NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

DR. FALK PHARMA GMBH,
Appellant

v.

GENERICO, LLC, FLAT LINE CAPITAL LLC, MYLAN PHARMACEUTICALS INC.,
Appellees

2017-2312

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-00297, IPR2016-01386, IPR2016-01409.

SALIX PHARMACEUTICALS, INC., DR. FALK PHARMA GMBH,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC.,
Defendants-Appellees

2017-2636, 2018-1320

Appeals from the United States District Court for the Northern District of West Virginia in No. 1:15-cv-00109-IMK, Judge Irene M. Keeley.

Decided: June 12, 2019

MARY W. BOURKE, Womble Bond Dickinson (US) LLP, Wilmington, DE, argued for appellant in 2017-2312 and plaintiffs-appellants in 2017-2636. Also represented by DANIEL M. ATTAWAY, KRISTEN HEALEY CRAMER, DANA KATHRYN SEVERANCE; JOHN W. COX, Atlanta, GA.

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ZACHARY DAVID SILBERSHER, Kroub Silbersher & Kolmykov PLLC, New York, NY, for appellees GeneriCo, LLC, Flat Line Capital LLC in 2017-2312. Also represented by GASTON KROUB.

Before LOURIE, O'MALLEY, and REYNA, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

This case arises from two parallel proceedings involving U.S. Patent No. 8,865,688 ("the '688 patent"), which is owned by Dr. Falk Pharma GmbH ("Dr. Falk") and exclusively licensed to Salix Pharmaceuticals, Inc. ("Salix"). Dr. Falk appeals from a final written decision of the U.S. Patent Trial and Appeal Board ("Board") finding that Mylan

Pharmaceuticals Inc., GeneriCo, LLC, and Flat Line Capital LLC (collectively, "appellees") had proven by a preponderance of the evidence that claims 1 and 16 of the '688 patent are unpatentable as obvious. *GeneriCo, LLC v. Dr. Falk Pharma GmbH*, Nos. IPR2016-00296, -01386, -01409 (P.T.A.B. May 19, 2017). Salix and Dr. Falk appeal from a decision of the United States District Court for the Northern District of West Virginia holding, after bench trial, that claim 1 of the '688 patent would not be infringed. *Salix Pharms., Inc. v. Mylan Pharms., Inc.*, No. 1:15-cv-00109, (N.D. W. Va. Apr. 12, 2016). For the reasons stated below, we *affirm* the Board's conclusion that claims 1 and 16 are unpatentable as obvious and *dismiss* as moot the appeal from the district court's judgment of noninfringement of claim 1.

I. BACKGROUND

This case involves a method of treating ulcerative colitis by administering a granulated mesalamine formulation. Salix is the holder of New Drug Application ("NDA") No. 22-301 for mesalamine extended release capsules (375 mg), which is sold and prescribed in the United States under the trademark Apriso®. The '688 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," as covering Apriso®.

In 2015, Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") submitted Abbreviated New Drug Application ("ANDA") No. 20-7271 seeking approval to market a generic version of Apriso®, consisting of a 375 mg mesalamine oral extended release capsule ("proposed product"). Salix and Dr. Falk received Mylan's Paragraph IV notice letter on May 15, 2015 certifying, *inter alia*, that certain claims of the '688 patent are invalid and/or would not be infringed by Mylan's proposed product. On June 26, 2015, within 45 days of receiving Mylan's notice letter, Salix and Dr. Falk filed suit alleging that Mylan's proposed

product, if approved, would infringe the '688 patent. Mylan filed affirmative defenses and counterclaims challenging the validity of the '688 patent, which were dismissed without prejudice pending the final resolution of the Board proceedings in *Dr. Falk*. Following a three-day bench trial, the district court issued an opinion dated September 12, 2017 construing terms and finding that claim 1 of the '688 patent would not be infringed by Mylan's proposed product.

