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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAN VERTOMMEN and MARIE SOPHIE MARTINA

Appeal 2019-003534
Application 14/655,049
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134(a) involving claims to an enteric coating for a soft capsule shell. The Examiner rejected the claims as lacking written description and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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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 Capsugel Belgium NV (*see* Br. 4).

[2] We have considered and herein refer to the Specification of June 23, 2015 ("Spec."); Final Office Action of Jan. 4, 2018 ("Final Act."); Appeal Brief of Aug. 21, 2018 ("Br."); and Examiner's Answer of Jan. 28, 2019 ("Ans.").

Statement of the Case

Background

"Different techniques have been used to impart enteric release properties to [] hard or softgel capsule shells" (Spec. ¶ 6). "For soft capsules, [] post-treatment spraying or film coating may result in shells that are brittle and hard to handle, or that agglomerate into a non-functional mass" (*id.*). "[E]nteric coatings for softgel capsules . . . must be stable, must not impart undesirable stickiness, and must not adversely affect characteristics of dissolution and/or brittleness in the finished softgel dosage form" (*id.* at ¶ 10).

"The instant disclosure relates to an innovative enteric coating formulation for softgel capsules having selective concentrations of glidant, emulsifier, and plasticizer" (Spec. ¶ 11). "A lower percentage of glidant in the coating composition . . . failed to prevent severe stickinesses of the coated capsules during storage" (*id.* at ¶ 12). "Reduction of the emulsifier as typically reported [in] literature concentrations . . . resulted in cracking of the coating (*id.*). "Surprisingly, it was found that polysorbate 80 . . . of a 15% dry copolymer content composition . . . resulted in favorable adhesion and flexibility of the coating on . . . softgel capsules (*id.* at ¶ 47). "This content was found to prevent the coating from cracking . . . The minimum content, which can also be defined to be above about 5% calculated by weight of dry copolymer, is higher than the maximum amounts of polysorbate 80 reported in the literature" (*id.*). "Moreover, [glycerol monostearate ("GMS")], acting as an anti-tacking agent, only proved its efficiency on enteric coated . . . softgel capsules when a percentage above about 5% by weight of dry polymer was added" (*id.*).

The Claims

Claims 1–5 and 15–18 are on appeal. Claims 6–14 and 19 are withdrawn. Independent claim 1 is representative and reads as follows:

> 1. A softgel dosage form enteric coating composition comprising:
>
> an aqueous coating composition including
>
> at least one methacrylic acid/acrylate copolymer, in an amount ranging from about 10% to about 30% by weight of the aqueous coating composition;
>
> at least one glidant, in an amount ranging from greater than 5% to about 15% by weight of the dry copolymer;
>
> at least one emulsifier, in an amount ranging from greater than about 10% to about 30% by weight of the dry copolymer; and
>
> at least one plasticizer, selected from the group consisting of polyethylene glycol, glycerol, sorbitol, dicotyl-sodium sulfosuccinate, triethyl citrate (TEC), tributyl citrate, mono-, di, or tri-acetates of glycerol, dibutyl sebecate, di- and triethyl phthalate, polyethylene glycol 6000, and mixtures thereof, in an amount ranging from about 10% to about 25% by weight of the dry copolymer.

(Br. 17).

The Rejections

Claims Rejected	Basis	References	Final Act. Citation
1–5, 15–18	§ 112 (pre-AIA) first paragraph, written description		2–4

1–5, 15–18	§ 103(a)	EP'830,[3] Rao,[4] Durig[5]	4–13

A. 35 U.S.C. § 112, first paragraph, written description

The Examiner finds the amendment of claim 1 to recite "'at least one methacrylic acid/acrylate copolymer, in an amount ranging from about 10% to about 30% by weight **of the aqueous coating composition**' . . . does not have any support in the original specification" (Final Act. 3). The Examiner finds "[a]ll the amounts of the copolymer are described in the form of a dry copolymer not with respect to the aqueous coating composition" (*id.* at 4).

