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.
11/635,361	12/07/2006	Horst G. Zerbe	Intelgenx 143939-0018	6120

35684 7590 02/25/2013
BUTZEL LONG
IP DOCKETING DEPT
150 West Jefferson
Suite 100
Detroit, MI 48226

EXAMINER
LEA, CHRISTOPHER RAYMOND

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
02/25/2013	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):

PATENT@BUTZEL.COM

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HORST G. ZERBE, NADINE PAIEMENT,
and POMPILIA ISPAS-SZABO

Appeal 2011-005243
Application 11/635,361
Technology Center 1600

Before DONALD E. ADAMS, ERICA A. FRANKLIN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a nutritional solid oral dosage form. The Patent Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification states that "[i]t is well recognized that concurrent calcium and iron supplementation using a single oral dosage form has been difficult due to undesirable interactions between these minerals, which

reduce bioavailability," in particular, the significant inhibition of iron absorption by calcium. (Spec. [0003].) However, various forms of calcium, such as lactate, gluconate, carbonate, citrate, and citrate malate salts have been suggested to improve iron bioavailability. (*Id*.) The Specification states that "[t]he present invention provides an innovative solution to the problem of preventing and/or reducing interactions between a calcium nutrient and an iron nutrient present in a single dosage form by isolating the calcium nutrient in an enterically coated particle, granule or pellet." (*Id*. at [0008].)

Claims 1, 3, and 6-13 are on appeal. Claim 1 is representative and reads as follows:

1. A nutritional solid oral dosage form, comprising:
an immediate release matrix material in which are dispersed enterically coated particles, granules or pellets containing a calcium nutrient and a nutritionally acceptable acid selected from the group consisting of citric acid, tartaric acid, malic acid, succinic acid, fumaric acid, phosphoric acid, gluconic acid, acetic acid, tannic acid, lactic acid and glycolic acid, the nutritionally acceptable acid being present in an amount that is effective to provide a microenvironment that facilitates conversion of the calcium nutrient into a form exhibiting enhanced bioavailability, wherein the dosage form further comprises an iron nutrient located in the immediate release matrix material external to the enterically coated particles, granules or pellets.

The Examiner rejected the claims 1, 3 and 6-13 under 35 U.S.C. § 103(a) as unpatentable over Anastasia[1] and Andon.[2]

---

[1] Patent Application Publication No. EP 0 208 362 A1 by Frank Bernard Anastasia et al., published Jan. 14, 1987.
[2] US Patent No. 5,468,506 issued to Mark B. Andon, Nov. 21, 1995.

Claims 3 and 6-13 have not been argued separately and therefore stand or fall with independent claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS

The Examiner found that Anastasia taught a dietary supplement containing immediate release iron and delayed release calcium so that the calcium does not interfere with the absorption of the iron. (Ans. 4-5.) The Examiner also found that Anastasia taught that the calcium source is a calcium salt such as calcium citrate, calcium lactate, calcium gluconate, and particularly preferred, calcium carbonate and mixtures of calcium citrate and calcium malate. (*Id*. at 5.) According to the Examiner, Anastasia's supplement differed from the claimed nutritional solid dosage form by not including a nutritionally acceptable acid in the granules containing the calcium nutrient. (*Id*. at 6.)

However, the Examiner found that Andon disclosed a highly bioavailable calcium source containing calcium and a combination of citric and malic acid. (*Id*.) According to the Examiner, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to couple citric and malic acids with a calcium nutrient, as taught by Andon, to increase the bioavailability of the calcium source. (*Id*. at 7.)

Appellants contend that "[n]either of the applied prior art references recognize the problem of reduced solubility and reduced bioavailability associated with release of a solid calcium nutrient from a solid oral dosage form in the higher pH regions of the gastrointestinal tract" nor do the references suggest "adding a nutritionally acceptable acid to a solid oral

dosage form to enhance bioavailability of a calcium nutrient in the higher pH regions of the gastrointestinal tract." (App. Br. 4.)

