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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/597,514	11/27/2006	Markus Rudolph	MERCK-3253	5580

23599 7590 02/28/2018

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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/28/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARKUS RUDOLPH, STEFAN HENKE, and IRIS MANNECK[1]

Appeal 2017-000647
Application 11/597,514
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims directed to an oral administration form comprising a pharmaceutically acceptable carrier and at least one species of a probiotic microorganism. Claims 1–26 are on appeal as rejected under 35 U.S.C. § 103. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part and enter a new ground of rejection for claim 26 under 35 U.S.C. § 103(a), pursuant to our authority under 37 C.F.R. § 41.50(b).

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[1] Appellants identify the Real Party in Interest as "Merck Patent GmbH." App. Br. 1 (we consider and reference herein the Amended Appeal Brief submitted May 10, 2016).

STATEMENT OF THE CASE

Claims 1, 22, 23, and 26 are the independent claims; they are representative and are reproduced below:

> 1. An oral administration form comprising a pharmaceutically acceptable carrier and at least one species of a probiotic microorganism, wherein the oral administration form and/or the probiotic microorganism is/are provided with a coating comprising at least two cellulose ethers which contain hydroxyalkyl groups as substituents
>
> wherein said oral administration form does not contain a gastric juice resistant coating and does not contain a softener.
>
> 22. An oral administration form comprising a pharmaceutically acceptable carrier and at least one species of a probiotic microorganism that is Lactobacilli, Bifidobacteria or Streptococci,
>
> wherein the oral administration form and/or the probiotic microorganism is/are provided with a coating comprising hydroxypropylmethylcellulose, hydroxypropylcellulose and a stearate and said coating has a thickness of 5 to 15mg per cm^2.
>
> 23. An oral administration form comprising a pharmaceutically acceptable carrier and at least one species of a probiotic microorganism, wherein the oral administration form and/or the probiotic microorganism is/are provided with a coating comprising hydroxypropylmethylcellulose and hydroxypropylcellulose and
>
> wherein the survival rate of said probiotic microorganisms in the small intestine is at least 5-fold compared with the uncoated administration form.
>
> 26. An oral administration form comprising a pharmaceutically acceptable carrier and at least one species of a probiotic microorganism, wherein the oral administration form and/or the probiotic microorganism is/are provided with a coating comprising hydroxypropylmethylcellulose and the

> hydroxypropylcellulose in a weight ratio to one another of 90:10 to 10:90
>
> wherein said oral administration form does not contain a gastric juice resistant coating and does not contain a PEG softener.

App. Br. 13, 15–16 (Claims App'x).

The following rejections are on appeal:

Claims 1–10, 12–19, 21, and 23–26 stand rejected under 35 U.S.C. § 103(a) over Giampapa[2] and Bechtold-Peters.[3] Final Action 3.

Claims 1–25 stand rejected under 35 U.S.C. § 103(a) over Giampapa, Bechtold-Peters, and Robinson.[4] *Id.* at 5.

FINDINGS OF FACT

FF1. The Specification states, "[t]he object of the present invention was to provide an oral administration form which liberates the probiotic microorganisms reproducibly in the human and/or animal intestine in order to ensure the activity of the probiotic microorganisms." Spec. 2.

FF2. The Specification states, "[t]he mixing ratios of the cellulose ethers [HPMC and HPC] to one another which are necessary in each case for the desired release profile and the layer thickness which is necessary in each case can be determined and optimised here with reference to experiments in *in-vitro* models." Spec. 4.

FF3. Appellants state, "the present invention provides an oral administration form which reproducibly liberates probiotic

[2] US 2004/0001817 A1 (pub. Jan. 1, 2004) ("Giampapa").
[3] US 2002/0160048 A1 (pub. Oct. 31, 2002) ("Bechtold-Peters").
[4] US 2002/0160046 A1 (pub. Oct. 31, 2002) ("Robinson").

microorganisms in the small intestine and ensures the activity of the probiotic microorganisms without the disadvantages of an enteric coating or a softener." App. Br. 4. Further, Appellants state,

> the present invention releases probiotic organisms. Rapid release of probiotic organisms would result in release in the stomach after oral intake, which would lead to loss of activity of the probiotic microorganisms due to their destruction in acid gastric juice. The aim of the present invention is to avoid destruction of the probiotic microorganisms in gastric juice.

