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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAMES T. DALTON and DUANE D. MILLER¹

Appeal 2014-007036
Application 11/826,195
Technology Center 1600

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims relating to a chemical compound, which have been rejected as anticipated and obvious.

We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

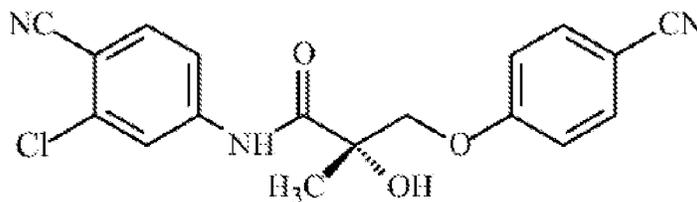
The Specification discloses “substituted acylanilide compounds and uses thereof in treating a variety of diseases or conditions in a subject,

¹ Appellants identify the Real Parties in Interest as the University of Tennessee Research Foundation and GTx, Inc. (Appeal Br. 1.)

including, *inter-alia*, a muscle wasting disease and/or disorder or a bone-related disease and/or disorder.” (Spec. 1 ¶ 2.)

Claims 2, 4, 80, and 81 are on appeal. Claim 2 is representative and reads as follows:

2. A compound represented by the structure of formula S-(I)



S-(I).

The claims stand rejected as follows:

Claims 2, 4, 80, and 81 under 35 U.S.C. § 102(b) as anticipated by Steiner² (Ans. 2) and

Claims 2, 4, 80, and 81 under 35 U.S.C. § 103(a) as obvious based on Steiner (Ans. 9).

I

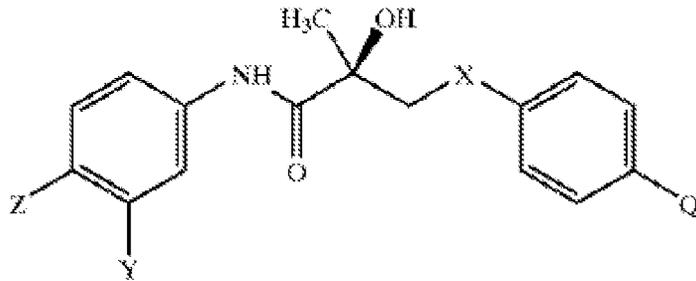
The Examiner has rejected all of the claims on appeal as anticipated by Steiner. The Examiner finds that Steiner discloses a chemical formula that includes compound S-(I) as part of a limited genus. (Ans. 3.) The Examiner also finds that Steiner’s exemplary compounds would have led a person of ordinary skill in the art to a subgenus (*id.* at 4–8) that is small

² Steiner et al., US 2005/0038110 A1, Feb. 17, 2005.

enough that “[t]he skilled artisan would at once envisage each member of this subgenus,” including compound *S*-(I). (*Id.* at 9.)

We agree with the Examiner that Steiner’s disclosure effectively describes the claimed compound. Steiner describes

a selective androgen receptor modulator (SARM) compound represented by the structure of formula (IIA):



wherein

X is O;

Z is NO₂, CN, COR, or CONHR;

Y is I, CF₃, Br, Cl, or SnR₃;

R is an alkyl group or OH; and

Q is CN.

(Steiner ¶¶ 17–23.) Steiner also describes an embodiment in which “Z in compound (IIA) is CN.” (*Id.* ¶ 25.)

Thus, Steiner describes an embodiment of compound (IIA) that differs from the claimed compound *S*-(I) only in the choice of substituent Y: Cl in compound *S*-(I); any of I, CF₃, Br, Cl, or SnR₃ in compound (IIA). We agree with the Examiner that the person of ordinary skill in the art would immediately envisage compounds having any of I, CF₃, Br, Cl, or SnR₃ at position Y, and therefore Steiner’s disclosure anticipates claim 2 on appeal. *See In re Petering*, 301 F.2d 676, 681–82 (CCPA 1962) (A disclosure that allows one skilled in the art to “at once envisage each member of [a] limited

class” describes each member of the class “as if [the reference] had drawn each structural formula or had written each name.”).

