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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte INDRAJIT GHOSH and JIA-AI ZHANG

Appeal 2019-005051
Application 15/934,595
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals[2] from Examiner's decision to reject claims 37, 38, and 47–54. 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 "Novartis AG" (Appellant's January 23, 2019 Appeal Brief (Appeal Br.) 4).

[2] This Appeal is related to Appeal 2018-009026 (Application 15/017,084) (*see* Appeal Br. 5). A Decision in Appeal 2018-009026 affirming indefiniteness, obviousness, and obviousness-type double patenting rejections was entered July 25, 2019.

STATEMENT OF THE CASE

Appellant's disclosure "describes formulated compositions and the corresponding technology of manufacturing tablets for Exjade™ (deferasirox) to prevent gastrointestinal irritation, having no food effect and improve patient compliance" (Spec.[3] 2). Appellant's claims 37, 47, 48, and 51 are reproduced below:

> 37. A method of treatment of chronic iron overload in a patient, comprising directly orally administering 90 mg deferasirox or a pharmaceutically acceptable salt thereof in a solid swallowable dosage form, wherein the dosage form is a whole and intact tablet, wherein the tablet exhibits a reduced deferasirox dissolution rate and *an equivalent AUC in the patient compared to administration of a dispersible tablet containing 125 mg deferasirox approved by Food and Drug Administration as Product Number 001 of New Drug Application 021882*.

(Appeal Br. 48 (emphasis added).)

> 47. A method of treatment of chronic iron overload in a patient, comprising directly orally administering an amount of deferasirox selected from the group consisting of 90, 180, and 360 mg in a solid swallowable dosage form, wherein the solid swallowable dosage form is a whole and intact tablet, and wherein the tablet comprises
>
> (i) at least one filler selected from the group consisting of microcrystalline cellulose, and ethylcellulose in a total amount of 10% to 40% by weight based on total weight of the tablet,
>
> (ii) at least one disintegrant selected from the group consisting of cross-linked polyvinylpyrrolidone, starch, CMC-Ca, CMC-Na, microcrystalline cellulose, alginic acid, sodium alginate, and guar gum in a total amount of 1 % to 10% by weight based on the total weight of the tablet; and,

[3] Appellant's March 23, 2018 Specification.

> (iii) at least one binder selected from the group consisting of polyvinylpyrrolidone, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, microcrystalline cellulose, hypromellose, and starch in a total amount of 1% to 5% by weight based on the total weight of the tablet,
>
> wherein the tablet exhibits an *equivalent AUC in the patient compared to administration of a dispersible tablet containing 125, 250, and 500 mg deferasirox, respectively, wherein each of the dispersible tablet containing 125, 250, and 500 mg deferasirox is approved by Food and Drug Administration as correspondingly Product Numbers 001, 002 and 003 of New Drug Application 021882*.

(*Id.* at 48–49 (emphasis added).)

48. A method according to claim 47 wherein the tablet comprises about 1-55% microcrystalline cellulose.

(*Id.* at 49.)

> 51. A method of treatment of chronic iron overload in a patient, comprising directly orally administering an amount of deferasirox selected from the group consisting of 90, 180, and 360 mg in a solid swallowable dosage form, wherein the solid swallowable dosage form is a whole and intact tablet, and wherein the tablet comprises at least one binder selected from the group consisting of polyvinylpyrrolidone, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, microcrystalline cellulose, and starch in a total amount of 1% to 5% by weight based on the total weight of the tablet, wherein the tablet exhibits a disintegration time of 5-10 minutes when measured by a standard USP disintegration test, and wherein the tablet exhibits an *equivalent AUC and a similar therapeutic effect in the patient compared to administration of a dispersible tablet containing 125, 250, and 500 mg deferasirox, respectively, wherein each of the dispersible tablet containing 125, 250, and 500 mg deferasirox is approved by Food and Drug Administration as*

> *correspondingly Product Numbers 001, 002 and 003 of New Drug Application 021882*.

(*Id*. at 49 (emphasis added).)

Grounds of rejection before this Panel for review:[4]

Claims 37, 38, and 47–54 stand rejected under 35 U.S.C. § 112, second paragraph.

Claims 37, 38, and 47–54 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 37, 38, and 47–54 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Zadok.[5]

DEFINITENESS:

ISSUE

Does the preponderance of evidence support Examiner's conclusion that Appellant's claims are indefinite?