Id. at 5. Moreover, Appellants state, "[r]elease [of probiotic microorganisms] in the intestine ensures the probiotic viability, activity and health-promoting benefits." *Id.*

FF4. Robinson discloses:

> a time-release dosage form for delivering an acid-labile pharmaceutical, such as omeprazole, into the upper portion of the gastrointestinal tract downstream of the stomach. The dosage form includes a drug-containing core surrounded by an inert time-release coating that delays release of the drug from the core until expiration of a certain time period after administration, generally 0.5-5.0 hours or 1-3 hours. When the gastrointestinal fluid contacts the core, the drug is released rapidly into the GI tract. The dosage form does not contain an enteric coating.

Robinson Abstract; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF5. Robinson discloses, "[t]he core of the solid dosage form is a substrate such as a . . . tablet core," which "is formulated into an immediate-release formulation," and which "is surrounded by a time-release coating." Robinson ¶¶ 27, 31–32; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF6. Robinson discloses "[a] solid dosage form that provides a delayed and subsequently rapid release" that comprises "a core" and "a ***time-release non-enteric*** water soluble or water erodible ***coating*** surrounding and in contact with the core," where "the time-release coating comprises ***one or more components selected from*** the group consisting of ***HPMC***, ***HPC***, PVP, ethylcellulose, non-enteric acrylic polymer, protein, talc, clay, kaolin, ***glycerin monostearate***, wax, silicon dioxide, polysaccharide, polyethylene oxide, and alkaline buffering agent." Robinson claims 1, 21 (emphasis added); *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF7. Robinson discloses:

> ***The time-release coating will generally comprise film-forming compounds such as*** cellulosic derivatives, such as ***hydroxypropylcellulose [HPC], methylcellulose, hydroxypropyl methylcellulose [HPMC]***, hydroxyethylcellulose, ***and/or*** acrylic polymers including the non-enteric forms of the Eudragit™ brand polymers. ***Other film-forming materials may be used*** alone or in combination with each other or with the ones listed above. These other film forming materials ***generally include*** poly(vinylpyrrolidone), Zein, ***poly(ethylene glycol) [PEG]***, poly(ethylene oxide), poly(vinyl alcohol), poly(vinyl acetate), and ethyl cellulose, as well as other pharmaceutically acceptable hydrophilic and hydrophobic film-forming materials.

Robinson ¶ 33 (emphasis added); *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF8. Robinson discloses that "[s]uitable binders," such as "poly-ethylene glycol," "***can be added*** to the formulation." Robinson ¶ 53 (emphasis added); *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF9. Robinson teaches that its disclosed time-release coating is necessary because the disclosed drug, omeprazole, degrades very rapidly in acidic aqueous solutions, such as found in the stomach, and teaches that while an enteric coating could protect the drug for release downstream from the stomach, there are disadvantages to enteric coatings making an alternative desirable. Robinson ¶¶ 2–7; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF10. Robinson discloses:

> [t]he pH of the film coating during application onto the core is generally maintained in the neutral to alkaline range, or in the pH range of about 8-10. This pH range may be achieved by the incorporation of suitable buffering agents or inherently alkaline additives, such as . . . magnesium stearate . . . , into the composition from which the time-release coating is made.

Robinson ¶ 50; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson). Robinson also discloses stearates, such as magnesium stearate, can be included in the composition as an anti-adherent or lubricant. Robinson ¶¶ 59, 63; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF11. Robinson discloses:

> The quantity of time-release coating needed for each formulation will depend upon the surface area of the core, or the particle size of the pellets/granules, in order to control the lag time for drug released from the core.
>
> The thickness of the time-release coating will control the time required for an aqueous solution to penetrate or erode the coating and reach the core. The influence of film thickness on the lag time for the core tablet to disintegrate and release drug is depicted in FIG. 3. As additional coatings of the same composition are applied to tablet cores, the thickness of the time-

> release coating increases, and the time (lag time) to disintegrate the tablet and to release the drug into solution increases, as shown by Profiles "A-C". Generally, the time-release coating will be about 100-5000 microns, or about 250-1000 microns, or at least about 200 microns thick, depending upon the material(s) from which it is made.

