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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROGER IMBODEN,
ERICH ROTHENBUHLER, and JUERG LUTZ

Appeal 2015-004126
Application 11/997,348
Technology Center 1600

Before DEMETRA J. MILLS, JEFFREY N. FREDMAN, and
RYAN H. FLAX, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134 involving a pharmaceutical composition comprising either indomethacin and/or acemetacin. The Examiner rejected the claims as indefinite, as being of improper dependent form, and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ Appellants identify the Real Party in Interest as the Drossapharm AG (*see* Br. 3).

Statement of the Case

Background

“[I]ndomethacin and acemetacin and their preparation are known. The compounds have anti-inflammatory, pain-relieving and antipyretic properties” (Spec. 1:8–9). “[B]oth active ingredients, especially acemetacin, have a bitter taste, making them unsuitable for peroral administration, e.g. in the form of an effervescent preparation. Unexpectedly, the bitter taste, e.g. in an effervescent preparation or a suspension, could not be masked with the flavorings conventionally used in pharmacy” (Spec. 1:19–23).

The Specification teaches that “the bitter taste of micronized indomethacin and acemetacin is efficiently masked by the addition of flavonoid derivatives” (Spec. 2:23–24).

The Claims

Claims 1–31 are on appeal.² Claim 1 is representative and reads as follows:

1. Pharmaceutically effective composition in a pharmaceutical form for oral administration containing at least one of the active ingredients indomethacin and acemetacin and optionally other additives, characterized in that
 - (i) this composition contains the active ingredient or a mixture of these active ingredients in micronized form, whereby said micronized form has been obtained by micronization using mechanical means;
 - (ii) the micronized active ingredient has a particle size distribution in the range of 0.1µm (micron) to 100µm (micron);

² The Examiner denied entry of Appellants’ amendment in the Advisory Action mailed Jan. 17, 2014, which results in claims 1, 2, 4–11, 16, 17, 19–22, 24, 25, and 28–31 remaining pending and claims 3, 12–15, 18, 23, 26, and 27 being withdrawn from consideration (*see* Final Act. 1 and Summary).

(iii) said active ingredient in micronized form being present in the form of microcrystals;

(iv) said composition consisting of the active ingredient(s) in a mixture with at least one compound selected from the group consisting of: chalcone[] glycosides and dihydrochalcone[] glycosides, and combinations thereof.

The Issues

- A. The Examiner rejected claims 1, 9, and 10 under 35 U.S.C. § 112, second paragraph, as indefinite (Ans. 2–3).
- B. The Examiner rejected claim 9 under 35 U.S.C. § 112, fourth paragraph, as failing to further limit the subject matter of a previous claim (Ans. 3–4).
- C. The Examiner rejected claims 1, 2, 4–11, 16, 17, and 28–30 under 35 U.S.C. § 103(a) as obvious over Machoczek,³ Samejima,⁴ and Felisaz⁵ (Ans. 5–10).
- D. The Examiner rejected claims 1, 24, and 25 under 35 U.S.C. § 103(a) as obvious over Nakamichi,⁶ Samejima, and Felisaz (Ans. 10–13).
- E. The Examiner rejected claims 1, 2, 4–8, 19–22, 24, 25, and 31 under 35 U.S.C. § 103(a) as obvious over Dell,⁷ Samejima, Zerbe,⁸ and Felisaz (Ans. 13–19).

³ Machoczek, H., US 6,066,335, issued May 23, 2000 (“Machoczek”).

⁴ Samejima et al., US 5,202,129, issued Apr. 13, 1993 (“Samejima”).

⁵ Felisaz et al., US 6,599,534 B2, issued July 29, 2003 (“Felisaz”).

⁶ Nakamichi et al., US 5,456,923, issued Oct. 10, 1995 (“Nakamichi”).

⁷ Dell et al., US 4,900,557, issued Feb. 13, 1990 (“Dell”).

⁸ Zerbe et al., US 5,948,430, issued Sept. 7, 1999 (“Zerbe”).

A. *35 U.S.C. § 112, second paragraph*

The Examiner finds the “use of open and closed language in the same claims makes the metes and bound unclear, rendering claim 1 indefinite. For examin[ation] purposes the claim will be interpreted as open language” (Ans. 3). The Examiner also finds that “[c]laims 9–10 recite[] the limitation ‘flavonoid derivatives’[, and t]here is insufficient antecedent basis for this limitation” (*id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s finding that claims 1, 9, and 10 are indefinite?

