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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/900,415	07/28/2004	Isa Odidi	220112-1080	7076

24504 7590 09/23/2016

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ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
09/23/2016	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ISA ODIDI and AMINA ODIDI

Appeal 2015-000769
Application 10/900,415[1]
Technology Center 1600

Before ERIC B. GRIMES, RICHARD J. SMITH, 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 a controlled release device (e.g., a tablet). Claims 37–44, 48, 51–58, 60–62, 64–66, and 75–78 are on appeal as rejected under 35 U.S.C. §§ 103(a) and 112, fourth paragraph. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] The Real Party in Interest is Intellipharmaceutics Corp. App. Br. 2.

STATEMENT OF THE CASE

The appealed claims can be found in the Claims Appendix of the Appeal Brief. Claims 37 and 75 are the independent claims and are representative. Claim 37 reads as follows:

> 37. A controlled release device, comprising a homogenous blend of:
>
> (a) a disintegrant selected from a swelling disintegrant and a super-disintegrant,
>
> (b) a water soluble polymer, in an amount of from about 20% to about 60% by weight based on the total amount of material in the device,
>
> (c) an active pharmaceutical ingredient selected from a water soluble active pharmaceutical ingredient and a water insoluble active pharmaceutical ingredient, and
>
> (d) trehalose, in an amount of from about 5% to about 50% by weight based on the total amount of material in the device.

App. Br. 16 (Claims App'x). Claim 75 reads as follows:

> 75. A universal tableting granulated excipient, which is free-flowing and directly compressible, for controlled release of a therapeutically active medicament selected from a water soluble a therapeutically active medicament or an insoluble a [*sic*] therapeutically active medicament, comprising a homogenous blend of:
>
> from about 5 to about 50 percent by weight of trehalose,
>
> from about 5 to about 95 percent by weight of a super-disintegrant,
>
> from about 20 to about 60 percent by weight of a water soluble polymer material,
>
> from about 5 to about 75 percent by weight of an inert pharmaceutical filler, and

from 0 to about 35 percent by weight of silicon dioxide.

Id. 21.

The following rejections are on appeal:

Claims 37–44, 48, 51–58, 60–62, 64–66, and 75–78 rejected under 35 U.S.C. § 103(a) over Gribbon[2] and Sowden.[3] Office Action 4 (dated July 19, 2013) (hereinafter "Rejection").

Claim 42 rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form. *Id.* 9.

Claims 37, 39, 41–43, 51–55, 57, 66, and 75 rejected under 35 U.S.C. § 103(a) over Ohkouchi.[4] *Id.* 10.

DISCUSSION

We adopt the Examiner's findings of fact, reasoning on scope and content of the prior art, and conclusions set out in the Final Action and Answer.

The rejection under 35 U.S.C. § 103(a) over Gribbon and Sowden.

The Examiner has established a prima facie case for the obviousness of claims 37 and 75 over Gribbon and Sowden. *Id.* 4–9. Appellants do not contend that Gribbon and Sowden, together, fail to disclose each element of claims 37 and 75. Instead, Appellants argue that a person of ordinary skill in

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[2] U.S. Patent No. US 6,194,001 B1 (issued to Gribbon et al. on Feb. 27, 2001) (hereinafter "Gribbon").
[3] U.S. Patent Application Pub. No. US 2003/0235616 A1 (published Dec. 25, 2003) (hereinafter "Snowden").
[4] U.S. Patent No. US 6,740,339 B1 (issued to Ohkouchi et al. on May 25, 2004) (hereinafter "Ohkouchi").

the art would not have combined the disclosures of Gribbon and Sowden to provide a water soluble polymer (e.g., a filler) to the controlled release device, as recited by the claims, and as otherwise disclosed by Gribbon. App. Br. 6.

Appellants' argument hinges on their contention that Gribbon's active ingredient must be co-amoxiclav (amoxycillin trihydrate and potassium clavulanate), which Appellants contend is extremely hygroscopic and prone to degradation even in the presence of low amounts of humidity, therefore, requiring its combination with the filler microcrystalline cellulose (sold under the trade name Avicel), which Appellants contend is uniquely suitable for such combination because it has a moisture content of not more than 1.5–3%. App. Br. 6–7; Reply Br. 4–5. Appellants contend other fillers, such as Sowden's disclosed dextrin (which Appellants argue has a moisture content of 8–10%), are not suitable for combination with the co-amoxiclav of Gribbon because their moisture contents are too high. Appellants' arguments are not persuasive for several reasons.

First, Gribbon does not limit active ingredients to only co-amoxiclav. Gribbon discloses that the active ingredient of its invention is preferably amoxicillin / clavulanic acid, but, more broadly discloses, "[i]n preferred embodiments of the invention the active ingredients, especially antibiotics, preferably clavulanate, are combined with the trehalose as a preliminary step before blending with the other components for tabletting." Gribbon col. 2, ll. 10–32. Gribbon also states that its "invention relates to dosage forms for pharmaceutical preparations of antibiotics, particularly but not exclusively incorporating the active ingredients potassium clavulanate and amoxycillin

trihydrate." *Id.* at col. 1, ll. 5–8. Therefore, any antibiotic may be Gribbon's active ingredient, e.g., an antibiotic that is more tolerant of moisture than co-amoxiclav, and Appellants' argument that polymers/fillers that may be combined with Gribbon's tablet formulation are limited to a specific moisture content and/or limited to microcrystalline cellulose is unpersuasive.

