid are interpolymers of acrylic acid as claimed ([2]). Final Act. 8. The Examiner cited Example 7 of Barnscheid which discloses a dosage of tramadol ([1] a cationic drug) and carbopol ETD 2020NF. *Id.* The Examiner found, relying on Lubrizol, that carbopol ETD 2020NF is a carbopol interpolymer type B, meeting the claim limitation of [2] the poly(acrylic acid) interpolymer. *Id.* at 10. Although both [1] and [2] are described by Barnscheid in a dosage form, the Examiner stated that Barnscheid does not state that the drug is "ionically bound" to the anionic polymer as required by the claim. *Id.* at 8 (i.e., "[1] the cationic drug in the tablet or capsule is ionically bound to [2] the poly(acrylic acid) interpolymer in [4] a solid drug-polymer complex").

To meet the limitation of the claim that the "[1] the cationic drug in the tablet or capsule is ionically bound to [2] the poly(acrylic acid) interpolymer" to form the "[4] solid drug-polymer complex," the Examiner further cited Ghebre-Sellassie. Final Act. 9. The Examiner found Ghebre-Sellassie discloses a tamper resistant dosage form that comprises a therapeutic agent and a substrate which forms a complex held together by ionic bonds as recited in claim 1. *Id.* The Examiner found that Ghebre-Sellassie describes a cationic drug, dextromethorphan, as the therapeutic agent and polyacrylic acid as the substrate, corresponding to [1] and [2] of claim 1, respectively. *Id.* The Examiner cited Mehta as teaching that

dextromethorphan is a drug with cationic functionality that would complex with the anionic polymer of Barnscheid. *Id.* at 11.

With respect to the limitation in claim 1 of how the drug-polymer complex is made, the Examiner cited the teaching in Tracy that adjusting the pH of a solution in accordance with the pKa of the compounds in it, determines the proportion of ionized and nonionized molecules in it. Final Act. 10. The Examiner also cited Florence for teaching a specific pKa. *Id.*

Based on the teachings in Barnscheid, Ghebre-Sellassie, Tracy, and Mehta, the Examiner determined that one of ordinary skill in the art would have had reason to form the cationic drug and anionic polymer of Barnscheid into a complex with ionic binding, as described by Ghebre-Sellassie, to control the release of the drug as taught by each of Barnscheid and Ghebre-Sellassie. Final Act. 10. The Examiner also found it obvious to use a cationic drug as taught by Mehta so it can form a complex with the anionic polymer described in Barnscheid. *Id.* at 11.

The Examiner also determined it would have been obvious to one of ordinary skill to manipulate the pH in accordance with the pKa, as taught by Tracy, to produce ionized forms of the drug and polymer which would form the complexes held together by ionic bonds as taught by Ghebre-Sellassie. Final Act. 11. The Examiner stated to "to minimize waste, one skilled in the art would manipulate the pH in order to maximize the ionic interactions." *Id.*

The Examiner also found the [3] nonionic amphiphilic polymer and the specific weight ratios recited in the claim to be obvious based on Barnscheid and Ghebre-Sellassie. Final Act. 12.

Discussion

Claim 1 recites that "more than 50% of [1] the cationic drug in the tablet or capsule is ionically bound to [2] the poly(acrylic acid) interpolymer in [4] a solid drug-polymer complex." Appellant argues that Barnscheid "says nothing" about the polymer being ionically bound to the drug. Appeal Br. 9 (emphasis omitted). Appellant contends that in all the examples in Barnscheid "the tablet ingredients were simply mixed and then hot-melt extruded – conditions which would not place the polymer and drug at a pH which would lead to significant ionic binding between the polymer and drug." *Id.* Appellant further argues that Barnscheid teaches there is no limitation as to the type of drug which can be incorporated into its tablet, "indicating that the inventors thereof did not contemplate any type of ionic bonding between the drug and the matrix polymer (e.g., an anionic drug would not ionically bond an anionic polymer, and a non-ionic drug could not form ionic bonds with and [sic, any] type of polymer)." Appeal Br. 9.