Robinson ¶¶ 45–46; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF12. Robinson discloses, "the time-release coating is about 100-5000, or 250-1000 at least about 100, microns thick and delays the release of omeprazole from the core at least about 1 hour after administration; 11) the time-release coating delays the release of omeprazole from the core 1-3 hours after administration." Robinson ¶ 15; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF13. Robinson discloses "an exemplary relationship between the thickness of the time-release coating on the release of omeprazole from a time-release pellet or tablet. As the thickness of the coating layer increases from A to C, the lag time, i.e., the delay in the period of time it takes to begin releasing omeprazole from the core, increases." Robinson ¶ 23; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF14. Robinson discloses examples with varying amounts (% by wt.) of cellulose ethers, e.g., HPMC at 37%, 5%, and 2%, and without an enteric/gastric juice resistant component or identified softener component. Robinson ¶¶ 80–96; *see also* Final Action 5, 7 and Answer 5, 7, 9, 11–13 (discussing Robinson).

FF15. Giampapa discloses a nutritional supplement tablet for oral administration that, among many other things, includes probiotic microorganisms, such as "*Lactobacillus acidophilus*, *Lactobacillus plantarum*, *Bifidobacterium bifidum* and *Lactobacillus casei*," to "markedly decrease the inflammatory processes that occur at the cellular level." Giampapa Abstract, ¶¶ 48–49, 61, 117–18, 174–75, 227–28, 419–20, claims 1, 29–34; *see also* Final Action 3–7 and Answer 2–13 (discussing Giampapa).

FF16. Further to the preceding finding of fact, Giampapa discloses a range of doses of probiotic microorganisms from 6.5 x 10^7 CFU to 1 x 10^8 CFU in formulations for administering up to three times per day and also at higher concentrations for once-a-day formulations, e.g., at 175 mg. Giampapa ¶¶ 117–18, 174–75, 227–28, 233, 419–20; *see also* Final Action 3–7 and Answer 2–13 (discussing Giampapa).

FF17. Giampapa discloses that the aforementioned probiotic microorganism complexes are compatible with and provided with magnesium stearate and a "film coat (hydroxypropyl methylcellulose [HPMC], hydroxypropyl cellulose [HPC] and polyethylene glycol [PEG])." Giampapa ¶¶ 121, 178, 231, 310, 364, 423; *see also* Final Action 3–7 and Answer 2–13 (discussing Giampapa).

DISCUSSION

In analyzing obviousness "[t]he 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). "[I]f a technique [or component] has been used to improve one

device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 417.

"There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant's invention itself." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). "[I]nterrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all [should be considered] in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed." *KSR*, 550 U.S. at 418.

Obviousness over Giampapa and Bechtold-Peters

The Examiner determined claims 1, 23, and 26 would have been obvious over Giampapa and Bechtold-Peters, combined, finding Giampapa essentially taught all the components of the oral pharmaceutical form claimed, but for the survival result of claim 23 and the specific HPMC:HPC ratio range of claim 26, and the exclusion of a PEG softener of claims 1 and 26. Final Action 3–4. The Examiner determined the survival result of claim 23 was an inherent, newly discovered property of a coating as disclosed by Giampapa and that the component ratio range of claim 26 was the result of obvious optimization of the coating components. *Id.* As for a coating with HPMC and HPC, but without an enteric component and a softener, such as PEG, the Examiner looked to Bechtold-Peters as disclosing the HPMC and HPC components and optional inclusion or exclusion of PEG in a tablet

coating, which, the Examiner determined, evidenced that "HPMC and HPC were routinely used alone and known to be effective film forming agents without PEG softeners." *Id.* at 4 (citing Bechtold-Peters ¶ 17 and claims).

Appellants argue Giampapa discloses coatings that contain HPMC, HPC, and PEG, in every case together, and that PEG is a well-known softener used in tablet formulations (a point not contested by the Examiner); therefore, Giampapa does not teach a coating without a softener. App. Br. 4. Appellants argue the coatings of Giampapa are not identical to the claimed coatings for this reason, therefore, the Giampapa coatings cannot be considered to inherently have the same properties of the claimed coating. *Id.* Appellants argue the skilled artisan would not have looked to Bechtold-Peters to teach a coating for a probiotic formulation because one of ordinary skill would know it would not be prudent to rapidly release a probiotic ingredient, unlike the small molecule active of the reference (a point not contested by the Examiner). *Id.* at 5. Appellants argue Bechtold-Peters discloses that plasticizers, such as PEG, may be included in its coatings, as shown in its examples. *Id.* at 6–7. Appellants argue claim 26 claims a coating of two cellulose ethers in a ratio of 90:10 to 10:90, which is not taught by Giampapa or Bechtold-Peters. *Id.* at 7–8. Appellants note that claim 26 is not also rejected over Giampapa, Bechtold-Peters, *and Robinson*. *Id.* at 8. Appellants argue claim 23 claims a survival rate of probiotic microorganisms in the small intestine is at least 5-fold better with the coating than without it, which is not taught or suggested by the Giampapa and Bechtold-Peters references, and would not be inherent to Giampapa's coating, which is not identical to the claimed invention's. *Id.* at 4, 8–9.