Second, Sowden discloses "starch hydrolysates, which include dextrin" (a "water-soluble compressible carbohydrate[]") can be substituted for microcrystalline cellulose (i.e., Avicel; a "water-insoluble, plastically deforming material[]") as a suitable filler for modified release dosage forms of pharmaceutical delivery devices. Sowden ¶¶ 12, 40. This expressly suggests that the dextrin of Sowden could be substituted for the microcrystalline cellulose of Gribbon as a suitable "low moisture content" filler (there is no evidence of record as to what a skilled artisan would consider to be the threshold moisture content of such a filler). Therefore, it would have been obvious to substitute dextrin in place of microcrystalline cellulose in the formulation(s) disclosed by Gribbon with respect to the recited "water soluble polymer" elements of claims 37 and 75.

Third, Sowden discloses that the active ingredient for its modified release dosage forms can be an antibiotic, including amoxicillin. *See id.* ¶ 24. Sowden teaches that a suitable filler for combining with such an active ingredient is dextrin. *Id.* ¶ 40. Therefore, the skilled artisan would understand that the water soluble polymer dextrin could be combined with the other components disclosed by Gribbon, including an antibiotic active ingredient.

For the above reasons, we find that the preponderance of evidence of record supports the Examiner's determination that the claims would have been obvious over Gribbon and Sowden. We affirm the rejection.

The rejection under 35 U.S.C. § 112, fourth paragraph.

The Examiner has established that dependent claim 42 fails to further limit the subject matter of the claim from which it depends. Rejection 9–10. Appellants state that "dependent claim 42 will be cancelled once the substantive issues relating to obviousness are dealt with." App. Br. 10–11.

We, therefore, summarily affirm this rejection.

The rejection under 35 U.S.C. § 103(a) over Ohkouchi

The Examiner has established a prima facie case that claims 37 and 75 would have been obvious over Ohkouchi. Rejection 10–11. Appellants do not contend that Ohkouchi fails to disclose each element of claims 37 and 75. Instead, Appellants argue the claims are directed to a "controlled release" device or medicament and that this claim language distinguishes the invention from the "quickly disintegrating" solids disclosed by Ohkouchi. App. Br. 11 and 13. The evidence of record does not support Appellants' proposed claim language interpretation or the related argument.

The Examiner contends the Specification does not define the term "controlled release" and the broadest reasonable interpretation of this term, consistent with Applicants' disclosure at, e.g., ¶¶ 14 and 51 of the published version of the Specification (US 2006/0024361 A1, published Feb. 2, 2006), is *any rate of release that is controlled*. Rejection 10. We find this is a

reasonable interpretation of the claim language—Appellants do not point to any persuasive evidence to the contrary.

Appellants provide no evidence that a drug release device designed to quickly disintegrate in a controlled manner, e.g., under the influence of certain liquids, would not have been considered to be a controlled release device by the skilled artisan. It is well settled that arguments of counsel cannot take the place of factually supported objective evidence. *See*, *e.g.*, *In re Huang*, 100 F.3d 135, 139–40 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). Ohkouchi disclosed its "invention relates to solid preparations that disintegrate quickly in the presence of saliva or a small amount of water in the oral cavity," therefore, the reference teaches controlling the release of an active ingredient, i.e., a controlled release device. Ohkouchi col. 1, ll. 6–10. Therefore, Appellants' argument is not persuasive.

In addition, claims 60–64, which depend from claim 37, recite that the controlled release device can provide "sustained release," "pulsed release," or "delayed release," or "modulates the release of the active pharmaceutical ingredient in order to produce multiple peaks." That dependent claims limit the device of claim 37 to one of several different types of controlled release devices, one of which is a "sustained release" device, belies Appellants' argument that "controlled release" is interchangeable with "sustained release." App. Br. 11–12; *cf.* Reply Br. 6 (argument modified to "[s]ustained release is a category of controlled release."). A claim construction that results in a dependent claim having the same scope as the independent claim from which it depends, and which thus renders the

dependent claim superfluous, is "presumptively unreasonable." *Beachcombers, Int'l Inc. v. Wildewood Creative Prods., Inc.*, 31 F.3d 1154, 1162 (Fed. Cir. 1994). For this reason also, Appellants' argument is not persuasive.

For the above reasons, we find that the preponderance of evidence of record supports the Examiner's determination that the claims would have been obvious over Ohkouchi. We affirm the rejection.

SUMMARY

The rejection of claims 37 and 75 under 35 U.S.C. § 103(a) over Gribbon and Sowden is affirmed. Claims 38–44, 48, 51–58, 60–62, and 64–66 fall with claim 37, and claims 76–78 fall with claim 75. 37 C.F.R. § 41.37(c)(1)(iv).

The rejection of claim 42 under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form is affirmed.

The rejection of claims 37 and 75 under 35 U.S.C. § 103(a) over Ohkouchi is affirmed. Claims 39, 41–43, 51–55, 57, and 66 fall with claim 37. 37 C.F.R. § 41.37(c)(1)(iv).

TIME PERIOD FOR RESPONSE

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