On December 8, 2015, after Salix and Dr. Falk sued Mylan in district court, GeneriCo and Flat Line filed a petition for inter partes review challenging claims 1 and 16 of the '688 patent as obvious over certain prior art references: a September 2007 Press Release, Endonurse, and Davis-1985, in view of either Marakhouski or Brunner. The Board instituted on June 10, 2016, after when, Mylan filed its own petition. The Board joined all proceedings on November 30, 2016. Following an oral hearing, the Board issued a final written decision dated May 19, 2017 finding claims 1 and 16 unpatentable as obvious over the asserted references. The following sections detail the relevant technology, prior art, and procedural history.

A. The '688 Patent

The '688 patent relates to a method of maintaining remission of ulcerative colitis with a granulated mesalamine formulation. Ulcerative colitis is a chronic inflammatory disease of the colonic mucosa, i.e. the lining of the colon, for which there is no known cause. '688 patent, col. 1, ll. 15–17, 32–34. The inflammation caused by the disease makes it difficult for the body to absorb water and electrolytes, resulting in dehydration, weight loss, and serum electrolyte disturbances. *Id.* at col. 1, ll. 19–24. It can also lead to erosions, which cause rectal bleeding, and smooth muscle spasms, which cause an urgency to defecate. *Id.* at col. 1, ll. 24–28. The background of the patent explains that ulcerative colitis can thus have a "profound emotional and

social impact on the affected individual." *Id.* at col. 1, ll. 32–33.

People with ulcerative colitis experience periods of remission, but symptoms eventually return in most. *Id.* at col. 1, ll. 51–54. The patent explains that "active therapy" treatments aim to treat patients who are actively experiencing symptoms of ulcerative colitis, whereas "maintenance therapy" treatments, such as the treatment claimed in the '688 patent, aim to maintain remission and keep patients in a disease-free or limited disease state. *Id.* at col. 1, ll. 51–59.

The specification explains that the clinical efficacy of any available oral treatments depends on delivery of the intact molecule to the colonic mucosa. *Id.* at col. 1, ll. 60–63. This is because the molecule can breakdown during digestion and prior to entering the colon. *Id.* at col. 1, ll. 61–63. Previous delivery methods for oral treatments known at the time of invention were problematic due to the "variation . . . in the release of mesalamine, including premature release, the possibility of dose dumping, and sensitivity to conditions that increase gastric pH and cause premature release of mesalamine (e.g., ingestion of a meal)." *Id.* at col. 2, ll. 3–8. Accordingly, the specification states that formulations available at the time of invention could not adequately treat people suffering from a variety of bowel diseases. *Id.* at col. 2, ll. 12–15.

The invention of the '688 patent purports to improve upon past methods by administering an effective amount of granulated mesalamine formulation. *Id.* at col. 3, ll. 26–30. Representative claim 1 recites:

> 1. A method of maintaining the remission of ulcerative colitis in a subject comprising
>
> administering to the subject a granulated mesalamine formulation comprising four capsules each

> comprising 0.375 g of granulated mesalamine once per day in the morning, *without food*, wherein:
>
> said method maintains remission of ulcerative colitis in a subject for a period of at least 6 months of treatment;
>
> *remission is defined as a DAI score of 0 or 1*;
>
> the granulated mesalamine formulation is not administered with antacids; and
>
> wherein 85% to 90% of the mesalamine reaches the terminal ileum and colon.

Id. at col. 34, ll. 10–22 (emphases added). Challenged claim 16 is substantially identical to claim 1 but recites the additional step of "advising the subject that granulated mesalamine should not be taken with antacids." *Id.* at col. 35, ll. 4–17.

As the Board noted in its final written decision, the first and fourth limitations recite steps in the claimed method whereas the remaining limitations recite the results of the claimed method. The relevant claim limitations for the purposes of resolving the issues on appeal include the "DAI score" limitation, which recites a result of the method, and the "without food" limitation, which recites a step of the method. The specification expressly defines the term "DAI score":

> Ulcerative colitis disease activity was assessed using a modified Sutherland Disease Activity Index1 (DAI), which is a sum of four subscores based on stool frequency, rectal bleeding, mucosal appearance on endoscopy, and physician's rating of disease activity. Each subscore can range from 0 to 3, for a total possible DAI score of 12.