We are persuaded that Giampapa's disclosure of a probiotic-comprising formulation would not be combined with a coating designed for rapid release in the stomach upon oral administration, as is the coating in Bechtold-Peters. *See* Bechtold-Peters ¶ 4. Combining references can be based on common sense as long as the reasoning is explained sufficiently. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009). However, the opposite is also true: not combining references can also be based on common sense. Appellants state throughout their Specification and in their briefing that it was well known that the conditions in the stomach harm probiotic microorganisms and oral therapeutic administration of probiotic microorganisms relies upon protecting the microorganisms until they have passed the stomach and reach the small intestine, which ensures their survival. FF1, FF3. It would be common sense and scientifically logical to formulate a probiotic composition in such a way that it is not destroyed in the stomach upon ingestion. Therefore, we are persuaded that the Examiner did not provide sufficient evidence that the skilled artisan would have combined Giampapa's and Bechtold-Peter's disclosures.

Further, we are also persuaded by Appellants' argument that the coating of Giampapa is not identical to the coating of the claimed invention. FF17. Where the claimed invention includes HPMC and HPM and excludes components such as PEG, each embodiment of a film coating disclosed by Giampapa includes all three components. The Examiner did not provide sufficient evidence that Giampapa's film coating would behave identically to

that of the claimed invention so as to protect probiotic microorganisms passing through the stomach.

For the above reasons, we reverse the rejection of claims 1–10, 12–19, 21, and 23–26 over Giampapa and Bechtold-Peters.

Obviousness over Giampapa, Bechtold-Peters, and Robinson

The Examiner determined that claims 1, 22, and 23 would have been obvious over Giampapa, Bechtold-Peters, and Robinson combined, finding, again, that Giampapa taught an oral dosage formulation with a probiotic microorganism and with a coating having HPMC and HPC. *See* Final Action 5–6; FF15–FF17. The Examiner again noted that Giampapa did not teach to exclude PEG (relevant to claim 1 as an express limitation and to claim 23 by virtue of its claimed function/result). Final Action 6. While again citing Bechtold-Peters as disclosing the claimed coating, the Examiner also determined that Robinson taught pharmaceutical compositions with film coatings made from HPMC and HPC. *See* Final Action 6–7; FF4–FF8. The Examiner also noted that Giampapa does not teach the thickness of the coating recited at claim 22, but determined that Robinson taught non-enteric coatings (of HPMC/HPC) where thickness was routinely varied depending on materials and desired lag time for (delayed) release of the active component, finding that the claimed thickness range was an obvious optimizable variable. *See* Final Action 7; FF9, FF11–FF14.

Appellants generally renew their arguments over the Giampapa-Bechtold-Peters combination as relevant to the rejection also including Robinson. App. Br. 9. Appellants argue Robinson teaches including PEG in dosage forms. *Id.* (not persuasive, as Robinson is clear this is merely optional—FF8, FF14). Appellants also argue that, while the Examiner relies

on Robinson's disclosure of stearate in its formulation, not all claims rejected over the reference require stearate. *Id.* (i.e., claim 22). Appellants argue that Robinson's disclosure of film materials is generic and lists components with "very different properties," and so it is only with improper hindsight that the rejection is made. *Id.* at 10. Regarding claim 23, Appellants contend the coating disclosed in the Specification, which includes two cellulose ethers with hydroxyalkyl groups and different swelling/gel-formation behaviors, protects probiotics by delaying their release until released into the intestine, which results in at least a 5-fold increased survival rate compared to an uncoated formulation, which the prior art combination does to address. *Id.* at 10–11. Regarding claim 22, Appellants argue the combined prior art does not teach the "matched combinations of coating agents," and Robinson, the only reference mentioning coating thicknesses, is too general to lead a skilled worker to the specific matched combination of HPMC, HPC, and stearate agents. *Id.* at 11. These arguments are not persuasive.

While we found that one of skill in the art would not have combined the rapid release coating of Bechtold-Peters with the probiotic components of Giampapa, we conclude that Robinson remedies this deficiency by its teaching of a delay-release formulation to protect its active component from the hazards of the stomach by releasing only to the small intestine. FF4–FF7, FF9.