Appellants argue, however, that *Petering* does not apply here. Appellants argue that the possible substituents at position Y of Steiner’s compound (IIA) include SnR_3 , where R can be alkyl or OH, and “[a]t its broadest R may have 1–12 carbons.” (Appeal Br. 8.) Appellants argue that “ SnR_3 represents $\text{Sn}(\text{alkyl})_3$, $\text{Sn}(\text{alkyl-1})(\text{alkyl-2})(\text{alkyl-3})$, $\text{Sn}(\text{alkyl-1})_2(\text{alkyl-2})$, $\text{Sn}(\text{alkyl})_2\text{OH}$, $\text{Sn}(\text{alkyl-1})(\text{alkyl-2})\text{OH}$, and $\text{Sn}(\text{alkyl})(\text{OH})_2$ were [sic] alkyl may vary from 1-12 carbons and be substituted or unsubstituted.” (*Id.*) Thus, Appellants argue, “the genus of Formula **IIA** contains an impractically large number of compounds.” (*Id.*)

We disagree with Appellants’ characterization of Steiner’s substituent Y. Steiner defines Y as I, CF_3 , Br, Cl, or SnR_3 ; thus, there are only five possibilities for Y and only SnR_3 includes more than one chemical group. So even if the subgenus of SnR_3 substituents is large, the genus of substituents for the Y position is limited to five possibilities.

Appellants also argue that Steiner shows a clear preference for CF_3 at the Y position, and does not exemplify any compounds of formula IIA where Y is Cl. (Appeal Br. 11.) However, Steiner expressly states that the Y substituent can be chlorine and therefore a skilled artisan would have at once envisaged Steiner’s disclosed embodiment in which $\text{Z}=\text{CN}$, and the Y substituent is Cl.

Claims 4, 80, and 81 have not been argued separately and therefore fall with claim 2. 37 C.F.R. § 41.37(c)(1)(iv).

II

The Examiner has rejected claims 2, 4, 80, and 81 as obvious in view of Steiner. The Examiner finds that Steiner's formula (IIA) defines a genus of compounds that includes compound *S*-(I), and that Steiner's compound N-4 is the same as compound *S*-(I) except at position Y, where N-4 has CF₃ instead of Cl, as claimed. (Ans. 11.) The Examiner also finds that Steiner's compound 7 is the same as compound *S*-(I) except at position Q, where N-4 has F instead of CN, as claimed. (*Id.*) The Examiner concludes that the claimed compound would have been obvious in view of Steiner (*id.* at 14) and Appellants' evidence of nonobviousness does not outweigh the evidence favoring obviousness (*id.* at 15).

We agree. Even if a person of ordinary skill in the art did not at once envisage compound *S*-(I) based on Steiner's disclosed embodiment in which position Z is CN and position Y can only be I, CF₃, Br, Cl, or SnR₃, it would have been obvious to choose Cl for position Y, and thus result in the claimed compound.

Appellants argue that the claimed compound would not have been *prima facie* obvious based on Steiner (Appeal Br. 14–18) but, for the reasons discussed above, we disagree.

Appellants also argue that the Dalton Declaration³ presents evidence that the claimed compound has unexpectedly superior properties compared to the closest prior art. (*Id.* at 18–22.)

³ Declaration under 37 C.F.R. § 1.132 of James T. Dalton, signed April 15, 2013.