We are not persuaded by this argument that the claimed invention is nonobvious. Establishing a case of prima facie obviousness does not require the prior art to provide the same reasoning as Applicants for combining known elements. *See In re Dillon*, 919 F.2d 688, 693 (Fed. Cir. 1990). Rather, the test is whether the combined teachings of the prior art provided an apparent reason to combine the known elements in the fashion claimed. *KSR Int' l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (requiring a determination of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). Here, the Examiner soundly reasoned that Andon provided motivation to substitute its calcium salt combination in place of the calcium salt used in Anastasia's dosage form to improve the bioavailability of the calcium. (Ans. 7, 9.)

Appellants also assert that Andon did "not teach anything relevant to simultaneous coadministration of an iron nutrient and a calcium nutrient from a solid oral dosage form, and does not recognize or address any problems associated with solid oral dosage forms containing iron and/or calcium nutrients." (App. Br. 4-5.)

We remain unpersuaded by this argument. The Examiner concluded that the claimed invention was obvious over a *combination* of Anastasia and Andon. In the combination, the Examiner correctly found that Anastasia squarely addressed potential interactions of iron and calcium when simultaneously administered in a solid oral dosage form and disclosed a solution to overcome this problem, *i.e.*, applying a delayed release coating to the calcium source. (Ans. 4-5.)

With respect to the combination of Anastasia and Andon, Appellants assert that "Andon is limited to disclosing concentrated bioavailable calcium sources in the form of liquid sweetener supplements… [and] is not reasonabl[y] pertinent to the problems addressed by Anastasia et al., such that the person of ordinary skill in the art would not know how to apply the teachings of Andon to the [solid] oral dosage forms of Anastasia et al." (*Id*. at 5.) In particular, Appellants assert that (a) "Andon only discloses liquid compositions in which all of the solid components, including the calcium salt, the malic acid and the citric acid <u>must</u> be dissolved in water" (Reply Br. 2) and; (b) that "improved bioavailability is achieved only in the presence of sugar" (*id*.). Thus, according to Appellants, Andon's teachings would have led a person having ordinary skill in the art away from expecting a beneficial result from adding solid edible acids to enterically coated calcium particles as disclosed by Anastasia. (App. Br. 6-7; Reply Br. 2.)

We are not persuaded by Appellants' arguments. Andon is reasonably pertinent to Anastasia in that both references are directed to calcium supplementation. The analogous nature of the prior art is unchanged by the fact that Andon's calcium supplement is in the form of a liquid sweetener rather than a solid dosage form. *See In re Clay*, 966 F.2d 656, 658-659 (Fed. Cir. 1992). Appellants assert that Andon's solid components must be dissolved in water. (Reply Br. 2.) However, Andon is directed toward a liquid supplement, so we understand that Andon's teaching to dissolve the solids in water is necessary to achieve an effective liquid supplement. However, we do not find, nor have Appellants provided evidence, that the enhanced bioavailability of Andon's combination of calcium salt, edible acids and sugar is dependent upon the dissolution of the solids in water.

Rather, as Appellants stated, Andon taught that "improved bioavailability is achieved only in the presence of sugar." (Reply Br. 2.)

With respect to the addition of a sugar, both Anastasia and the claimed invention use the open claim language "comprise" or "comprising" when reciting the components of their respective dosage forms. Thus, both the supplement of Anastasia and the claimed invention are open to adding sugar to the calcium source, as taught by Andon. Thus, we do not agree with Appellants that Andon taught away from combining a calcium salt with malic acid, citric acid and a sugar in a solid dosage form. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Consequently, we agree with the Examiner that modifying the supplement of Anastasia according to the teachings of Andon amounted to a predictable variation that could have been implemented by a person of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. at 417.

Accordingly, we affirm the obviousness rejection.

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

cdc