Regarding claim 1, even though Bechtold-Peters teaches a rapid release coating, we conclude Robinson teaches a coating of HPMC and HPC, in various amounts and thicknesses, to provide a delayed-release

formulation that would protect the probiotic microorganisms of Giampapa (in disclosed dosages) in the same way it protects the omeprazole of its own disclosure. FF4–FF17. There would have been motivation to combine the Robinson and Giampapa disclosures because, as stated by Appellants, it is crucial to protect probiotics from the stomach environment and doing so with a coating of HPMC and HPC (and a stearate, but without PEG and without an enteric component) as disclosed by Robinson provides this crucial protection so as to allow a probiotic to survive to the small intestine. FF1, FF3–FF14. Moreover, there would have been motivation to use a probiotic complex, as taught by Giampapa, with a coating, as taught by Robinson, because Giampapa teaches that there are important anti-inflammatory benefits to be obtained from such probiotics and also that its *Lactobacillus* and *Bifidobacterium* microorganisms are compatible with the HPMC and HPC coating components of Robinson. FF6, FF15, FF17.

Regarding claim 22, we conclude Robinson teaches and suggests a range of thicknesses for its HPMC/HPC coating and that such thicknesses can be selected for desired control of the timing of active component release. FF11–FF13. Further, Robinson teaches its coating components, e.g., HPMC, can be provided in varying amounts (% by wt.). FF14. Based on such teachings, it would have been obvious to find the optimum value for coating thickness, as claimed. "[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). Appellants' Specification also confirms that coating thickness and amounts of components are optimizable variables. FF2.

Regarding claim 23, we conclude the coating taught and suggested by Robinson is the same coating of the claim and as disclosed in the Specification as achieving the claimed survival of the probiotic microorganisms.

> Where . . . the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977) (citations and footnote omitted). Here, it would be expected that the coating of Robinson would necessarily protect the probiotic microorganisms of Giampapa through the hazards of the stomach environment to then be safely and rapidly released in the small intestine in the same way the Robinson coating protects omeprazole. FF5, FF6, FF9. Without its protective coating, the Robinson tablet core is an immediate-release formulation, which would release probiotic (or omeprazole) into the stomach, where the environment would cut the survival rate of microorganisms just as it was shown to do to the uncoated comparison tablets described in the Specification. FF4–FF6; Spec. 10.

For the reasons above, we affirm the rejection over Giampapa and Robinson, with or without Bechtold-Peters.

NEW GROUND OF REJECTION

As noted by Appellants in the Appeal Brief, "[c]laim 26 has not been rejected in view of Giampapa, Bechtold-Peters and Robinson." App. Br. 8. As a new ground of rejection, we find claim 26, which requires "a probiotic microorganism" and "a coating comprising hydroxypropylmethylcellulose and [] hydroxypropylcellulose in a weight ratio to one another of 90:10 to 10:90," but explicitly "does not contain a gastric juice resistant coating and does not contain a PEG softener," would have been obvious over the Robinson-Giampapa combination, with or without Bechtold-Peters.

As discussed above, it would have been obvious to combine Giampapa and Robinson to use the HPMC/HPC, non-enteric coating in a delayed-release probiotic formulation to protect the probiotic microorganisms in the stomach environment and deliver them to the small intestine. We incorporate our findings of fact and discussion, set forth *supra*, here.

Further, the claimed ratio range of claim 26 is extremely broad, failing to include only extreme differences in amounts of HPMC and HPC. Robinson teaches and suggests incorporating HPMC and HPC in its coating and teaches and suggests adjusting the amounts of such components. FF11–FF14.

> The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. These cases have consistently held that in such a situation, the applicant must show that the

> particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (citations omitted, emphasis in original). Here, there is no evidence that the claimed range of ratios is critical or non-obvious over the prior art, which discloses the combination of coating components as claimed. Appellants' Specification also confirms that the ratio of HPMC to HPC is optimizable. FF2.

SUMMARY

The obviousness rejection over Giampapa and Bechtold-Peters is reversed.

The obviousness rejection over Giampapa, Bechtold-Peters, and Robinson is affirmed.

We reject claim 26 under 35 U.S.C. § 103(a) as unpatentable over Robinson and Giampapa, with or without Bechtold-Peters, in a new ground of rejection.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b), which provides, "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." 37 C.F.R. § 41.50(b) also provides:

> When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:
>
> > (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter

> reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

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; 37 C.F.R. § 41.50(b)