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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MANOJ C. DESAI, ALLEN YU HONG, HON CHUNG HUI,
HONGTAO LIU, RANDALL W. VIVIAN, and LIANHONG XU

Appeal 2020-000201
Application 15/340,538
Technology Center 1600

Before ERIC B. GRIMES, LINDA M. GAUDETTE, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 42–53. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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 in this appeal as Gilead Sciences, Inc., the assignee of this application. Appeal Br. 2.

STATEMENT OF THE CASE

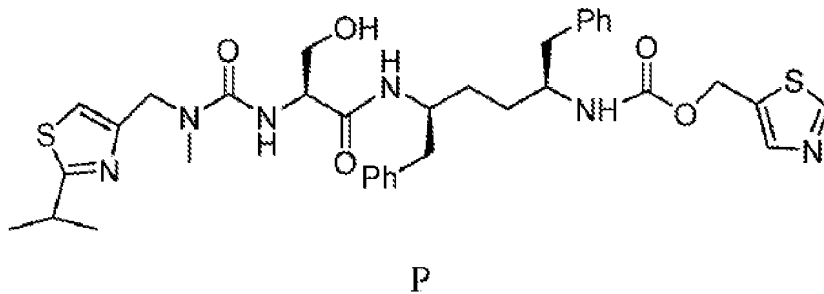
The following rejections are before us for review:²

(1) Claims 42–49, under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as being indefinite (Ans. 3–4); and

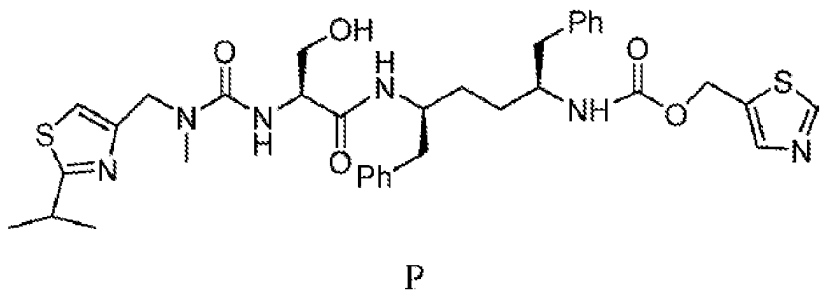
(2) Claims 50–53, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–4 of U.S. Patent No. 8,067,449 B2, issued Nov. 29, 2011 (Ans. 5–6).

Appellant's claims 42, 50, and 51 illustrate the subject matter on appeal and read as follows:

42. An in vivo metabolic product of Compound P:



50. A prodrug of Compound P:



² The Final Action included a rejection under 35 U.S.C. § 101. *See* Final Act. 7–9 (entered April 25, 2018). The Examiner has withdrawn the rejection under § 101. Ans. 6.

51. The prodrug of claim 50 which is an ester of Compound P.
Appeal Br. 8, 9.

INDEFINITENESS

The Examiner's Prima Facie Case

The Examiner concluded that Appellant's claim 42 is indefinite "because of the recitation of a[n] 'in vivo metabolic product' of the claimed compound P." Ans. 3. In particular, the Examiner reasoned that "[w]ith respect to the claimed metabolites, this term includes any compound which can be produced from the *in vivo* breakdown or metabolism of the claimed compounds." *Id.* at 3–4.

The Examiner determined, however, that "there is no disclosure of the particular metabolic pathway of the instant compounds, nor would it be possible to know every single enzyme which could potentially react with and thus transform the instant compounds *in vivo*." Ans. 4. Therefore, the Examiner reasoned:

Without the particular information including which enzymes will necessarily act on the claimed compound, and what particular chemical transformation occurs as a result of this action, it is not possible for the skilled artisan to determine which particular compounds are embraced by the claimed "metabolite" and the use of the term renders the claim indefinite. Since dependent claims 43–49 do not provide any additional clarification, the dependent claims are also rejected for the same reasons.

Id.

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[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.

A claim does not comply with 35 U.S.C. § 112, second paragraph, “when it contains words or phrases whose meaning is unclear.” *In re Packard*, 751 F.3d at 1310, 1314 (Fed. Cir. 2014) (approving, for pre-issuance claims, the standard from MPEP § 2173.05(e)); *see also Ex parte McAward*, Appeal 2015-006416, 2017 WL 3669566, at *5 (PTAB Aug. 25, 2017) (precedential) (adopting the approach for assessing indefiniteness approved by the Federal Circuit in *Packard*). That is, “claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms.” *Packard*, 751 F.3d at 1313.

In the present case, we are not persuaded that Appellant has explained persuasively why the Examiner erred in determining that the language at issue in the rejected claims is unclear. The language at issue appears in independent 42, and recites “[a]n *in vivo* metabolic product of Compound P.” Appeal Br. 8. Appellant does not dispute the Examiner’s finding that “[n]either the claims nor the [S]pecification set forth specifically, or even suggest, how the structure is modified from the depicted Compound P upon administration *in vivo*.” Ans. 8.