Appellant contends "the application itself is based on the percentage of enteric polymer relative to the aqueous coating composition, and such is explicitly stated in the application" (Br. 5). Appellant contends:

> [First] that in the application, the coating composition (or enteric coating composition as it is at times called) disclosed is an *aqueous coating composition*. Second, in the application the enteric polymer (e.g., the "at least one methacrylic acid/acrylate copolymer" in the current claims) is disclosed as being from about 10% to about 30% by weight *of the coating composition*

(*id.* at 6). Appellant cites to several portions of the Specification for support, including exemplary ranges of preferred components (*see id.* at 6–7). For example, the Specification discloses:

> Enteric Polymer in amounts ranging from about 10% to about 30% (w/w of the final composition); Triethyl citrate (TEC) in amounts ranging from about 10% to about 25% (w/w, based on dry polymer content); Glyceryl monostearate (GMS) ranging from greater than about 5% to about 15%, or about 6% to about

[3] EP 2283830 A1, published Feb. 16, 2011.
[4] Rao et al., US 2005/0095285 A1, published May 5, 2005.
[5] Durig et al., US 2011/0002986 A1, published Jan. 6, 2011.

> 12%, or about 6% to about 10% (w/w, based on dry polymer content); polysorbate 80 ranging from greater than about 5% to about 30%, or from about 6% to about 20%, or from about 6% to about 10% (w/w, based on dry polymer content)

(*id.* at 7, citing Spec. ¶ 48). This paragraph distinguishes between the amount of enteric polymer based on the final composition, and the amount of additives based on dry polymer content, e.g., plasticizer, i.e., TEC; glidant, i.e., GMS; and emulsifier, i.e., polysorbate 80. The Specification provides a similar contrast when comparing Table 1 of the Specification, which describes additives in terms of w/w as % of dry copolymer and Table 2 of the Specification, which describes all of the components in terms of weight in an aqueous composition (*see* Spec. ¶¶ 38, 43).

We are persuaded by Appellant's argument that the Specification demonstrates possession of the amendment to claim 1 by disclosing an amount of enteric polymer by weight of the aqueous coating composition. Although we do not find the Examiner's position unreasonable, we do not sustain the Examiner's rejection for lack of written description because the evidence better supports a finding that the amounts claimed were disclosed in the Specification. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) ("[T]he description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*").

B. 35 U.S.C. § 103(a)

The Examiner finds EP'830 teaches "an enteric capsule coating . . . comprising a mixture at a ratio of between and about 50/50–45/55 of a first copolymer [m[e]thacrylic acid-ethyl acrylate]; and a second copolymer

[methacrylic acid-methyl acrylate-methyl methacrylate]" (Final Act. 5). The Examiner finds EP'830 teaches that each of the copolymers represents about 30 and 50% wt. of the composition (*id.*, emphasis omitted). The Examiner determines that methacrylic acid-ethyl acrylate "reads on appellant's claim of at least one methacrylic acid/acrylate copolymer" (Ans. 5, emphasis omitted). The Examiner determines further that the transitional phrase "an aqueous coating composition including" means a "second copolymer can be added in the composition" (*see* Ans. 7).

The Examiner finds EP'830 teaches the coating further includes a plasticizer, a lubricant, and an emulsifier (Final Act. at 5–6). The Examiner finds EP'830 teaches "when the plasticizer is triethyl citrate, its content will generally not exceed about 20% wt. of the formulation" (*id.* at 6, emphasis omitted). The Examiner finds EP'830 teaches "when the lubricant is glycerol monostearate, its content will generally not exceed about 10% wt. of the formulation" (*id.*, emphasis omitted). The Examiner finds EP'830 teaches "when the emulsifier is polysorbate 80, its content will generally not exceed about 5% wt. of the formulation" (*id.* at 7, emphasis omitted).

The Examiner finds EP'830 does "not specifically teach in claim 2 that the at least one methacrylic acid/acrylate copolymer is present in an amount of about 15% by weight of the composition"[6] (Final Act. 7). The Examiner finds EP'830 does not specifically teach "the emulsifier[s] such as polysorbate 80 are incorporated in an amount ranging from greater than

[6] The Examiner mistakenly refers to claim 2 as reciting the limitation "of about 15% by weight of the composition" (Final Act. 7). Claim 18 recites "wherein the at least one methacrylic acid/acrylate copolymer is present in an amount of about 15% by weight of the composition" (Br. 19). We deem this harmless error.

about 10% to about 30%" (Final Act. 8). The Examiner finds Rao teaches a soft gel capsule including an enteric polymer ranging from 5 to 40% by weight of the dry shell (*id.* at 8, emphasis omitted). The Examiner finds Durig teaches enteric coatings for soft gel capsules that may include the combination of polysorbate 80 and glyceryl monostearate (*id.* at 10, emphasis omitted). The Examiner finds Durig teaches the amount of glyceryl monostearate may range from about 3% to about 25% and the amount of polysorbate 80 may range from about 0.5% to about 12% by weight of a water dispersible powder blend (*id.* at 9, emphasis omitted).