Findings of Fact

1. Claim 9 recites: “Composition according to claim 1, characterized in that said flavonoid derivatives being a chalcone glycosides and/or a dihydrochalcone glycosides” (Br. 44).

Principles of Law

Miyazaki stated that “if a claim is amenable to two or more plausible claim constructions, the USPTO is justified in requiring the applicant to more precisely define the metes and bounds of the claimed invention by holding the claim unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite.” *Ex parte Miyazaki*, 89 USPQ2d 1207, 1211 (BPAI 2008).

Analysis

Claim 1

Appellants contend the “language from claim 1, as in the example, specifies that the composition contain at least one active ingredient, but may also contain other ingredients. Claim 1 then, using the closed language,

limits the active ingredients to chalcone glycosides and/or dihydrochalcone glycosides” (Br. 15).

We find that the Examiner has the better position. As *Zletz* notes “during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.” *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). Here, the instant claim 1 is reasonably open to multiple conflicting interpretations.

One interpretation, proposed by Appellants, is that the closed “consisting of” clause limits the active ingredients to “chalcone glycosides and/or dihydrochalcone glycosides” (Br. 15). However, this interpretation might be read to exclude indomethacin and acetaminophen as active ingredients, even though these compounds are expressly recited as “active ingredients.”

A second interpretation is that the open “containing” phrase regarding “active ingredients” permits the inclusion of any active ingredient, and that the composition must further “consist” of these active ingredients with either chalcone glycosides and/or dihydrochalcone glycosides.

A third interpretation compares the “optionally other additives” language in the preamble of claim 1, with no constraint on any chemical whatsoever functioning as an additive, with the “consisting of” language in step (iv), and reasons that this language directly conflicts because, as the Examiner points out, the claim cannot be both “open” and “closed” at the same time.

A fourth reasonable interpretation is that the “consisting of” clause at paragraph “iv” limits the claimed pharmaceutically effective composition to one or both of indomethacin and acetaminophen (i.e., the active ingredient(s))

and one or both of chalcones glycosides and dihydrochalcones glycosides, and nothing more. This presents issues with the subsequent depending claims, which seek to add further components to the limited composition.

In view of the ambiguity present in claim 1, we agree with the Examiner that claim 1 requires clarification and is reasonably interpreted as indefinite.

Claims 9 and 10

Appellants do not dispute the Examiner's rejection of claims 9 and 10 for lack of antecedent basis for the term "said flavonoid derivatives," and we agree that there is no literal basis for this limitation in claim 1. We therefore agree with the Examiner that claims 9 and 10 are indefinite.

Conclusion of Law

The evidence of record supports the Examiner's finding that claims 1, 9, and 10 are indefinite.

B. 35 U.S.C. § 112, fourth paragraph

We summarily affirm the 35 U.S.C. § 112, fourth paragraph rejection because no arguments were presented. *See* MPEP § 1205.02 ("If a ground of rejection stated by the examiner is not addressed in the appellant's brief, that ground of rejection will be summarily sustained by the Board.").

C. 35 U.S.C. § 103(a) over Machoczek, Samejima, and Felisaz

The Examiner finds that Machoczek teaches "producing effervescent tablets which consist of at least one active substance or a combination of

active substances, of at least one binder, possibly carriers as sweeteners, flavors . . . and include indomethacin” (Ans. 5).

The Examiner acknowledges that Machoczek does not teach “the indomethacin being micronized” and “does not teach the use of a flavonoid, particularly the elected neohesperidin dihydrochalcone” (*id.*).

The Examiner finds that Samejima teaches “a process for micronizing a slightly-soluble drug . . . to produce a micronized drug having an average diameter of less than about 2-3 mm” and that “[i]ndomethacin is taught as a micronized drug with 50% average diameter ($[\mu]m$) of 1.3 and 0.35” (Ans. 5–6). The Examiner finds that Felisaz teaches a “masking agent for pharmaceutical tastes comprising a sapid agent and an enhancer”; that the agent “can have a grain size comprised between 10 and 100 $[\mu]m$ ”; and that the enhancer may comprise “neohesperidin dihydrochalcone.” *Id.* at 6–7.