Rather, Appellant argues that a skilled artisan “does not need to know a metabolic pathway in order to recognize a metabolite. Metabolites of drugs are routinely identified from the administration of pharmaceutical compounds to humans and animals without full knowledge of the metabolic pathway.” Appeal Br. 5. Further, Appellant argues, a skilled artisan need not know every enzyme that could transform claim 42’s Compound P into a

metabolite because “[t]he metabolite is recognized as a derivative of a drug compound after administration to a human or animal, and just as the metabolic pathway need not be known, the enzymes transforming the drug need not be known in order to identify a metabolite.” Appeal Br. 5.

Appellant, however, does not direct us to any specific evidence supporting its assertion that identifying metabolites in the posited manner is routine. Appellant’s contentions in that regard are therefore unsupported attorney argument, which we do not find persuasive of error by the Examiner. “Attorneys’ argument is no substitute for evidence.” *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

Appellant fails to explain, moreover, how the alleged ability to generate metabolites by administering compound P to a human or animal establishes that the language at issue in claim 42 clearly delineates, with reasonable certainty, between compounds encompassed by claim 42, and compounds falling outside of the claim. Absent some reasonably clear delineation between compounds that fall within the scope of the language at issue in claim 42, and compounds that fall outside of claim 42’s scope, Appellant does not persuade us of error in the Examiner’s conclusion of indefiniteness. *See Miles Labs. Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) (“The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification.”). Given the undisputed absence in the Specification of any specific guidance explaining the particular modifications resulting from in vivo metabolism of compound P, Appellant does not persuade us that the language at issue in claim 42, even when read in light of the Specification, clearly informs a skilled artisan about the scope of the claims.

In sum, for the reasons discussed, Appellant does not persuade us that the Examiner erred in concluding that the language at issue in claim 42 is unclear, ambiguous, and vague. We therefore affirm the Examiner's rejection of claim 42, and its dependent claims, for indefiniteness.

DOUBLE PATENTING

The Examiner's Prima Facie Case

In rejecting Appellant's claims 50–53 for obviousness-type double patenting over claims 1–4 of U.S. Patent No. 8,067,449 (“the '449 patent”), the Examiner determined that the rejected claims are not patentably distinct from the patented claims because claim 2 of the '449 patent recites a compound having the same structural formula as Compound P, the compound recited in Appellant's claim 50. *See* Ans. 5. Further, the Examiner reasoned, “the patented claims also recite ‘stereoisomers thereof of the claimed compounds, which encompasses the instantly claimed compound.” *Id.* at 5–6. Therefore, the Examiner reasoned, “[b]ecause the instant claims are encompassed by the claims of the '449 patent, with the specifically claimed compound taught as compound P in the patent, a nonstatutory double patenting rejection is proper.” *Id.* Further, the Examiner notes, “the claim also recites ‘and/or esters thereof.’ The instant claims recite prodrugs thereof of Compound P, where dependent claim 51 specifically recites that the compound is an ester of Compound P.” *Id.* at 10.

Analysis

The doctrine of obviousness-type double patenting “prohibits the issuance of claims in a second patent that are not patentably distinct from the claims of the first patent. A later patent claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the

earlier claim.” *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (internal quotations and citations removed).

In the present case, Appellant does not persuade us that the Examiner erred in determining that Appellant’s claims 50–53 are not patentably distinct from the claims of the ’449 patent. Appellant contends that rejected claims 50–53 “are directed to prodrugs of Compound P, not Compound P itself. So the allegation that the claims of the ’449 patent encompass the instant claims is not correct.” Appeal Br. 6. In addition, Appellant contends, the Examiner “has not pointed to any motivation or reasoning that would lead one of skill in the art to modify the subject matter of the claims of the ’449 patent to arrive at the subject matter of the instant claims.” *Id.*

We acknowledge that rejected claim 50 recites “[a] prodrug of Compound P.” Appeal Br. 9. As noted above, rejected claim 51 recites “[t]he prodrug of claim 50 which is an ester of Compound P.” *Id.* Thus, rejected claim 50’s recitation of a prodrug of Compound P encompasses an ester of Compound P.

It is undisputed that claim 2 of the ’449 patent recites a compound that has the same structural formula as compound P, except for the stereochemical specificities shown in rejected claim 50. As the Examiner found, however, in addition to the compounds listed, claim 2 of the ’449 patent recites “pharmaceutically acceptable salts, *esters*, and/or *stereoisomers* thereof.” The ’449 patent, 267:26–27 (emphasis added).

Because rejected claim 50’s recitation of a prodrug of Compound P encompasses esters of Compound P, and because claim 2 of the ’449 patent recites esters of a compound undisputedly having the same structural formula as Compound P, and stereoisomers of those compounds, Appellant

does not persuade us that the Examiner erred in determining that the prodrug of Compound P recited in rejected claim 50 would have been obvious over claim 2 of the '449 patent. We therefore affirm the Examiner's rejection of Appellant's claim 50 for obviousness-type double patenting. Claims 51–53 fall with claim 50. *See* 37 C.F.R. 41.37(c)(1)(iv).

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
42–49	112(b) or 112, second paragraph	Indefiniteness	42–49	
50–53		The '449 Patent; Obviousness-Type Double Patenting	50–53	
Overall Outcome			42–53	

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