ANALYSIS

Examiner finds that "[t]he FDA document referred to [in Appellant's claims, specifically New Drug Application ("NDA") 021882,] does not

[4] Appellant acknowledges that "[c]laims 37, 38 and 47-52 stand rejected on the ground of nonstatutory double patenting as being unpatentable over claims of U.S. Patent No. 9,283,209, of copending Application Nos. 15/017,084, 15/263[,]531, and 15/625,863" and asserts that "[t]hese obviousness-type double patenting rejections are not on appeal" (Appeal Br. 11). Appellant, instead, asserts that "[u]pon an indication of the allowable subject matter, a terminal disclaimer will be filed" (*id.*). Therefore, these rejections are not included in our deliberations.

[5] Zadok et al., US 2009/0142395 A1, published June 4, 2009.

appear to be of record in the instant Application" (Final Act.[6] 3). Examiner further finds that, upon "search of the FDA website," the FDA product claimed is based on the trademark Exjade®" (*id.* (emphasis omitted)). Thus, Examiner concludes that Appellant's claims are indefinite for failing to identify or describe the claimed product (*see id.* at 3–4). We find no error in Examiner's conclusion.

"If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph." MPEP § 2173.05(u). Therefore, we are not persuaded by Appellant's contentions relating to subject matter based on the use of a trademark in the claims (*see* Appeal Br. 19).

We recognize Appellant's contention that "the NDA claim language was an amendment in an effort to replace 'Exjade® . . .' in order to overcome the previous rejections" (Appeal Br. 17). In other words, Appellant amended the claims in an effort to describe the claimed invention without resort to the use of a trademark or trade name. The evidentiary documents Appellant relied upon to support claim limitations relating to the NDA, submitted with Appellant's November 16, 2018 After-Final Amendment, however, were not entered into this record and, therefore, are not properly before this Panel for review (*see* Appeal Br. 17–18 ("Applicants made of record that New Drug Application 021882 Product Numbers 001, 002 and 003 refer to EXJADE®"); *cf.* Advisory Action ¶ 9 (denying entry of the evidence submitted with Appellant's November 16,

[6] Examiner's September 27, 2018 Final Office Action.

2018 After-Final Amendment). Because the evidence relied upon by Appellant is not properly before this Panel for review, we decline Appellant's invitation to consider this evidence (*see* Appeal Br. 19–21).

Thus, in sum, because the evidence necessary to identify the scope of Appellant's claimed invention is not properly before this Panel for review, the scope of Appellant's claims cannot be ascertained. *See, Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1217 (Fed. Cir. 1991) (The legal standard for indefiniteness under 35 U.S.C § 112, second paragraph, is whether a claim reasonable apprises those of skill in the art of its scope).

CONCLUSION

The preponderance of evidence supports Examiner's conclusion that the Appellant's claim 37 is indefinite. Appellant's claims 38 and 47–54 are not separately argued and fall with Appellant's claim 37.

WRITTEN DESCRIPTION:

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention?

ANALYSIS

Examiner finds that Appellant contends "that the instantly recited FDA-NDA number is equivalent to the trademark Exjade®. However, no documentation confirming such is of record. Thus, the recitation of the FDA-NDA number constitutes new matter" (Final Act. 4). We find no error in Examiner's findings. Because the evidence relied upon by Appellant to

support its contentions is not properly before this Panel, we are not persuaded by Appellant's contentions relating to the written description rejection (*see* Appeal Br. 17–21).

CONCLUSION

The preponderance of evidence on this record supports Examiner's finding that Appellant's Specification fails to provide written descriptive support for the claimed invention. The rejection of claim 37 under the written description provision of 35 U.S.C. § 112, first paragraph is affirmed. Appellant's claims 38 and 47–54 are not separately argued and fall with Appellant's claim 37.

OBVIOUSNESS:

ISSUE

Should this rejection be reversed, *pro forma*?

ANALYSIS

Because the appealed claims fail to satisfy the requirements of the second paragraph of 35 U.S.C. § 112, we reverse, *pro forma*, Examiner's obviousness rejection. *See Ex parte Miyazaki*, 89 USPQ2d 1207, 1217–18 (BPAI 2008) (precedential) (prior art rejections of indefinite claims reversed by Board "*pro forma*" where claim interpretation required resort to "speculative assumptions as to the meaning of the claims"); *accord*, *In re Steele*, 305 F.2d 859, 862 (CCPA 1962) (it is legal error to analyze claims based on "speculation as to meaning of the terms employed and assumptions as to the scope of such claims").

CONCLUSION

The rejection of claims 37, 38, and 47–54 under 35 U.S.C. § 103(a) as unpatentable over Zadok is reversed, *pro forma*.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
37, 38, 47–54	112(a)	Written Description	37, 38, 47–54	
37, 38, 47–54	112(b)	Indefiniteness	37, 38, 47–54	
37, 38, 47–54	103	Zadok		37, 38, 47–54
Overall Outcome			37, 38, 47–54	

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