The Examiner finds it obvious to “use micronized indomethacin . . . because micronization has long been recognized as a way to solve poor solubility in gastrointestinal fluids of slightly soluble drugs” and finds it obvious “to include masking agent including a sweetener and an enhancer to enhance the sweeten flavor of the sweetener and to hide the parasitic taste of the sweetener” and “to hide the taste of the pharmaceutical ingredient” (Ans. 6–7).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that the prior art renders claim 1 obvious?

Findings of Fact

2. Machoczek teaches “a method of producing effervescent tablets which consist of at least one active substance or a combination of active substances, of at least one binder, possibly of carriers as sweeteners, flavours, colourings, scents, softeners and bleaches” (Machoczek 1:5–10).

3. Machoczek teaches the “active substances to be used in the method and for the effervescent tablet according to the invention are not limited at all. They include . . . indomethacin” (Machoczek 2:19–25).

4. Machoczek teaches “flavourings such as sweeteners, sugar substitutes, flavours or additional or alternate further carriers as colourings or scents” (Machoczek 2:35–37).

5. Samejima teaches “a process for micronizing a slightly-soluble drug, which comprises grinding said drug in the presence of a sugar or sugar alcohol” (Samejima 1:10–13) and teaches “to improve bioavailability of a drug through micronization” (Samejima 2:13–14).

6. Samejima teaches that “ultrafine particles of a slightly-soluble drug, whose average diameter is less than about 2 to 3 μm , preferably less than 1 μm , can be easily obtained by grinding the drug in the presence of a grinding aid selected from a sugar and a sugar alcohol by means of a high-speed stirring mill or impact mill” (Samejima 2:43–49).

7. Samejima teaches “[s]pecific examples of the slightly-soluble drugs are . . . anti-inflammatory agents such as indomethacin” (Samejima 2:67 to 3:6).

8. Table 1 of Samejima is reproduced, in part, below:

TABLE 1

compound	Particle Sizes of Various Compounds Micronized in the Presence of D-mannitol		
	50% Average Diameter (μm)		
	Before Milling	After Milling	
		alone	mixture
indomethacin	9	1.3	0.35

“Table 1 shows that the particle size of each micronized compound is less than 1 μm ” (Samejima 5:13–14).

9. Felisaz teaches that:

Traditionally, masking agents for unpleasant pharmaceutical tastes are used whenever the patient, especially a young child, has to take the medicament orally. The substances used are of various types and are generally added to the pharmaceutical formulation as an excipient. For example, we can cite sweeteners including saccharine and its derivatives.

(Felisaz 1:22–28).

10. Felisaz teaches “a powdered masking agent for pharmaceutical tastes in the form of an intimate mixture of a sapid agent and a potentiator” (Felisaz 2:26–28).

11. Felisaz teaches “[p]referably, the powdered masking agent according to the invention has a particle size comprised between 10 and 100 μm ” (Felisaz 2:37–39).

12. Felisaz teaches that “[a]s potentiators, one can use . . . glycosides such as neohesperidine dihydrochalcone (NHDC) These substances insure a great lingering of the sweet taste and cover the bitter and metallic aftertaste of saccharine and its salts” (Felisaz 3:7–12).

13. Felisaz teaches the “masking agent according to the invention can be used with a large number of pharmaceutical or therapeutic products having unpleasant taste, belonging to many different categories thereof, for example . . . antiinflammatory . . . agents” (Felisaz 3:48–54).

14. Felisaz teaches, in Example 14, that 95.5% quinine is combined with 4.6% masking agent, specifically containing “500 mg of quinine hydrochloride+23.56 mg of masking agent” and that “a sweet and slightly bitter taste appear at the same time, whereafter the bitter taste disappears after 3 minutes 45 seconds, whereas the sweet taste is extended until 4 minutes 25 seconds” (Felisaz 7:30–55).

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). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417. As noted by the Supreme Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *Id.* at 421.

Analysis

We begin with claim interpretation. While we recognize that claim 1 is indefinite as discussed above, “each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement” (MPEP § 2103(I)).