Id. at col. 17, ll. 6–11. The specification also discloses various studies, including phase III clinical trials, that consider the effect of food on absorption. It expressly states

that overall systemic absorption was "essentially unaltered by a high-fat meal eaten before dosing" and that "[t]he ability to take mesalamine granules with or without food, along with its once-daily dosing, may improve patient compliance and treatment success." *Id.* at col. 7, ll. 28–34.

B. Asserted Prior Art

In *Dr. Falk*, appellees argued before the Board that claims 1 and 16 are unpatentable as obvious over the September 2007 Press Release[1], Endonurse[2], and Davis-1985[3] in view of either Marakhouski[4] or Brunner[5]. Each asserted reference is described below.

1. September 2007 Press Release & Endonurse

The September 2007 Press Release is Salix's announcement of the "successful completion and outcome of the first of two Phase III registration trials to evaluate the safety

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[1] Salix Announces Statistically Significant Top-Line Results of a Unique Granulated Mesalamine Product Registration Study in Ulcerative Colitis (September 2007), http://www.sec.gov/Archives/edgar/containers/fix021/1009356/00011931 2507195530/dex992.htm

[2] XIFAXAN® Trials Initiated in C. difficile-Associated Diarrhea, Irritable Bowel Syndrome and Hepatic Encephalopathy, New Article EndoNurse, 12 January 2006.

[3] S. S. Davis, *The Design and Evaluation of Controlled Release Systems for the Gastrointestinal Tract*, 2 J. Controlled Release 27–38 (1985).

[4] Y. Marakhouski et al., *A Double-blind Dose-escalating Trial Comparing Novel Mesalazine Pellets with Mesalazine Tablets in Active Ulcerative Colitis*, 21 Aliment Pharmacol. Ther. 133–140 (2005).

[5] M. Brunner et al., *Gastrointestinal Transit and Release of 5-aminosalicylic Acid from 153Sm-labelled Mesalazine Pellets vs. Tablets in Male Healthy Volunteers*, 17 Aliment. Pharmacol. Ther. 1163–1169 (2003).

and efficacy of" its granulated mesalamine formulation in maintaining remission in patients with ulcerative colitis. J.A. 970. The results indicated that patients dosed once daily "with 1.5 grams of granulated mesalamine remained relapse-free over 6 months of treatment" as compared with patients dosed with a placebo. J.A. 970. Dr. Falk contends that the reference does not define "relapse-free" or mention whether the treatment was administered with or without food.

Endonurse is another press release from Salix that reports that "[g]ranulated mesalamine is being investigated in two 300-subject, multi-center, placebo-controlled, double-blind, randomized trials," and that "[e]nrollment is ongoing in these Phase III trials designed to evaluate the efficacy and safety of granulated mesalamine, dosed four 375 mg tablets once daily, for the maintenance of remission of ulcerative colitis." J.A. 981. Dr. Falk notes that Endonurse does not provide any results of the trials nor does it mention whether the treatment is administered with or without food.

2. Davis-1985

Davis-1985 is an academic paper published in the Journal of Controlled Release that discusses three factors relevant to controlled release delivery systems, including the characteristics of the gastrointestinal tract. Specifically, Davis-1985 teaches that the presence of food can affect the pH of the stomach as well as the process of gastric emptying. It states that "[d]elivery systems, administered to a fasted stomach, will empty rapidly from the stomach." J.A. 949. It teaches that, "if the important absorption sites for the administered drug are in the upper small intestine, the measured bioavailability in the fasted state will be considerably different to that measured in the fed state." J.A. 949.