These arguments are not persuasive. Barnscheid teaches:

> by selection of an appropriate amount of an appropriate matrix polymer bearing anionic functional groups the release profile of the pharmaceutical dosage form can be varied over a broad range and . . . the release of the pharmacologically active ingredient can be particularly retarded compared to a pharmaceutical dosage form not containing said amount of said matrix polymer bearing anionic functional groups.

Barnscheid ¶ 23.

Thus, the presence of the anionic group, which is charged, is specifically described by Barnscheid as retarding the release of the pharmacologically active ingredient. While Barnscheid does not expressly describe the complex as being formed from ionic bonds, an ionically

charged polymer is required by Barnscheid to be part of the complex, indicating the importance of charged groups. Furthermore, Example 7 of Barnscheid, as found by the Examiner comprises the same anionic polymer and same cationic drug as claimed.[6] Thus, contrary to Appellant's assertion, it is not clear from reading Barnscheid that the inventors did not "contemplate" ionic binding as holding the complex together as asserted by Appellant.

Appellant asserts, with no objective evidence, that the hot melt conditions in Barnscheid would not lead to significant ionic binding. "[A]ttorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness." *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

Appellant also argues that Ghebre-Sellassie does not teach ionic bonding between the drug and substrate. Appeal Br. 10. Rather, Appellant states that Ghebre-Sellassie defines "complex" as meaning:

> a chemical association of a drug substance with a substrate through ionic bonds, polar covalent bonds, covalent bonds, and [**not "or" or "and/or"**] hydrogen bonds (see definition in paragraph 35), thus unequivocally indicating that the reactive extrusion process described in that reference results in not just ionic binding between the drug and substrate, but also polar covalent, covalent, and hydrogen binding.

Appeal Br. 10 (brackets and emphasis in the original).

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[6] Appellant disparages Barnscheid's teaching of an acrylic polymer because it is among a list of possible polymers. Appeal Br. 9. However, Appellant did not address Barnscheid's teaching that acrylic acid based polymers are preferred (at ¶ 72) and the same polymer which is claimed is actually used by Barnscheid in Example 7 (at ¶ 313) in combination with tramadol which is a cationic drug.

We do not agree with Appellant's interpretation of Ghebre-Sellassie. As stated by Appellant, Ghebre-Sellassie discloses that the complex of drug and polymer can be a chemical association of "ionic bonds, polar covalent bonds, covalent bonds, and hydrogen bonds." Ghebre-Sellassie ¶ 35. One of ordinary skill in the art would not have interpreted the definition to require each of these bonds because not all molecules comprise the atom types that would enable each of an ionic, polar covalent, covalent, and hydrogen bond to form between the therapeutic agent and substrate. Moreover, even if all such bonds were required in the complex of Ghebre-Sellassie, the claim does not exclude other types of bonds from being present in the claimed drug-polymer complex in addition to the claimed requirement of the drug being ionically bound to the polymer. Thus, we find that the Examiner provided adequate evidence that Ghebre-Sellassie teaches a complex between a drug and an acrylic polymer (at ¶ 56), the same preferred polymer of Barnscheid, where the complex is a chemical association comprising ionic bonds between the polymer and the drug.

Appellant argues that Ghebre-Sellassie does not teach the claimed poly(acrylic acid) interpolymer. Appeal Br. 10. However, Ghebre-Sellassie teaches poly(acrylic) polymers and acrylic acid, which generically include the poly(acrylic acid) interpolymer of Barnscheid, reasonably suggesting that the specific species of acrylic polymer of Barnscheid would be useful in the complex described by Ghebre-Sellassie. While Ghebre-Sellassie describes other polymers asserted by Appellant (Appeal Br. 11), these teachings do not nullify the specific teaching in Ghebre-Sellassie that acrylic polymers are suitable for its complex.