We interpret claim 1 for prior art purposes to be consistent with *In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004). *Crish* found that the “reasonable interpretation of the claims containing both of the terms ‘comprising’ and ‘consists’ is that the term ‘consists’ limits the ‘said portion’ language to the subsequently recited numbered nucleotides, but the earlier term ‘comprising’ means that the claim can include that portion plus other nucleotides.” *Crish*, 393 F.3d at 1257. Applying *Crish* to instant claim 1, we interpret the “said composition” limitation to require a mixture of the active ingredient with a glycoside, but the earlier open transitional phrase “containing” means that the claim can include additional components along with the required active ingredient and glycoside. Therefore, we interpret claim 1 as lacking any limitation excluding the presence of sugar or other flavor additives. This is consistent with the depending claims, which seek to add further components to the composition of claim 1.

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 5–10; FF 2–14) and agree that the claims are obvious over Machoczek, Samejima, and Felisaz.

Appellants contend that “Machoczek contains 23 examples, however, not a single one of these examples refers to indomethacin and taste-masking is never mentioned or even hinted at”; that “Samejima simply never mentions anything about masking the bitter taste of a drug, let alone specifically masking the bitter taste of indomethacin and/or acetaminophen”; and that “Felisaz does not contain any teaching with reference to using a chalcone glycoside and/or dihydrochalcone glycoside as a single species, let alone that Felisaz could teach combining micronized indomethacin and/or

acemetacin with a chalcone glycoside and/or dihydrochalcone glycoside alone” (Br. 20, 22, 24).

We do not find these arguments persuasive. “Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). A reference “must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *Id.*

Here, Machoczek and Samejima teach forming therapeutic tablets using drugs including the anti-inflammatory indomethacin (FF 3, 7) that may include flavorings (FF 4). And Samejima teaches that delivery of slightly soluble drugs such as indomethacin is improved by micronization (FF 5, 7) specifically teaching micrometer particles of indomethacin (FF 8). Felisaz teaches combining masking agents with “therapeutic products having unpleasant taste . . . for example . . . antiinflammatory . . . agents” (FF 13) while Samejima identifies indomethacin as an anti-inflammatory agent (FF 7).

We therefore agree with the Examiner’s analysis that this combination falls squarely within *KSR*’s guidance that predictable combination of known elements are likely obvious, and particularly that the use of a masking agent with a known drug to improve the taste of that drug and “to hide the taste of the pharmaceutical ingredient” would have been obvious (*see* Ans. 7). This is consistent with the traditional adage that *a spoonful of sugar helps the medicine go down* (*see* FF 9 “Traditionally, masking agents for unpleasant pharmaceutical tastes are used whenever the patient, especially a young

child, has to take the medicament orally. . . . For example, we can cite sweeteners”).

Appellants contend that “surprising and inventive feature of the defined powdery form is that it needs only a small amount of the specific taste-making compound to mask the taste which allows the production of oral administration forms, such as pellets, containing a surprisingly high amount of active ingredient” (Br. 17).

We find this argument unpersuasive because Felisaz suggests that only 4.6 % masking agent was required to mask the taste of 95.5 % quinine, a bitter pharmaceutical, suggesting that Felisaz would have expected low amounts of the masking agent to effectively function (FF 14). *See In re Skoner*, 517 F.2d 947, 950 (CCPA 1975) (“Expected beneficial results are evidence of obviousness of a claimed invention. Just as unexpected beneficial results are evidence of unobviousness.”) We note that the weight ratio of the active agent quinine to masking agent in Example 14 is 500 mg/23.56 mg (FF 14) or 21:1, requiring lower amounts of masking agent than any pending claim.

In addition, claim 1 includes no limitations regarding the relative amounts of the taste-masking compound relative to the active compound, so the claims are not commensurate in scope with this argued result. *See In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971) (“objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support”).

Appellants contend that “[a]ccording to Samejima, a mixture of the micronized active compound with a high amount of a sugar or a sugar

alcohol is always obtained, which is undesirable for the present invention.

Without the addition of a sugar or a sugar-alcohol, the micronization as claimed in Samejima is impossible to obtain” (Br. 21). Appellants contend that in “the present invention, the active ingredient is used in a micronized form, whereby the micronized form has been obtained by conventional micronization without the addition of any additive, such as a sugar or alcohol as is required by Samejima” (*id.*).

