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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte IKUO MITANI, YOSUKE OGOSHI, TAKUYA MATSUI, MASAHIRO YOKOTA, MASAKAZU TERASHITA, DAI MOTODA, KAZUHITO UEYAMA, HIROYUKI ABE, TAKAHIRO HOTTA, and TAKASHI ITO

_____

Appeal 2020-004647
Application 14/749,966
Technology Center 1600

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Before ERIC B. GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 6–9, 14, and 26. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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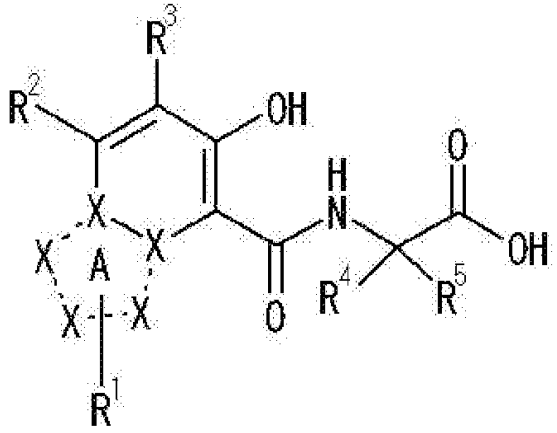
[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Japan Tobacco Inc. as the real party in interest. Appeal Br. 1.

STATEMENT OF THE CASE

The sole rejection before us for review is the Examiner's rejection of claims 1, 6–9, 14, and 26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–30 of U.S. Patent No. 8,283,465 B2.[2] Ans. 3–6 (entered Apr. 2, 2020).

Appellant's claim 1 is representative and reads as follows:

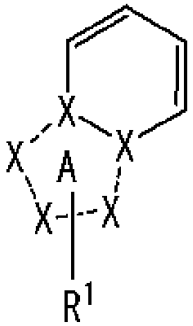
1. A compound represented by the following formula [I], or a pharmaceutically acceptable salt thereof, or a solvate thereof:



[I]

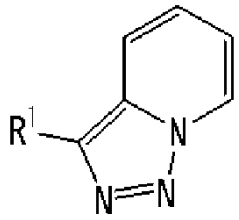
wherein

the partial structural formula:



is a group represented by:

[2]Ikuo Mitani et al., US 8,283,465 B2 (issued Oct. 9, 2012) ("the '465 patent").



R^1 is

(1) a hydrogen atom,

(2) a C_{1-6} alkyl group,

(3) a C_{6-14} aryl group,

(4) a C_{3-8} cycloalkyl group,

(5) a C_{6-14} aryl-C_{1-6} alkyl group, or

(6) a C_{3-8} cycloalkyl-C_{1-6} alkyl group;

R^2 is

(1) a hydrogen atom,

(2) a C_{1-10} alkyl group,

(3) a C_{6-14} aryl group optionally substituted by the same or different 1 to 5 substituents selected from the following group B,

(4) a C_{3-8} cycloalkyl group optionally substituted by the same or different 1 to 5 substituents selected from the following group B,

(5) a C_{3-8} cycloalkenyl group optionally substituted by the same or different 1 to 5 substituents selected from the following group B,

(6) a heteroaryl group optionally substituted by the same or different 1 to 5 substituents selected from the following group B (wherein the heteroaryl has, besides carbon atom, 1 to 6 hetero atoms selected from nitrogen atom, oxygen atom and sulfur atom),

(7) a C_{6-14} aryl-C_{1-6} alkyl group (wherein C_{6-14} aryl is optionally substituted by the same or different 1 to 5 substituents selected from the following group B), or

(8) a C_{3-8} cycloalkyl-C_{1-6} alkyl group (wherein C_{3-8} cycloalkyl is optionally substituted by the same or different 1 to 5 substituents selected from the following group B);

R^3 is

(1) a hydrogen atom,

(2) a halogen atom,

(3) a C_{1-6} alkyl group,

(4) a C_{6-14} aryl group,

(5) a C_{3-8} cycloalkyl group, or

(6) a C_{6-14} aryl-C_{1-6} alkyl group; and

R^4 and R^5 are each independently

(1) a hydrogen atom, or

(2) a C_{1-6} alkyl group,

group B:

(a) a halogen atom,

(b) a C_{1-6} alkyl group,

(c) a C_{3-8} cycloalkyl group,

(d) a cyano group, and

(e) a halo-C_{1-6} alkyl group.

Appeal Br. 10–12.

DISCUSSION

The Examiner's Rejection

The Examiner initially determined that the compounds recited in rejected claims 1, 6–9, 14, and 26 are unpatentable over claims 1–30 of the '465 patent "because both the compounds of the U.S. Patent claims anticipate the compounds of the instant claims." Ans. 4.

The Examiner determined further that, "in the absence of showing unobvious results, it is obvious to one of ordinary skill in the art at the time

of the invention when faced with the US patent claims to make the instantly claimed derivatives of a known product." Ans. 5.

In particular, the Examiner reasoned, the compounds recited in rejected claims 1, 6–9, 14, and 26, and the compounds recited in the '465 patent, "are common derivatives known as isomers. Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties." Ans. 5 (citing *In re Wilder*, 563 F.2d 457 (CCPA 1977); MPEP § 2144.09(11)).

The Examiner determined that, "[g]uided by the teaching of [the] US patent claims, one skilled in the art would be able to make similar compounds by making isomers of the known compound. The motivation would be to prepare similar compounds that are pharmacologically active compounds that have the same utility." Ans. 6.