Davis-1985 also discusses the "[p]ositioned release of drugs in the colon." J.A. 951. It notes that the use of 5-

aminosalicylic acid, the active ingredient administered in the claimed invention, for the treatment of ulcerative colitis is a good example of a treatment in which "it would be advantageous to have the delayed, positioned release of a drug in the various regions of the colon" rather than in the small intestine. J.A. 951. It then teaches that, "[i]n designing a positioned release system[,] one needs to be aware of physiological factor(s) that can be exploited to signal the release of the dosage form in the intended region," including slight and variable "pH change." J.A. 951. Dr. Falk contends that Davis-1985 does not mention the impact of food on bioavailability when discussing the positioned release of drugs at the colon and that it only discusses the use of 5-aminosalicylic acid in tablet, not pellet, form.

3. Marakhouski

Marakhouski compares the efficacy of a pellet formulation of 5-aminosalicylic acid with a tablet formulation for the treatment of ulcerative colitis. It explains that pellets are more advantageous because they offer "a unique combination of delayed and prolonged release characteristics." J.A. 1092. Their small size, Marakhouski explains, "guarantees their continuous transit through the stomach into the intestine." J.A. 1092. This prevents the premature release of the active ingredient regardless of whether it is taken with or without food. J.A. 1092 ("Because of their small size (approximately 1 mm), the pellets pass the pylorus continuously and not only during an interdigestive phase, thus preventing the so-called dose-dumping effect. Hence, the pellets can be taken independent of meals.").

4. Brunner

Brunner also compares the movement and release of pellet and tablet formulations of 5-aminosalicylic acid. Brunner explains that the pellet formulation "could show some advantages compared with tablets, such as passage

through the stomach independent of concomitant food intake." J.A. 1103.

C. The Procedural History

1. *Dr. Falk*

Appellees filed petitions for inter partes review challenging claims 1 and 16 of the '688 patent as obvious over the September 2007 Press Release, Endonurse, and Davis-1985, all in view of either Marakhouski or Brunner. The Board instituted on June 10, 2016. In its institution decision, the Board found that Marakhouski discloses administration without food of the same or similar granulated mesalamine formulation for treatment of the same disease. It also found that it did not matter that "Marakhouski makes no comparison between administration with and without food" because such a comparison "is not necessary to persuade [the Board] to institute review" when advantages such as the ability to administer the drug independent of food provide a motivation to combine Marakhouski with the September 2007 Press Release and Endonurse. J.A. 300–01.

The Board held an oral hearing and, on May 19, 2017, issued a final written decision construing the DAI score limitation and finding claims 1 and 16 unpatentable as obvious over the September 2007 Press Release, Endonurse, and Davis-1985, in view of either Marakhouski or Brunner. The Board construed the DAI score limitation as "remission is defined as a DAI score of 0 or 1, where the DAI score is a sum of four subscores." J.A. 11. The Board rejected Dr. Falk's proposal to construe the term to mean that the DAI score is the sum of two, rather than four, subscores. The Board explained that the patent specification expressly defines DAI score as the sum of four subscores. J.A. 11 (citing the '688 patent, col. 17, ll. 7–12). The Board therefore rejected Dr. Falk's proposed construction and adopted a construction consistent with the specification's express definition of DAI score.

The Board then found claims 1 and 16 unpatentable as obvious. It found that all claimed limitations, including the without food and DAI score limitations, were satisfied by the prior art and that there was a motivation to combine the asserted references with a reasonable expectation of success. Specifically, the Board found that a skilled artisan would have been motivated to combine the method of the September 2007 Press Release and Endonurse with the teachings of either Marakhouski or Brunner that the granulated mesalamine formulation could be administered without food. The Board cited as its rationale the fact that all four prior art references pertain to the same or similar granulated mesalamine formulation for treatment of the same disease and because Marakhouski and Brunner teach that an advantage of a granulated mesalamine formulation is the ability to administer the drug *independent of food*. The Board also concluded that a skilled artisan would have been motivated to combine these references with Davis-1985. This is because Davis-1985 discloses using the same active ingredient, 5-aminosalicylic acid, to treat ulcerative colitis and because its teachings are relevant to the question of whether a "drug intended for topical action in the colon should be administered with or without food." J.A. 38.