The Examiner finds an ordinary skilled artisan would have had a reasonable expectation of success in combining the references, as all of the references teach enteric compositions for soft gel capsules (*see* Final Act. 11–12). The Examiner finds that the claimed ranges of amounts of ingredients overlaps with those of the prior art; therefore "a *prima facie* case of obviousness exists" (*id.*).

The issues with respect to these rejections are:

(i) Does a preponderance of evidence of record support the Examiner's conclusion that the prior art renders the claims obvious?

(ii) If so, has Appellant presented evidence of secondary considerations, that when weighed with the evidence of obviousness, is sufficient to support a conclusion of non-obviousness?

Findings of Fact ("FF")

1. EP'830 teaches "[a]n enteric capsule coating . . . comprising a mixture . . . of a first copolymer [methacrylic acid-ethyl acrylate]; and a second copolymer [methacrylic acid, methyl acrylate-methyl methacrylate]" (EP'830 6:11–13).

2. EP'830 teaches:

> Aqueous enteric capsule coatings are know from the art. For example, US7094425 provides enteric capsule coatings comprising the water-soluble copolymer [methacrylic acid-ethyl acrylate] or [methacrylic acid-methyl acrylate-methyl meth-acrylate]. The copolymer [methacrylic acid-ethyl acrylate], however, is designed to only dissolve from pH 7.0, whereas the copolymer [methacrylic acid-methyl acrylate-methyl meth-acrylate] is designed to dissolve from pH 5.5. Therefore, coating with either one of these copolymers alone, does not result in the desired disintegration profile for the coatings of the present invention (resistance at pH values of about 5.5 and rapid disintegration at pH values of about 6.8).

(EP'830 ¶ 5).

3. EP'830 teaches "[f]or the intestinal delivery of active ingredients, the enteric coated capsules . . . should be stable at low pH (up to pH 5.5) and in having an accelerated dissolution profile at higher pH (above pH 5.5). The optimal release is realized when the capsules disintegrate at a pH of about 6.8" (EP'830 ¶ 26).

4. EP'830 teaches "the enteric capsule coating further comprises a plasticizer, and optionally a lubricant, an emulsifier, or both" (EP'830 ¶ 10).

5. EP'830 teaches "[t]he amount of plasticizer used in the formulation will depend upon its composition, physical properties, [and] effect upon the copolymer . . . By way of example, when the plasticizer is triethyl citrate, its content will generally not exceed about 20% wt. of the formulation" (EP'830 ¶ 13).

6. EP'830 teaches "[t]he amount of lubricant used in the formulation will depend upon its composition, physical properties, [and] effect upon the copolymer . . . By way of example, when the lubricant is glycerol

monostearate, its content will generally not exceed about 10% wt. of the formulation" (EP'830 ¶ 17).

7. EP'830 teaches "[t]he amount of emulsifier used in the formulation will depend upon its composition, physical properties, [and] effect upon the copolymer. . . By way of example, when the emulsifier is polysorbate 80, its content will generally not exceed about 5% wt. of the formulation" (EP'830 ¶ 21).

8. EP'830 teaches the concentrations of components "are based on dry polymer substance" (EP'830 ¶ 24).

9. EP'830 teaches the following compositions of enteric coatings:

Table 3. Composition of enteric coatings (% wt/wt)

Batch	L30D-55	FS30D	TEC	GMS	Polysorbate 80	Total
692/41	9,3 mg 39%	11,3 mg 47%	1,85 mg 8%	1,02 mg 4,3%	0,41 mg 1,7%	23,9 mg 100%
692/43	15,37 mg 43%	15,37 mg 43%	2,76 mg 8%	1,53 mg 4,3%	0,62 mg 1,7%	35,65 mg 100%

(EP'830 ¶ 38).

10. Rao teaches an "enteric polymer used in [a] soft gel capsule composition . . . selected from . . . methacrylic acid ester copolymers . . . The amount of such enteric polymer may range from 5.0–40.0 percent, preferably 5.0–25.0 percent by weight with reference to the dried shell" (Rao ¶ 30).

11. Rao teaches an example of a soft gelatin shell formulation in the form of an aqueous composition containing 7.5 percent by weight methacrylic acid co-polymer Type C (Rao ¶ 85).

12. Durig teaches "[a] formulation for a blend of food grade ingredients that can be readily dispersed in water and the dispersion coated onto solid dosage forms to provide an enteric coating" (Durig ¶ 20).