Appellant also contends that the cited publications do not teach that "more than 50% of the cationic drug in the tablet or capsule is ionically bound to the poly(acrylic acid) interpolymer in a solid drug-polymer complex" as recited in claim 1. Appeal Br. 8, 10, 11. The Examiner responded that Ghebre-Sellassie describes washing the complex to remove "any free uncomplexed drug" (Ghebre-Sellassie ¶ 93), which the Examiner found would result in 100% of the drug bound by the complex, meeting the claim limitation. Ans. 8. Appellant did not respond to this evidence, which we find supports the Examiner's finding and determination that the 50% bound limitation is met by Ghebre-Sellassie. For this reason, we find Appellant's arguments regarding this limitation to be unavailing.[7]

Appellant argues that Ghebre-Sellassie does not describe modifying the reaction between the substrate and drug by modifying the pH at which it takes place. Appeal Br. 11. Appellant contends that this deficiency is not cured by Tracy or Barnscheid. *Id.* Appellant argues that Tracy does not describe anything about complexing a drug with a polymer. *Id.* Appellant asserts:

> [It] would be an extraordinarily huge creative leap for such artisan to understand that the technologies described in Barnscheid and/or Ghebre-Sellassie should be modified to increase the level of ionic bonding between the drug and polymer, and to do so by extrapolating Tracy's teaching about the

[7] Appellant argues that because "neither Barnscheid nor Ghebre-Sellassie teach that a high level of ionic bonding between a drug and a polymer substrate is important for making an extraction-resistant drug formulation, these references do not provide the skilled artisan with any motivation to seek a method of making a formulation with more than 50% of the cationic drug ionically bound to a polymer." Appeal Br. 11. However, the Examiner established that the 50% bound limitation is met by Ghebre-Sellassie, rebutting this contention with factual evidence.

> role of pKa and pH in drug absorption and distribution (not drug formulation for abuse resistance) to fashion a method of controlling pH in a reaction between a drug and polymer to achieve such increase.

Appeal Br. 11–12.

This argument does not demonstrate error in the Examiner's rejection.

Ghebre-Sellassie provides an express statement that its complex comprises ionic bonding between the substrate and drug. Ghebre-Sellassie ¶ 35. An ionic bond by definition is a linkage between oppositely charged ions.[8] Because Ghebre-Sellassie states that the complex can be formed by ionic bonds between the drug and substrate, Ghebre-Sellassie reasonably suggests to one of ordinary skill in the art using a charged drug and charged substrate to form the complex. This is explicitly described by Mehta, which is also cited by the Examiner in the rejection.[9] Mehta teaches:

> Use of ion-exchange resins to form a drug-ion exchange resin complex is well known and is described, for example, in U.S. Pat. No. 2,990,332. In this patent, the use of an ion-exchange resin to form a complex with ionic drugs and thereby delay the drug release from such complexes is described.

Mehta, col. 1, ll. 14–19. A similar statement was cited by the Examiner in Barnscheid at ¶ 13.

Mehta further explains that the ion-exchange resin, used as the substrate to which the drug binds, is charged, under the appropriate pH:

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[8] "The definition of ionic bond is when a positively charged ion forms a bond with a negatively charged ions and one atom transfers electrons to another." https://www.yourdictionary.com/ionic-bond (last accessed Aug. 10, 2020).

[9] Chen, discussed below in the second obviousness rejection, also describes a complex made of drug and polymer held together by ionic bonds. Chen ¶ 30.

> Ion-exchange resins suitable for use in these preparations are water-insoluble and comprise a preferably pharmacologically inert organic and/or inorganic matrix containing functional groups that are ionic or capable of being ionized under the appropriate conditions of pH.

Mehta, col. 5, ll. 42–46.

Mehta also refers to the drugs being ionically charged, and matching the charge of the drug to the charged substrate:

> Other suitable ion-exchange resins include anion exchange resins, such as have been described in the art and are commercially available. These resins are particularly well suited for use with acidic drugs.