The Board also found that a skilled artisan would have had a reasonable expectation of success in maintaining remission of ulcerative colitis by administering granulated mesalamine without food. The Board found that the September 2007 Press Release supports this finding because it announces a successful outcome of a Phase III trial to evaluate the safety and efficacy of the same or similar granulated mesalamine formulation for treatment of the same disease. Notably, the Board found "[t]here is no indication in the [September 2007 Press Release] that the granulated mesalamine had to be administered with food in order to obtain the reported success." J.A. 40. The Board also relied on Marakhouski, which reports successful results from

administering granulated mesalamine without food, Davis-1985, which suggests that a drug intended for delivery in the colon is best administered without food, and uncontroverted testimony from appellees' expert. The Board again rejected Dr. Falk's argument that a skilled artisan would need to conduct a food study to determine if the formulation should be administered with or without food. The Board reiterated that such comparative studies are not necessary in view of the evidence of record especially when the claims at issue do not recite an efficacy requirement related to the effect of food.

Finally, the Board considered evidence of objective indicia, including long felt need, failure of others, and unexpected results. The Board found Dr. Falk's evidence unpersuasive and afforded it low probative weight. Specifically, with regard to failure of others, the Board noted that Dr. Falk relied only on its own failures, which the Board found was insufficient. Based on the above findings, the Board concluded that appellees had demonstrated by a preponderance of the evidence that claims 1 and 16 are unpatentable as obvious.

2. *Salix*

As noted, Salix and Dr. Falk sued Mylan alleging that its submission of ANDA No. 20-7271, if approved, would infringe the '688 patent under 35 U.S.C. § 271(e). Mylan filed counterclaims on July 13, 2015, asserting that its proposed product would not infringe and that the patents were invalid as obvious. On June 22, 2017, after the Board entered its final written decision in *Dr. Falk*, the parties jointly stipulated to dismissal of these counterclaims pending resolution of the appeal in *Dr. Falk*.

The district court held a *Markman* hearing and, on April 12, 2016, issued an order construing terms. The parties agreed that the claim term "wherein 85% to 90% of the mesalamine formulation reaches the terminal ileum and colon" ("the 85% to 90% limitation") should be given its

plain and ordinary meaning. But Salix argued that the plain and ordinary meaning of the term encompasses "the understanding that a person of ordinary skill in the art would view the percent mesalamine reaching the terminal ileum or colon as a lower boundary for therapeutic effectiveness." J.A. 1274. The district court construed the term according to its "plain and ordinary meaning" without reading Salix's requested caveat into the claim. It, instead, read the limitation to impose both upper and lower boundaries. The parties did not ask the court to construe the claim term "granulated mesalamine formulation" at that time.

The district court held a bench trial from March 7 to March 9, 2017 on the issue of infringement of claim 1 of the '688 patent. At trial, the parties disputed the constructions of the granulated mesalamine formulation limitation and the 85% to 90% limitation. On November 29, 2017, the district court entered final judgment on behalf of Mylan. Specifically, the district court construed both disputed limitations and found that Salix had failed to demonstrate by a preponderance of the evidence that the proposed product would infringe the granulated mesalamine formulation and the 85% to 90% limitations of the '688 patent.

Salix and Dr. Falk appeal the district court's decision in *Salix* and Dr. Falk appeals the Board's decision in *Dr. Falk*. We have jurisdiction to review both decisions pursuant to 28 U.S.C. § 1295(a)(1) and 28 U.S.C. § 1295(a)(4)(A), respectively.