We have considered the Dalton Declaration but do not agree that it presents objective evidence of nonobviousness that outweighs the evidence favoring obviousness. Dr. Dalton declared that the Specification's Example 4 shows that compound *S*-(I) inhibits progesterone receptor activity, "indicating it possesses an unexpected anti-progestin activity." (Dalton Decl. ¶ 7.) However, the Specification's Example 4 shows results only for compounds *S*-(I), *S*-(II), and *S*-(III). (Spec. 128–131.) Compounds *S*-(II) and *S*-(III) are not encompassed by Steiner's formula (IIA). Thus, the Specification does not provide a comparison to the closest prior art, which would be Steiner's exemplified compound N-4.

Dr. Dalton, however, states that a "[d]irect comparison of progesterone receptor (PR) antagonist activity of **S-I** versus compound **N-4**, as presented in **Exhibit 1** [of the declaration], shows a 10-fold increased potency for **S-I**, *i.e.*, increased antagonist activity." (Dalton Decl. ¶ 8.)

Exhibit 1 attached to the Dalton Declaration shows a "Comparison of *S*-(I) and N4 on PR Activity," and states that *S*-(I) has an IC₅₀ of 17.05 nM and N4 has an IC₅₀ of 162.92 nM, a roughly ten-fold difference in their effect on "RLU," the parameter measured in Exhibit 1. But Dr. Dalton does not explain what, if any, experiments were done to generate the graph shown in Exhibit 1 or, if the data were drawn from references, what those references are. Therefore, we have no way to determine whether the graph shows a valid, side-by-side comparison of the two compounds. Because we cannot tell whether Exhibit 1 of the Dalton Declaration shows results for compounds *S*-(I) and N-4 under comparable conditions, we give the evidence presented therein little weight.

The same applies to Exhibit 4 of the Dalton Declaration. Dr. Dalton states that, in dogs, compound *S-I* “demonstrates a pharmacokinetic half-life of: $t_{1/2}$ (h) = 10.4 ± 0.5 and a clearance of CL (mL/min/kg) = 1.68 ± 0.13 .” (Dalton Decl. ¶ 11, citing Example 7 of the Specification.) Dr. Dalton states that Exhibit 4 of the declaration shows that “[t]he higher clearance (CL of 1.68 mL/min/kg vs. 0.59 mL/min/kg for compound **N-4**) affords the shorter half-lives for *S-I* compared to compound **N-4** by all routes studied, which better mimics endogenous testosterone levels.” (*Id.*)

Again, however, Dr. Dalton does not describe how the data presented in Exhibit 4 were derived. Neither Appellants’ Specification nor the Dalton Declaration describes how the data in the Specification’s Example 7 and the Dalton Declaration’s Exhibit 4 were generated. Thus, we cannot determine whether the data represent a valid, side-by-side comparison of the claimed *S-I* compound and the prior art **N-4** compound. We therefore give the evidence presented in Exhibit 4 of the Dalton Declaration little weight.

Dr. Dalton also declares that compound “**S-1** demonstrates enhanced tissue selective anabolic activity with respect to Steiner’s . . . Compound 7.” (Dalton Decl. ¶ 10.) Dr. Dalton states that the data in the declaration’s Exhibit 2 “shows increased levator ani muscle agonist efficacy in orchidectomized subjects of a compound of *S-I*, i.e. > 100% levator ani weight at 0.3 mg/d.” (*Id.*)

However, Steiner’s compound 7 is not encompassed by its formula (IIA) because it has a fluorine (F) at position Q, while formula (IIA) requires position Q to be CN. Steiner discloses that its compound **N-4**, which differs from the claimed compound *S-I* only at position Y (CF_3 in **N-4**, Cl in *S-I*)

“significantly increased the weight of the levator ani muscle to . . . 142%±17% . . . of that observed in intact controls.” (Steiner ¶ 190.) Appellants have not explained why the activity of compound S-(I) (>100%) would have been unexpected when compared to that of the prior art compound N-4 (142%±17%). The preponderance of evidence thus supports a conclusion that compound S-(I) would have been obvious based on Steiner.

Claims 4, 80, and 81 have not been argued separately and therefore fall with claim 2. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm both of the rejections on appeal.

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