Mehta, col. 6, ll. 52–55.

> Cation exchange resins, e.g., AMBERLITE IRP-69, are particularly well suited for use with drugs and other molecules having a cationic functionality. . . . Cationic exchange resins are readily selected for use of these basic drugs or other drugs identified herein and/or are those which are known to those of skill in the art.

Mehta, col. 7, ll. 15–30.

> The drugs that are suitable for use in these preparations in terms of chemical nature are acidic, basic, amphoteric, or zwitterionic molecules.

Mehta, col. 7, ll. 44–46.

Mehta also discloses the effect of pH on the anion exchange resin (col. 5, ll. 42–46) (reproduced above) and describes adjusting the pH of drug solutions (col. 28, ll. 15–16; col. 29, ll. 49–51).

The teachings in Mehta are therefore fully consistent with Ghebre-Sellassie's disclosure of forming complexes through ionic bonding. Tracy provides evidence of what one of ordinary skill in the art would know, namely, that pH determines the ionic state of a compound and that to choose

a pH at which a compound is ionized, the skilled worker would know to use the pKa value. Tracy 21.

Appellant's statement that it is "an extraordinarily huge creative leap" for a skilled worker to use the pKa to determine the drug or substrate ionization (Appeal Br. 11) fails to take into account the express teachings in Ghebre-Sellassie and Mehta that the drug-polymer complexes are formed by ionic bonding between ionized compounds, providing a direct reason to determine the appropriate pH at which the compounds are ionized, using the compound's pKa.

We further take note of the Examiner's finding, albeit with respect to claim 14, that "reacting" the drug and polymer at the recited pH range to form the complex is a product-by-process limitation, i.e., it defines the claimed product by how it is made. Final Act. 14. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). The patentability of the product therefore does not depend on the way the product was produced, unless the method of production imparts a structure or other characteristic to the product which distinguishes it over the prior art. Here, Appellant has not provided evidence that making the product by "reacting" the polymer and cationic drug as claimed results in a product any different than the product made by following the guidance in Barnscheid (example 7), Ghebre-Sellassie, or Mehta.

For the foregoing reasons, we affirm the rejection of 1, 3, 16–19, 22, and 24–30. The claims were not argued separately and therefore they fall together. 37 C.F.R. § 41.37(c)(1)(iv).

4. REJECTION BASED ON CHEN

Claim 14 depends from claim 1 and further recites "wherein the aqueous solution comprises an alkalinizing agent that causes the pH range of the aqueous solution to be greater than the pKa-1 of the poly(acrylic acid) interpolymer and lower than the pKa+1 of the cationic drug." In claim 15, which depends from clam 14, the alkalinizing agent is a bicarbonate salt.

The Examiner found that Chen teaches using an alkalinizing agent to adjust the pH in forming a complex between a drug with a nitrogen moiety and an anionic polymer. Final Act. 13. The Examiner found it obvious to adjust the pH based on the teachings described in Barnscheid and Ghebre-Sellassie as described above. *Id.* at 14.

Appellant argues

> Chen, in fact, does not expressly state that the drug microparticles described therein *have any ionic binding with a polymer*. Rather, the only mention of such ionic binding is at paragraph 30 and Fig. 2 ["Fig. 2 depicts the ionic interaction of acidic polymer (Eudragit L100) and amine drugs ["]]. This reference, however, does not make clear that the method described in paragraph 58 or in the Examples section leads to any ionic binding between the drug and the polymer much less the 50% threshold recited in claim 1.

Appeal Br. 14 (bracket around quoted portion in original).