We find this argument unpersuasive because claim 1 does not exclude the presence of sugar or sugar alcohols, nor does claim 1 require micronization occur without the presence of sugar or sugar alcohols. *See In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (“[A]ppellant’s arguments fail from the outset because . . . they are not based on limitations appearing in the claims.”) Claim 1 simply requires that the “micronized form has been obtained by micronization using mechanical means,” an element taught by Samejima, who teaches the use of mechanical mills (FF 6). Indeed, claim 1 expressly recites that the composition may contain, “optionally other additives,” positively permitting the presence of additional components such as sugar or sugar alcohols, rather than excluding these components.

Appellants contend that “according to the present invention, a chalcone glycoside and/or a dihydrochalcone glycoside alone is used in low concentration. This is a surprising and unexpected occurrence which results from a specific synergistic effect between the micronized indomethacin and/or acetaminophen and the [] chalcone glycoside and/or dihydrochalcone glycoside alone” (Br. 24).

We find this argument unpersuasive because claim 1 does not require that the glycoside compounds are used alone, but simply requires the presence of these compounds. As we discussed above, claim 1 lacks any limitation excluding the presence of sugar or other flavor additives as taught by the prior art of Samejima and Felisaz (FF 6, 10). “[L]imitations are not to be read into the claims from the specification.” *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). Indeed, claim 1 expressly recites that the composition may contain “optionally other additives,” positively permitting the presence of additional components rather than excluding these components.

Appellants contend that:

One having skill in the art would have no motivation to combine the teachings of Machoczek, Samejima or Felisaz in order to create the present invention. This is due to the fact that each of these references fail to even qualify as prior art regarding the present invention. Additionally, only hindsight reconstruction based upon the instant specification would lead the Examiner to the conclusion that the claims in the instant application are rejected under §103

(Br. 25–26).

We are not persuaded. While we are fully aware that hindsight bias may plague determinations of obviousness, *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966), we are also mindful that the Supreme Court has clearly stated that the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. In the instant case, the ordinary artisan applying Samejima’s micronization to Machoczek’s indomethacin tablets

would have expected to “obtain better absorption as is taught by [Samejima]” (Ans. 27; *cf.* FF 5 (“[T]o improve bioavailability of a drug through micronization”)). The ordinary artisan would further have expected that the Felisaz masking agent “can be used with a large number of pharmaceutical or therapeutic products having unpleasant taste, belonging to many different categories thereof, for example . . . antiinflammatory . . . agents” (FF 13) in order to improve palatability of these agents, and would therefore have had reason to include the masking agent in a composition comprising the anti-inflammatory agent indomethacin (FF 7).

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that the prior art renders claim 1 obvious.

D. 35 U.S.C. § 103(a) over Nakamichi, Samejima, and Felisaz

The Examiner finds that Nakamichi teaches “[i]ndomethacin is taught to be blended with a polymer resulting in a finely divided powder . . . to be used a powered or granules which can be used for oral administration” (Ans. 10). The Examiner relies upon Samejima and Felisaz as discussed above (*see* Ans. 10–12).

The Examiner finds it would have been obvious to “use the micronized form of indomethacin in order to increase the absorption of the drug which would increase bioavailability” and “to use the task masking system taught by [Felisaz] . . . in order to product [sic] a more pleasant tasting oral formulation which would result in better consumer acceptability” (Ans. 12–13).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the prior art renders claim 1 obvious?

Findings of Fact

15. Nakamichi teaches that “[s]olid dispersions are of use for an enhanced solubility of drugs or for controlling the rate of release of a drug from a dosage form or improving the bioavailability of drugs, thus being of significant commercial value” (Nakamichi 1:19–22).

16. Nakamichi teaches drugs including indomethacin (*see* Nakamichi 3:56) and exemplifies “[f]ive-hundred (500) grams of indomethacin was blended with 2500 g of hydroxypropylmethylcellulose phthalate . . . the composition was molded using a twin-screw extruder” (Nakamichi 6:56–61).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 10–13; FF 5–16) and agree that the claims are obvious over Nakamichi, Samejima, and Felisaz.

Appellants contend that “Nakamichi fails to mention anything related to the problem of masking the bitter taste of a drug, let alone of specifically masking the bitter taste of indomethacin and/or acetaminophen in a micronized state as defined in the present invention” (Br. 28).