II. DISCUSSION

In *Dr. Falk*, Dr. Falk argues on appeal that the Board erred in its construction of "remission is defined as a DAI score of 0 or 1" and that the Board's conclusion of obviousness is unsupported under the purportedly proper construction of the term. Dr. Falk also argues that the Board erred in its finding that the without food limitation would have been obvious.

In *Salix*, Salix and Dr. Falk argue on appeal that the district court erred in its claim construction and noninfringement findings with respect to the granulated mesalamine formulation and the 85% to 90% limitations. For the reasons stated below, we *affirm* the Board's finding in *Dr. Falk* that claims 1 and 16 are unpatentable as obvious; we therefore *dismiss* as moot the question of whether the district court in *Salix* erred in finding that Mylan's proposed product would not infringe claim 1.

A. The DAI Score Limitation

Dr. Falk argues that the Board erred when it construed "remission is defined as a DAI score of 0 or 1," as "remission is defined as a DAI score of 0 or 1, where the DAI score is a sum of four subscores" rather than a sum of two subscores. We disagree.

We review the Board's constructions de novo except for subsidiary fact findings based on extrinsic evidence, which we review for substantial evidence. *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 751 (Fed. Cir. 2016). The Board construes claims consistent with their broadest reasonable interpretation in view of the specification.[6] *Id.* Under both this standard and the

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[6] The U.S. Patent and Trademark Office has indicated that it intends to apply the *Phillips* claim construction standard to petitions filed on or after November 13, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42). Because GeneriCo filed its petition before November 13, 2018, we apply the broadest reasonable interpretation standard here (as the Board did below). Regardless, as explained herein, we find no error with the Board's construction based on principles underlying both claim construction standards.

Phillips standard, we construe terms according to their plain and ordinary meanings as understood by a skilled artisan unless the patentee acts as his or her own lexicographer and clearly sets forth a definition of the disputed claim term in either the specification or the prosecution history. *In re Schwemberger*, 410 F. App'x 298, 303 (Fed. Cir. 2010) (citing *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

Here, not only did Dr. Falk concede in front of the Board that the term DAI score is ordinarily understood in the art as the sum of four subscores, J.A. 10, the patentee expressly defined the term as such in the specification:

> Ulcerative colitis disease activity was assessed using a modified Sutherland Disease Activity Index1 (DAI), *which is a sum of four subscores* based on stool frequency, rectal bleeding, mucosal appearance on endoscopy, and physician's rating of disease activity. Each subscore can range from 0 to 3, for a total possible DAI score of 12.

'688 patent, col. 17, ll. 6–11 (emphasis added). Thus, we find that the Board did not err in construing DAI score as a sum of four subscores.

Dr. Falk contends that the "Board's construction contradicts the explicit, repeated definition of 'remission' used by the inventors." Appellant's Br. at 33. It notes that the specification at times describes clinical trials in which "remission" and "relapse-free" (which Dr. Falk contends is an equivalent term for "remission") are defined as a DAI score of 0 or 1 based on *two* subscores. This, according to Dr. Falk, demonstrates that the specification consistently provides a special definition of "remission" and that this special definition must control.

But, while Dr. Falk is correct that the specification at times references a special definition of remission, the claim language does not claim that special definition. This is

clear when we compare the portions of the specification to which Dr. Falk directs the court with the plain language of the claims. For example, Dr. Falk directs us to Examples 8 and 9 in which the specification refers to remission as a "*revised* Sutherland Disease Activity Index [SDAI]" score of less than 2 based on two subscores—rectal bleed and mucosal appearance. '688 patent, col. 26, ll. 51–55 (emphasis added); *see also id.* at col. 25, ll. 33–36; *id.* at col. 26, ll. 21–25; *id.* at col. 28, ll. 7–8. In contrast, the claim language plainly recites a definition of "remission" that does not reference a "revised" DAI score; rather it states that "remission is defined as a DAI score of 0 or 1." *Id.* at col. 34, ll. 18. If the patentee intended to define remission as based on a revised DAI score rather than a DAI score, it would have used the word "revised" in the claim language. Thus, we conclude that the district court did not err in its construction.