13. Durig teaches "the water dispersible powder blend also optionally comprises a plasticizer" (Durig ¶ 29).

14. Durig teaches "[i]f glyceryl monostearate is the plasticizer, then it may be used in an amount in the range of from about 3% to about 25% . . . If polysorbate 80 is the plasticizer, then it may be used in an amount in the range of from about 0.5% to about 12%" (Durig ¶ 30).

15. Durig teaches "[f]or coatings that are to be applied to soft gel capsules, combinations of plasticizers are most preferred, for instance . . . the combination of polysorbate 80 with glyceryl monostearate" (Durig ¶ 34).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398,416 (2007).

Analysis

We adopt the Examiner's findings of fact and conclusion of law (Final Act. 4–13; FFs 1–15) and agree that EP'830, Rao, and Durig render the claims obvious. We address Appellant's argument below.

Appellant contends "[t]he '830 Reference, alone or in combination with Rao, fails to teach or suggest from about 10% to about 30% copolymer in an aqueous coating composition as recited in claim 1" (Br. 8, emphasis omitted). Appellant contends, "[a]s stated in the '830 Reference . . . <u>both</u> of the disclosed methacrylic acid/acrylate copolymers are present, each in an amount between about 30% and 50% wt." (*id.* at 9). Appellant contends "[t]o the extent that the Examiner indicates a skilled artisan may choose just one of the two methacrylic acid/acrylate copolymers taught by the '830

Reference, the ’830 Reference explicitly teaches away from such a conclusion” (*id.*). Appellant appears to distinguish EP’830 on the basis that the reference requires a composition with two copolymers, as opposed to the claimed composition, which is allegedly limited to one copolymer.

We do not find this argument persuasive. Appellant’s claim 1 recites “an aqueous coating composition including at least one methacrylic acid/acrylate copolymer, in an amount ranging from about 10% to about 30% by weight of the aqueous coating composition” (Br. 17). The transitional phrase for the aqueous coating composition is “including,” which means the same thing as “comprising” and allows for additional elements in the composition. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345 (Fed. Cir. 2003). Moreover, the plain meaning of “at least one” indicates that more than one copolymer may be present in the coating composition. Giving the claim its broadest reasonable interpretation, we interpret claim 1 to allow for additional copolymers, in addition to the at least one required methacrylic acid/acrylate copolymer in an amount ranging from about 10% to about 30% by weight. “[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). EP’830 teaches an enteric coating composition comprising an aqueous coating composition including at least one methacrylic acid/acrylate copolymer, and therefore teaches the claimed element. We address the amounts of the copolymer below.

Appellant contends “[l]ike the ’830 Reference, Rao neither teaches nor suggests a softgel dosage form coating composition having, *inter alia*, methacrylic acid/acrylate copolymer in an amount ranging from about 10%

to about 30% by weight of an *aqueous coating composition*" (Br. 11). Appellant argues "the Examiner is not comparing 'apples-to-apples' and never addressed the fact that it is comparing Rao's dried shell composition to Appellant's aqueous coating composition (a solution)" (*id.*). Appellant contends "[a]s can be seen by review of Appellant's examples, a copolymer amount of 15% in the aqueous coating composition would be equal to about 70% once the coating composition is dried (*id.*, citing Spec. Table 2).

We find Appellant's argument unpersuasive. We begin with an "apples-to-apples" comparison of Appellant's claim 1 to EP'830. Appellant argues "a total of 60% to 100% methacrylic acid/acrylate copolymer material is present the '830 composition" (Br. 9). However, EP'830 teaches an amount of methacrylic acid/acrylate copolymers on a basis of the dry mixture, not an aqueous composition (FFs 8, 9). According to Appellant's statement in the Brief, the amount of copolymer in the dried coating of the claimed composition is 70%, which falls squarely within the range of 60 to 100% copolymers in the dry mixture taught by EP'830.

We agree with Appellant that Rao teaches an amount of enteric polymer ranging from 5 to 40% by weight with reference to the dried shell. As noted by Appellant, Rao further teaches that the "capsule shell composition appears to be an aqueous solution at some point" (Br. 8). Addressing Appellant's "apples-to-apples" comparison, Rao teaches an aqueous composition including methacrylic acid co-polymer Type C in an amount of 7.5% by weight (FF 11). Accordingly, Rao sets a lower boundary of the range in combination with EP'830 that is close enough to the claimed range "such that one skilled in the art would have expected them to have the same properties." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

Because the prior art teaches at least one methacrylic acid/acrylate copolymer in a range that overlaps the claimed range by weight of an aqueous coating composition, we are not persuaded that the Examiner erred.

