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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DOUGLAS BENJAMIN WEIBEL, YE JIN EUN, MARIE HAZEL FOSS, and KATHERINE ANN HURLEY

Appeal 2017-010258
Application 13/913,912
Technology Center 1600

Before ERIC B. GRIMES, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134 involving claims to a method of treating a subject in need of treatment for a bacterial infection with an antimicrobial compound. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

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[1] Appellants identify the Real Party in Interest as the Wisconsin Alumni Research Foundation (*see* App. Br. 2).

[2] We have considered and herein refer to the Specification of June 10, 2013 ("Spec."); Final Office Action of Nov. 4, 2016 ("Final Action"); Appeal Brief of Mar. 7, 2017 ("App. Br."); Examiner's Answer of June 2, 2017 ("Ans."), and Reply Brief of July 27, 2017 ("Reply Br.").

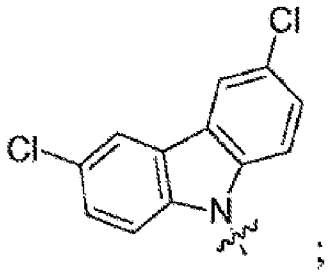
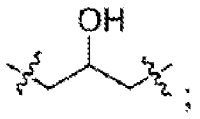
Statement of the Case

Background

"An effective strategy for combating slow-growing bacteria is to target the lipid membrane." (Spec. ¶ 5). "Peripheral and integral membrane proteins participate in various essential cellular processes . . . Compounds that perturb these processes disrupt growth and the maintenance of cell homeostasis and may serve as potent therapeutic antimicrobial agents" (Spec. ¶ 5).

The Claims

Claims 10, 11, 13–20 and 22 are on appeal. Claim 10 is representative and reads as follows:

> 10. A method of treating a subject in need of treatment for a bacterial infection comprising administering to the subject a pharmaceutical composition comprising an antimicrobial compound of Formula I, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient, wherein the antimicrobial compound of Formula I is:
>
> $$G\text{-}Q\text{-}NH\text{-}C(R^2)(R^3)(R^4) \qquad (I)$$
>
> wherein
>
> G is  ;
>
> Q is  ;
>
> R^2 and R^3 are hydrogen, and
>
> R^4 is C_6-C_8 alkyl optionally substituted with hydroxy,
>
> or
>
> R^2 is hydrogen, and R^3 and R^4 in $-C(R^2)(R^3)(R^4)$ together with the carbon (-C) form a C_6-C_7 cycloalkyl ring structure.

The Rejection[3]

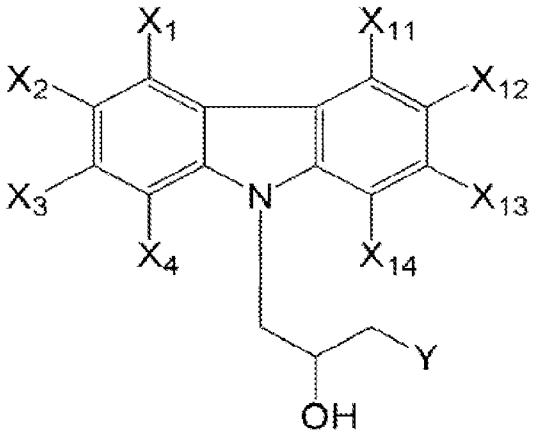
The Examiner rejected claims 10, 11, 13–20 and 22 under 35 U.S.C. § 103(a) as obvious over Amuro[4] (Final Act. 5–8).

The issue with respect to this rejection is: Does a preponderance of the evidence of record support the Examiner's conclusion that the prior art renders the claims obvious?

Findings of Fact (FF)

1. Amuro teaches "an object of the present invention is to provide a novel antibacterial agent capable of exhibiting excellent antibacterial effects against various bacteria" (Amuro ¶ 4).

2. Amuro teaches a structure as reproduced below:



"X_2 and X_{12} are each independently a halogen atom . . . a chlorine atom"; "X_1, X_3, X_4, X_{11}, X_{13}, and X_{14} are each . . . a hydrogen atom"; and "Y is an amino group"(Amuro ¶¶ 18–21).

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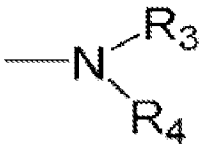
[3] The Examiner withdrew the rejection under 35 U.S.C. § 112, first paragraph for new matter (*see* Ans. 2).

[4] Amuro, JP 2007-223916 A1, published Sept. 6, 2007 (We rely on a machine translation of Amuro that was entered into the file on Mar. 23, 2015).

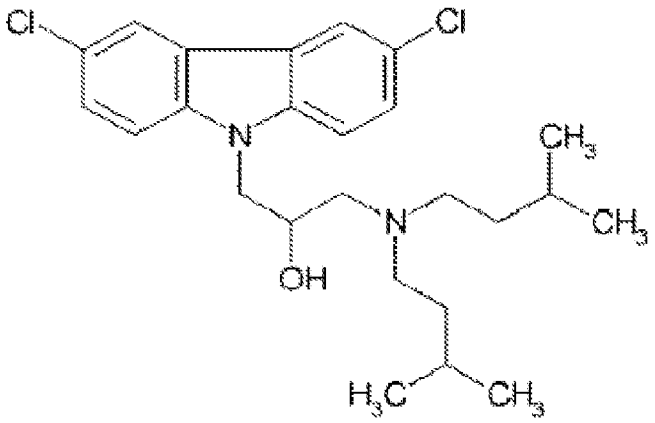
3. Amuro teaches that the amino group Y may be as reproduced below:



> R_3 and R_4 are each independently a hydrogen atom or a substituted or unsubstituted alkyl group, an alkenyl group or alkynyl group. R_3 and R_4 total number of carbon atoms of, in the range of 1 to 5. If the total of the number of carbon atoms is more than 5, it becomes difficult to obtain a good anti-microbial activity.

(Amuro ¶¶ 23–24).

4. Amuro teaches a compound, b-6, that is reproduced below:



Compound b-6 has chlorines at the X_2 and X_{12} positions and five carbon isopentyl groups at the R_3 and R_4 positions of the amino group Y relative to the general compound structure disclosed by Amuro (Amuro, table 2).

Principles of Law

A prima facie case for obviousness requires "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Analysis

Appellants contend

> Amuro clearly discourages one from preparing compounds in which R3 + R4 has more than 5 carbon atoms. Amuro, in translation, does not appear to refer to "good antimicrobial activity", rather referring to "it becomes difficult to obtain satisfactory antibiotic activity." In view of the disclosure of compounds with satisfactory antimicrobial activity, why would one be motivated to try compounds Amuro clearly stated have less than satisfactory activity? Appellants submit that Amuro provides a clear teaching away from the claimed compounds.

(App. Br. 7).

The Examiner responds

> Amuro teaches in paragraph 24 that "If the total of the number of carbon atoms is more than 5, it becomes difficult to obtain a good anti-microbial activity". The Examiner is reading, "good anti-microbial activity" subjectively and one skilled in the art would still be motivated to try a homologue of a 5 carbon alkyl chain . . . with an expectation that it still had activity. The Examiner does not read "difficulty to obtain good anti-microbial activity" as not having activity at all, because Amuro et al. does not teach that anything over 5 carbons does not have activity, which is a true "teaching away" or clear teaching that the compounds do not have activity.

(Ans. 3–4).

We agree with Appellants because claim 10 requires at least 6 carbons at the R^4 position of Formula I and Amuro teaches that "[i]f the total of the number of carbon atoms is more than 5, it becomes difficult to obtain a good anti-microbial activity" (FF 3). Amuro's teaching undercuts the Examiner's obviousness rationale based on the selection of homologs having similar properties because Amuro teaches that compounds with more than 5 carbon atoms would not be expected to have good anti-microbial activity.

Under the lead compound analysis rubric, we must first "determine[] whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012). "The second inquiry in the analysis is whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success." *Id.* at 1292.

In this case, while Amuro might reasonably provide several lead compounds as starting points, Amuro would not have supplied the ordinary artisan with a reason to modify any of these lead compounds to make the claimed compound because Amuro teaches that compounds with more than 5 carbons are less likely to have "good anti-microbial activity" (FF 3).

We also agree with Appellants that Amuro teaches away from the claimed structure "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). While we can agree with the Examiner that Amuro teaches antibacterial compounds with up to 5 carbons at the R_3 and R_4 positions of the amino group Y relative to the general compound structure disclosed by Amuro (FF 1–3), Amuro specifically teaches "[i]f the total of the number of carbon atoms is more than 5, it becomes difficult to obtain a good anti-microbial activity" (FF 3). This is not a situation where the prior art could not have synthesized the claimed compound based on Amuro, but rather a situation where Amuro discourages the use of more than

5 carbon atoms at these positions (FF 3), and the Examiner has advanced no persuasive positive reason to do so. We therefore agree with Appellants that "Amuro clearly teaches away from the presently claimed compounds as they are of the type expected to have less than satisfactory antimicrobial activity" (App. Br. 7).

Conclusion of Law

A preponderance of the evidence of record does not support the Examiner's conclusion that the prior art renders the claims obvious.

SUMMARY

In summary, we reverse the rejection of claims 10, 11, 13–20 and 22 under 35 U.S.C. § 103(a) as obvious over Amuro.

REVERSED