The Examiner explained that the rejection for obviousness-type double patenting is "based on the close structural similarity of the instantly claimed compounds to the [patented] compounds and the common utility shared among the compounds." Ans. 6. The Examiner determined that "[t]here is an expectation among those of ordinary skill in the art that similar structural compounds will have similar properties and that modification of a known structure is mere experimentation within the means of a skilled artisan." *Id.*

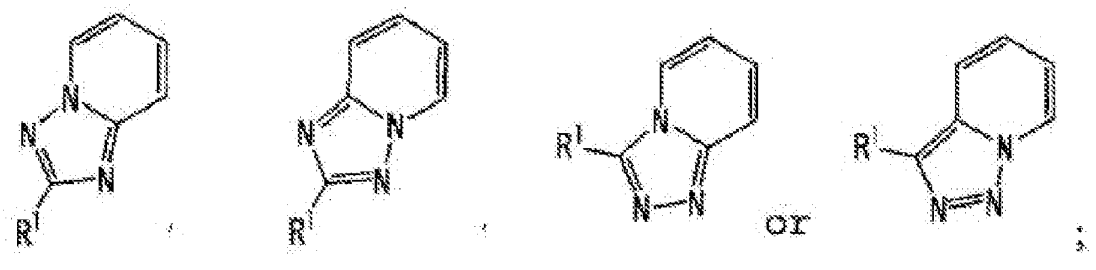
Analysis

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *see also In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) (holding that requiring an applicant to identify "reversible error" in an examiner's rejection is consistent with long standing Board practice).

In the present case, having carefully considered all of the evidence and argument presented by Appellant and the Examiner, we are not persuaded that Appellant has shown that the Examiner made reversible error in maintaining the rejection for obviousness-type double patenting.

Appellant does not assert that the Examiner erred in determining that the compounds recited in rejected claims 1, 6–9, 14, and 26 would have been obvious in view of the compounds recited in claims 1–30 of the '465 patent. Rather, Appellant contends that, during prosecution of the '465 patent, the Examiner issued a rejection asserting an improper Markush group between the following four alternative structures:



which the Examiner now asserts are obvious over each other in the double patenting rejection that is the subject of this appeal. Appeal Br. 2–3; Reply Br. 2–3.

Appellant contends that a rejection for an improper Markush group is tantamount to a restriction requirement, because a rejection for an improper Markush group finds its basis in lack of unity of invention. Appeal Br. 3–6 (citing *In re Harnisch*, 631 F.2d 716 (CCPA 1980)).

Appellant contends that because an improper Markush group rejection must be treated as a restriction requirement, the present application is properly considered a divisional application of the application that issued as the '465 patent, and the obviousness-type double patenting rejection is improper:

> Since the *de facto* restriction requirement placed each of the four alternative bicyclic structures into different groups, and required applicant to select only one group for prosecution in the application that gave rise to the '465 patent, the present claims must be treated as being directed to a different restriction group than what was claimed in the '465 patent and afforded the protection provided by 35 U.S.C. 121. It would be fundamentally unfair for the Office to be able to first prevent applicant from pursuing the present claims in the application that gave rise to the '465 patent (in the guise of an Improper Markush Group rejection rather than a formal restriction requirement) but then in the present application be permitted to reject the claims as patentably indistinct from the claims of the prior application. Accordingly, the present application is a divisional of the '465 patent and the '465 patent therefore cannot be used in a nonstatutory double patenting rejection of the claims.

Appeal Br. 9.

Appellant's arguments do not persuade us of reversible error by the Examiner.

As Appellant argues, 35 U.S.C. § 121[3] provides a safe harbor from obviousness-type double patenting rejections when a restriction requirement results in the filing of a divisional application:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121.

Our reviewing court, however,

> applies a strict test for application of § 121. *Specifically, § 121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance*. The restriction documentation must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions. In other words, § 121 requires a record that shows a discernable consonance.

Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003) (emphasis added).

In the present case, Appellant does not identify any documented restriction requirement between the subject matter recited in rejected claims 1, 6–9, 14, and 26, and the subject matter recited in claims 1–30 of the '465 patent, in the record of this application or any of the applications in the chain

[3] This application claims priority to applications filed before September 16, 2012. *See* Spec. 1 (amendment entered February 8, 2016). The pre-AIA (America Invents Act) version of the statute therefore governs this application.

of priority of this application. Appellant, moreover, does not identify any authority allowing this Board to substitute a purported improper Markush group rejection for a documented restriction requirement, so as to allow Appellant to avail itself of the safe harbor in § 121.

In particular, while we acknowledge Appellant's arguments regarding the unity of invention principles discussed in *Harnisch*, Appellant points to nothing in *Harnisch* or any other authority suggesting that the safe harbor of § 121 may be invoked by an improper Markush group rejection, rather than the restriction requirement expressly required by the statute. Accordingly, given our reviewing court's mandate for strict application of § 121, *see Geneva Pharms. v. GlaxoSmithKline supra*, and given the absence of a documented restriction requirement between the subject matter recited in rejected claims 1, 6–9, 14, and 26, and the subject matter of claims 1–30 of the '465 patent, we conclude that we must affirm the Examiner's obviousness-type double patenting rejection.

DECISION SUMMARY

In summary:

Claim(s) Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1, 6–9, 14, 26		Obviousness-type Double Patenting	1, 6–9, 14, 26	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED