UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/533,255	11/05/2014	Michael John ZAWOROTKO	292104-1781	6923

136746 7590 01/22/2019

Thomas Horstemeyer (USF)
3200 Windy Hill Road, SE
Suite 1600E
Atlanta, GA 30339

EXAMINER
WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
01/22/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@thomashorstemeyer.com
docketing@thomashorstemeyer.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL JOHN ZAWOROTKO, HEATHER CLARK, ARORA KAPILDEV, PADMINI KAVURU, ROLAND DOUGLAS SHYTLE, TWARITA PUJARI, LISSETTE MARSHALL, AND TIEN TENG ONG,

---

Appeal 2017-011332
Application 14/533,255[1]
Technology Center 1600

Before ULRIKE W. JENKS, JOHN E. SCHNEIDER, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition comprising a co-crystal of a nutraceutical and a co-crystal former, which have been rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

"Nutraceuticals refer to a food or food component claimed to human health benefits." (Spec. ¶ 3.) "[N]utraceuticals may be amorphous, may

---

[1] Appellants identify the real party in interest as the University of South Florida Division of Patents and Licensing. (Appeal Br. 3.)

have different crystalline polymorphs, or may exist in different solvation or hydration states. . . . [V]ariation of the crystalline state of a nutraceutical is one of many ways in which to modulate the physical properties thereof." (*Id.* ¶ 7)

"A co-crystal is a multiple component crystal containing two or more nonidentical molecules in which all components are solid under ambient conditions . . . when in their pure form." (*Id.* at ¶ 8.) Appellants' invention "is generally related to co-crystal compositions containing nutraceuticals." (*Id.* ¶ 2.)

Claims 1–6 and 16–18 are on appeal. Claim 1 is representative and reads as follows:

> 1. A composition comprising a co-crystal of a nutraceutical and a co-crystal former, the co-crystal with or without impurities wherein
>
> (i) the nutraceutical and the co-crystal former are hydrogen bonded to each other,
>
> (ii) the nutraceutical is selected from the group consisting of vitamin B2 (riboflavin), glucosamine HCl, chlorogenic acid, lipoic acid, catechin hydrate, creatine, acetyl-L-carnitine HCl, vitamin B6, pyridoxine, caffeic acid, naringenin, vitamin B1 (thiamine HCl), baicalein, luteolin, hesperedin, rosmarinic acid, epicatechin gallate, epigallocatechin, vitamin B9 (folic), genistein, methylvanillin, ethylvanillin, silibinin, diadzein, melatonin, rutin hydrate, vitamin A, retinol, vitamin D2 (ergocalciferol), vitamin E (tocopherol), diosmin, menadione (K3), vitamin D3 (caholecalciferol), phloretin, indole-3-carbinol, fisetin, glycitein, chrysin, gallocatechin, vitamin B4 (adenine), vitamin B5 (pantothenic acid), vitamin B7 (biotin), theobromine, quercetin, ferulic acid, ellagic acid, hesperitin, and protocatechuic acid, and

> (iii) a co-crystal former selected from the group consisting of pharmaceutically acceptable carbohydrates, amines, amides, sulfonamides, carboxylic acids, sulfonic acids, phenols, polyphenols, aromatic heterocycles, xanthines and alcohols.

(Appeal Br. 14.)[2]

The following ground of rejection by the Examiner is before us on review:

Claims 1–6 and 16–18 under 35 U.S.C. § 102(b) as anticipated by Almarsson.[3]

DISCUSSION

According to the Examiner, Almarsson "teaches the same broad composition [as] the applicants' present . . . broad claim 1." (Ans. 4.) The Examiner finds that Almarsson teaches a co-crystal of an API [(active pharmaceutical ingredient)] and co-crystal former where the "API is quercetin (page 375, Table IV) and the co-crystal former is caffeine, a xanthine (page 96, Table 1)." (*Id.* at. 2–3.) The Examiner notes that in such a composition, the API, which is a nutraceutical, and the co-crystal former would necessarily be hydrogen bonded because the composition would have the identical chemical structure claimed and a "composition and its properties are inseparable." (*Id.*)

We disagree with the Examiner's conclusion that Almarsson anticipates claim 1.

---

[2] Formatting added for ease of understanding.
[3] Almarsson et al., WO 2004/078163 A2, published Sept. 16, 2004.

"It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). While verbatim disclosure is not required to establish anticipation of a chemical composition where the prior art disclosure provides for combining lists of ingredients, our reviewing Court has explained that, in order to anticipate, the prior art disclosure must be such that a person of ordinary skill would "at once envisage" the specific claimed composition as being a member of a limited class. *See e.g., In re Petering*, 301 F.2d 676, 687 (CCPA 1962); *see also Nidec Motor Corp. v. Zhongsshan Broad Ocean Motor*, 851 F.3d 1270, 1274–75 (Fed. Cir. 2017) ("the relevant question [in *Kennametal Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376 (Fed. Cir. 2015) regarding anticipation] was 'whether the number of categories and components disclosed in [the prior art reference] is so large that the combination of ruthenium and PVD coatings would not be immediately apparent to one of ordinary skill in the art.'").

In *In re Schaumann*, 572 F.2d 312 (CCPA 1978), anticipation was found where the reference disclosed a genus limited to a single variable with 14 possibilities, (*id.* at 316), and in *Petering*, a vast number of permutations of substituent groups under a generic chemical formula was reduced to a subgenus of 20 compounds, including the claimed species, by recourse to "preferences" disclosed in the reference, (301 F.2d at 681). In *Kennametal*, "[t]he prior art reference disclosed five binding agents (one of which was ruthenium) and three coating techniques (one of which was PVD)" and "taught that any of the five binding agents could be used with any of the three coating techniques," which was deemed sufficient disclosure to

anticipate a claim that "required a ruthenium binding agent and a PVD coating to be used together." *Nidec*, 851 F.3d at 1274 (explaining the narrow decision in *Kennametal*).

As Appellants point out, Almarsson provides a list of possible API's in table IV and a list of possible co-crystal formers in Table I and does not specifically disclose the combination asserted by the Examiner. (Appeal Br. 11; Reply Br. 2.) Rather Almarsson states:

> In a further embodiment the co-crystal comprises an API from Table IV and a co-crystal former with a functional group of Table III. In a further embodiment, the co-crystal is from Table I or II.

(Almarsson at 33.)

Table IV, which lists possible API's that one may select to combine with a co-crystal former from Tables I, II or III spans over 200 pages and includes well over 2000 compounds. (*Id.* at 174–434.) Almarsson states that the API can have "at least one functional group selected from ether, thioether, alcohol, thiol, aldehyde, ketone, thioketone, nitrate ester, phosphate ester, thiophosphate ester, ester, thioester, sulfate ester, carboxylic acid, phosphinic acid, phosphonic acid, sulfonic acid, amide, primary amine, secondary amine, ammonia, tertiary amine, imine, thiocyanate, cyanamide, oxime, nitrile diazo, organohalide, nitro, S-heterocyclic ring, thiophene, N-heterocyclic ring, pyrrole, O-heterocyclic ring, furan, epoxide, peroxide, hydroxamic acid, imidazole, [and] pyridine." (*Id.* at 4.) The scope of that list is quite broad. To the extent that Almarsson narrows that group, it provides examples using the following API's: celecoxib (Example 1 and 2), topiramate (Example 3), olanzapine (Example 4), itraconazole (Examples 5–9), modafinil (Examples 10–12), 5-fluorouracil (Example 13);

hydrochlorthiazide (Examples 14–16), acetaminophen (Example 17), phenytoin (Example 18), acetylsalicylic acid (Example 19), ibuprofen (Example 20), flurbiprofen (Examples 21 and 22), carbamazepine (Example 23–30). The structure of these chemicals are diverse and does not point to a particular class of compounds or a subgenus of disclosed structures for the API selection.

Almarsson does not contain a disclosure comparable to that in *Schaumann, Petering*, or *Kennametal* such that one of ordinary skill in the art would at once envisage a limited class of API's that would fall within the scope of claim 1, or specifically the nutraceutical quercetin, which the Examiner selects from the vast listing in Table IV, to combine with a co-crystal former resulting in a composition where the nutraceutical and the co-crystal former are hydrogen bonded to each other. Thus, despite the fact that claim 1 on appeal recites nutraceuticals with disparate chemical structures, we conclude that the Examiner has failed to establish on the record before us that Almarsson anticipates claim 1.

We note that obviousness is not a rejection on appeal. Thus, we do not take an ultimate position on whether the invention of claim 1 would have been *prima facie* obvious from the disclosure of Almarsson.

SUMMARY

We reverse the rejection of claims 1–6 and 16–18 under 35 U.S.C. § 102(b) as anticipated by Almarsson.

REVERSED