This argument is not persuasive. Appellant quotes from Chen's description of Fig. 2. Figure 2 is copied below (annotated with a circle around the amine drug):

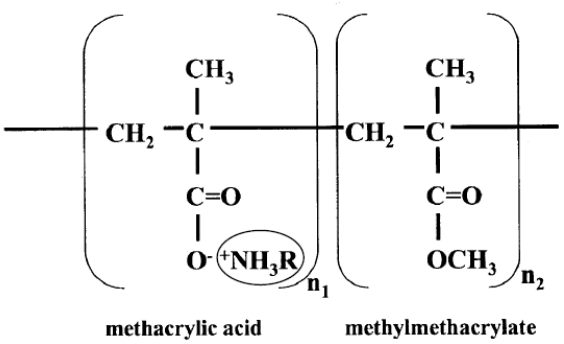

Figure 2, reproduced above, "depicts the ionic intera[c]tion of acidic polymer (Eudragit L100) and amine drugs." Chen ¶ 30. For reference, we annotated the drawing by circling the amine containing drug. The drawing expressly shows the polymer as negatively charged and the drug as positively charged drawn in a manner to convey the ionic bonding between the drug and polymer. Appellant's statement that it is not "clear" that Chen teaches ionic binding between the drug and substrate is wholly inconsistent with what is drawn in Fig. 2. Appellant does not provide an explanation as to what Chen means by this drawing other than to show that the drug is ionically bound to the polymer, the same teaching described by Ghebre-Sellassie and Mehta.

As to using the bicarbonate to adjust the pH, Appellant argues that Chen does not disclose that the sodium bicarbonate used in its formulations was for the purpose of adjusting the pH. Appeal Br. 14–15. While this may be true, the Examiner found, relying on more general knowledge, that the skilled worker "would manipulate the amount of the buffer in order to achieve the desired pH" and would have been motivated to "utilize known pH adjusting agents such as bicarbonates in order to provide the optimal pH for complex formation." Final Act. 14. Appellant states that this reasoning "fails to consider that there is no evidence on record that connects pH and

pKa to producing a cationic drug-poly(acrylic acid) interpolymer complex wherein more than 50% of the cationic drug is ionically bound to the poly(acrylic acid) interpolymer." Appeal Br. 15. However, as explained above, the evidence of record supports the Examiner's position that it would have been obvious based on the teachings in Barnscheid, Ghebre-Sellassie, Tracy, Mehta, Lubrizol, and Florence to adjust pH in accordance with the pKa of the drug and polymer to ionize them to form the complex of Ghebre-Sellassie.

In addition, as mentioned above, the Examiner also found that the requirement to add alkalinizing agent to produce the complex is a product-by-process limitation and does not impart patentability to the claimed process unless the process steps impart distinguishable characteristics to the product, which has not been demonstrated here. Final Act. 14.

For the foregoing reasons, we affirm the rejection of 1, 3, 14–19, and 22–30. The claims were not argued separately and therefore they all fall together. 37 C.F.R. 41.37(c)(1)(iv).

5. REJECTION BASED ON CHANG

Appellant relied on the same arguments made for the rejection based on Barnscheid, Ghebre-Sellassie, Tracy, Mehta, Lubrizol, and Florence. Appeal Br. 16. The rejection of claims 1, 3, 16–22, and 24–30 is therefore affirmed for the same reasons.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3, 14–30	112(a)	Written description		1, 3, 14–30
1, 3, 14–30	112(b)	Indefinite		1, 3, 14–30
1, 3, 16–19, 22, 24–30	103	Barnscheid, Ghebre-Sellassie, Tracy, Mehta, Lubrizol, Florence	1, 3, 16–19, 22, 24–30	
1, 3, 14–19, 22–30	103	Barnscheid, Ghebre-Sellassie, Tracy, Mehta, Lubrizol, Florence, Chen	1, 3, 14–19, 22–30	
1, 3, 16–22, 24–30	103	Barnscheid, Ghebre-Sellassie, Tracy, Mehta, Lubrizol, Florence, Chang, Neal, EMS World	1, 3, 16–22, 24–30	
Overall Outcome			**1, 3, 14–30**	

TIME PERIOD

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)(iv).

AFFIRMED