B. The Without Food Limitation

Dr. Falk also argues, based on our decision in *SAS Institute, Inc. v. ComplementSoft, LLC*, 825 F.3d 1341 (Fed. Cir. 2016), that the Board violated the Administrative Procedure Act ("APA") by changing theories on the evidence required to show obviousness of the "without food" limitation. According to Dr. Falk, the Board granted institution assuming that the limitation recites a food effect—i.e., that taking the formulation without food is preferable to taking it with food—but, in its final written decision, concluded that the claims do not recite such a food effect. In the alternative, Dr. Falk contends that, when assessing whether a skilled artisan would have been motivated to combine the prior art with a reasonable expectation of success to arrive at the without food limitation, the Board failed to consider evidence regarding the unpredictable impact of food on the absorption of mesalamine. We address each argument in turn.

First, the Board did not change theories on the evidence required to show obviousness of the without food limitation. In *SAS*, we held that it was improper for the Board to use a construction of a term in its final written decision that differed from its construction of the term in its institution decision. 825 F.3d at 1351 ("What concerns us is not that the Board adopted a construction in its final written decision, as the Board is free to do, but that the Board changed theories in midstream." (internal quotations and alterations omitted)). But our decision in *SAS* is distinguishable from this case because the Board here found that the claims do not recite a food effect and because Dr. Falk had adequate notice and opportunity to respond to the Board's conclusion that they do not, as evidenced by the arguments it raised during both the pre- and post- institution phases of the proceedings.

In its institution decision, the Board responded to Dr. Falk's contention that the claims impliedly contained a food effect limitation by stating that, obviousness "turns on whether administering granulated mesalamine without food would have been predictable and would have led to anticipated success." J.A. 298. It then stated that relevant to this inquiry were "record-supported rationales for why a [skilled artisan] seeking to practice the method disclosed in [the September 2007] Press Release and Endonurse would have known to administer granulated mesalamine without food." J.A. 298–99. In response to Dr. Falk's argument that this inquiry requires a food effect study, the Board stated that "[a] comparison between administration with and without food is not necessary to persuade [the Board] to institute review because Petitioners' contention regarding a motivation to combine Markhouski's disclosures with [the September] 2007 Press Release and Endonurse is adequately supported by other information." J.A. 300–01. It then concluded that "administering granulated mesalamine without food would have been known, predictable, and led to anticipated success." J.A. 299. These

statements were in response to Dr. Falk's assertion that a food effect limitation existed and that a food effect study must be disclosed in the prior art; they were not an unqualified agreement with that assertion. Instead, they reflect agreement with appellees' view that the prior art's failure *to require* that the formulation be administered with food was the relevant fact for its obviousness analysis.

Consistent with these statements in its institution decision, the Board stated in its final written decision that "[t]he requirement to show a reasonable expectation of success pertains to the subject matter of the claims," and, here, because "the claims do not recite a food effect," there was a reasonable expectation of success of arriving at the without food limitation even though none of the prior art discloses a food effect study. J.A. 43–44. The Board did not accept Dr. Falk's contention that food effect studies were needed and was not persuaded by Dr. Falk's expert testimony claiming that the impact of food on absorption was unpredictable at the time of the invention. Rather, it consistently indicated that *other* rationales existed for a motivation to combine with a reasonable expectation of success despite an absence of a food effect study in the prior art. Moreover, Dr. Falk raised, appellees rebutted, and the Board addressed during oral argument and in its final written decision the question of whether the claims contain a food effect limitation, as distinct from the without food limitation. That Dr. Falk pursued and lost the argument that they do not contain such a food effect limitation and that the prior art does not disclose one does not amount to inadequate notice and opportunity to respond. Thus, we conclude that the Board's analysis did not violate the APA.