Appellant argues "even if the Rao reference did disclose the copolymer amounts in Appellant's current claim 1, which it does not, one of ordinary skill in the art would not modify the '830 Reference composition in that manner" (Br. 12). Appellant contends "both methacrylic acid/acrylate copolymers must be present and the ratios of the methacrylic acid/acrylate copolymers present is vital to the success of the delayed dosage form enteric coating" (*id.*) (citing EP'830 ¶¶ 5, 6, 7). Appellant contends "the copolymer amounts in '830 are chosen because they are best for its delayed release objective" (*id.*, citing EP'830 ¶¶ 1, 4).

We do not find Appellant's argument persuasive. "Under the proper legal standard, a reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) (citations omitted). EP'830 teaches that a combination of copolymers provides the desired disintegration at pH 6.8, rather than 5.5 or 7.0, i.e., the dissolution pH of the individual polymers (FFs 2, 3). However, claim 1 recites any enteric coating, not one limited to a specific pH release profile (*see* Br. 17). EP'830 does not suggest that using at least one methacrylic acid/acrylate copolymer is unlikely to produce an enteric coating as claimed. Therefore, we are not persuaded that EP'830 teaches away from the combination with Rao.

Appellant contends "one skilled in the art reads the '830 Reference as generally teaching a maximum of about 5% wt. of an emulsifier is

acceptable" (Br. 13). Appellant contends "[o]ne of ordinary skill in the art would not be motivated to more than double the generally maximum amount of emulsifier, particularly since . . . the amount of emulsifier affects the composition characteristics. Furthermore, doubling or more the maximum stated amount of emulsifier would yield unpredictable results" (*id.*, citing EP'830 ¶ 21). Appellant contends emulsifiers are not required in the EP'830 composition (*id.* at 14). "Appellant's invention, on the other hand, requires a relatively large amount of emulsifier as Appellant's composition is directed to coatings to address different problems" (*id.*, emphasis omitted). Appellant contends "Durig faces different problems — it needs ready dispersion into solution for spraying of the coating and has a different purpose — it is directed to obtaining high concentration dispersions for spray coatings onto solid dosage forms" (*id.*, citing Durig ¶ 18).

We find Appellant's argument unpersuasive. "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). The combination of EP'830 and Durig teach an amount of emulsifier that overlaps the claimed range. The statement in EP'830 that the content of polysorbate 80 will generally not exceed about 5% wt. of the formulation does not "criticize, discredit, or otherwise discourage the solution claimed" and thus does not teach away. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Moreover, Durig expressly teaches that the most preferred combinations of additives for enteric coatings applied to soft gel capsules include polysorbate 80, i.e., emulsifier, ranging from about

0.5% to about 12%, and glycerol monostearate, i.e., glidant, ranging from about 3% to about 25% (FFs 14, 15). Accordingly, the objective reach of the claim encompasses the prior art, and we are not persuaded that the Examiner erred. Because Appellant does not argue the dependent claim separately, we agree with the Examiner that claims 1–5 and 15–18 are *prima facie* obvious over the prior art.

Appellant contends "[s]urprisingly, the inventors found that with [] high amounts of emulsifier the coating compositions not only were found to be flexible (able to withstand deformation), the coating compositions could adhere to the exteriors of the softgel capsules without removing the lubricant (on the capsules) or providing a subcoating" (Br. 14). Appellant contends "Figures 1A–1D of the present application illustrate the relative importance of having at least 10% by weight of emulsifier in the claimed softgel dosage form coating composition and the higher weight percentage range of glidant" (*id.* at 15). Particularly, Figure 1D containing 10% polysorbate 80 and 10% GMS shows no cracks or stickiness of capsules (*id.*).

We are not persuaded by Appellant's evidence. Appellant presents only one particular mixture of ingredients; however, the claims are much broader in scope and encompass a variety of different mixtures. *See In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972). Accordingly, the results are not commensurate in scope with claim 1. Unexpected results must be "commensurate in scope with the degree of protection sought by the claimed subject matter." *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005).

Conclusion of Law

A preponderance of the evidence of record supports the Examiner's conclusion that the prior art renders the claims obvious. Appellant has not presented evidence of secondary considerations, that when weighed with the evidence of obviousness, is sufficient to support a conclusion of non-obviousness.

CONCLUSION

In summary:

Claims Rejected	**Basis**	**Affirmed**	**Reversed**
1–5, 15–18	§ 112(a), written description		1–5, 15–18
1–5, 15–18	§ 103 EP'830, Rao, Durig	1–5, 15–18	
Overall Outcome		1–5, 15–18	

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