We do not find this argument persuasive. As already noted, “[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d at 1097. Here, it is the

combination of references including Samejima and Felisaz that renders the claims obvious, not Nakamichi's teaching of indomethacin in a bioavailable tablet, alone (FF 15–16).

We recognize, but find unpersuasive, Appellants' reiterated arguments regarding Samejima and Felisaz regarding the inclusion of additives such as sugar or sugar alcohols (*see* Br. 29–32) for the reasons extensively discussed already.

Conclusion of Law

The evidence of record supports the Examiner's conclusion that the prior art renders claim 1 obvious.

E. 35 U.S.C. § 103(a) over Dell, Samejima, Zerbe, and Felisaz

The Examiner finds that Dell teaches pellet formulations “to obtain sustained release without inhibiting bioavailability” (Ans. 13) and teaches actives “selected from a short list which includes acemetacin (60 to 200 mg) and indomethacin (10 to 60 mg)” (Ans. 14). The Examiner finds that Zerbe teaches “citric acid and tartartaric acid are commonly used to enhance the flavor of oral formulations” (Ans. 15). The Examiner relies upon Samejima and Felisaz as discussed above (*see* Ans. 14–15).

The Examiner finds it obvious to “use micronized indomethacin as taught by [Samejima] in the pellet taught by [Dell] because micronization has long been recognized as a way to solve poor solubility in gastrointestinal fluids of slightly soluble drugs” and “to include a sugar and enhancer (flavonoid) in the formulation . . . in order to mask the taste of the pharmaceutical agent and prolong the sweetener flavor in the oral formulation” (Ans. 15–16).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the prior art renders claim 1 obvious?

Findings of Fact

17. Dell teaches “pellets of increased density which are lacquered with a coating which is resistant to gastric juice are outstandingly suitable for sustained release of substances of limited absorption (Dell 1:40–44).

18. Dell teaches “[p]referred active compounds for the pellet formulations according to the invention are acemetacin (60 to 200 mg) . . . indomethacin (60 to 180 mg)” (Dell 2:38–40).

19. Zerbe teaches the “effect of flavors may be enhanced using flavor enhancers like tartaric acid, citric acid vanillin, or the like” (Zerbe 3:35–37).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 13–19; FF 5–14, 17–19) and agree that the claims are obvious over Dell, Samejima, Zerbe, and Felisaz.

Appellants contend that:

Dell simply does not teach mechanically micronizing indomethacin and/or acemetacin. Dell also fails to teach combining micronized indomethacin and/or acemetacin having a defined average particle size, with a chalcone glycoside and/or a dihydrochalcone glycoside. Dell does not contain any teaching referring to taste-masking indomethacin and/or acemetacin or to any other aspect of the present invention.

(Br. 35). Appellants also contend that “Zerbe does not contain any mention or even hint at any reference to masking the bitter taste of the drugs

indomethacin and/or acetaminophen and is therefore not relevant to the present invention” (Br. 37).

We do not find these arguments persuasive. As already noted, “[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d at 1097. Here, it is the combination of references of Dell and Zerbe including Samejima and Felisaz that renders the claims obvious, not Dell’s teaching of acetaminophen or indomethacin in a bioavailable tablet (FF 17–18) and Zerbe’s teaching of flavor enhancers (FF 19), alone.

We recognize, but find unpersuasive, Appellants’ reiterated arguments regarding Samejima and Felisaz and the inclusion of additives such as sugar or sugar alcohols (*see* Br. 36–39) for the reasons extensively discussed above.

SUMMARY

In summary, we affirm the rejection of claims 1, 9, and 10 under 35 U.S.C. § 112, second paragraph, as indefinite.

We summarily affirm the rejection of claim 9 under 35 U.S.C. § 112, fourth paragraph, as failing to further limit the subject matter of a previous claim.

We affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Machoczek, Samejima, and Felisaz. Claims 2, 4–11, 16, 17, and 28–30 fall with claim 1.

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We affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as obvious over Nakamichi, Samejima, and Felisaz. Claims 24 and 25 fall with claim 1.

We affirm the rejection of claim 1, under 35 U.S.C. § 103(a) as obvious over Dell, Samejima, Zerbe, and Felisaz. Claims 2, 4–8, 19–22, 24, 25, and 31 fall with claim 1.

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