Second, the Board did not fail to consider relevant evidence when assessing a motivation to combine with a reasonable expectation of success. Rather, it focused its analysis on the correct inquiry under our case law, which asks whether a skilled artisan would have "ha[d] a motivation to combine accompanied by a reasonable expectation

of achieving *what is claimed in the patent-at-issue*." *Intelligent Bio-Sys., Inc v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (emphasis added). Here, the Board correctly found that the claims do not recite a food effect. The plain language of the claim merely recites a requirement that the formulation be administered "without food." The language does not indicate the drug formulation is more or less effective depending on whether it is administered with or without food. Even Dr. Falk's own expert, when asked if the "claim requires that the administration of the drug is more effective without food versus with food," answered, "[n]o . . . . It doesn't state more effective with food or without food." J.A. 1208. And, although the specification contains food effect studies, the results of those studies suggest that the drug formulation may be administered *without regard to food*. '688 patent at col. 7, ll. 28–34 (stating that overall systemic absorption was "essentially unaltered by a high-fat meal eaten before dosing" and that "[t]he ability to take mesalamine granules with or without food, along with its once-daily dosing, may improve patient compliance and treatment success."); *id.* at col. 16, ll. 62–64 (studying in Example 4 the pharmacokinetic effect of food on absorption and concluding that "[t]he overall rate and extent of absorption of mesalamine and its N-acetyl metabolite were not affected by a high-fat meal"). Based on this reasonable reading of the claims, the Board found Dr. Falk's evidence regarding the alleged unpredictable impact of food was outside the scope of the claims.

Dr. Falk contends that, even if the claims do not recite a food effect, the Board still erred in disregarding Dr. Falk's evidence because evidence relating to unclaimed features is relevant to the inquiry of a motivation to combine with a reasonable expectation of success. In support of this proposition, Dr. Falk cites to *Intelligent Bio-Systems*, 821 F.3d at 1367–68, in which it contends that this court found evidence relating to an unclaimed feature central to the motivation to combine inquiry and to *Institut Pasteur &*

Universite Pierre et Marie Curie v. Focarino, 738 F.3d 1337, 1346 (Fed. Cir. 2013), in which it contends that this court similarly found that the Board erred in disregarding evidence relating to an unclaimed feature when assessing a motivation to combine with a reasonable expectation of success.

We disagree. In *Intelligent Bio-Systems*, we stated the opposite of what Dr. Falk now contends. 821 F.3d at 1367. Indeed, it is well established that "failure to consider the appropriate scope of the . . . patent's claimed invention in evaluating the reasonable expectation of success . . . constitutes a legal error that [is] review[ed] without deference." *Id.* (quoting *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 966 (Fed. Cir. 2014)). Similarly, in *Institut Pasteur*, we admonished the Board, not because it failed to consider evidence relevant to unclaimed features, but because it failed to consider evidence related to a feature that the Board admitted was implicit in the claims. 737 F.3d at 1346. In contrast, here, the claims do not recite any food effect—either expressly or implicitly. Therefore, we conclude that the Board did not disregard evidence of record, but rather correctly found Dr. Falk's evidence as falling outside the scope of the claims.

III. CONCLUSION

For the reasons stated above, we *affirm* the Board's final written decision in Dr. Falk that claims 1 and 16 of the '688 patent are unpatentable as obvious.[7] Accordingly, we

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[7] We have considered Dr. Falk's remaining arguments and find them unpersuasive. We conclude that the Board did not fail to consider evidence of the differences between the claimed method and the prior art and that substantial evidence supports the Board's finding of a motivation to combine with a reasonable expectation of success despite these differences. We also conclude that the

dismiss as moot Salix's appeal from the district court's judgment that claim 1 of the same patent would not be infringed.

AFFIRMED AS TO APPEAL NO. 17-2312;
DISMISSED AS TO APPEAL NO. 17-2636

COSTS

Costs to Appellees.

Board did not err in its analysis of objective indicia of non-obviousness; specifically, the Board balanced the evidence submitted by Dr. Falk and afforded it due weight in view of our case law.