IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC. and DR. FALK PHARMA GmbH, Plaintiffs, v. NOVEL LABORATORIES, INC., Defendant.	)	Civil Action No. 14-213-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 6,551,620; 8,337,886; 8,496,965; 8,865,688

The court having considered the submissions of the parties and having heard oral argument on the matter—IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 6,551,620 ("the '620 Patent"); 8,337,886 ("the '886 Patent"); 8,496,965 ("the '965 Patent"); and 8,865,688 ("the '688 Patent"):

The '620, '886 & '965 Patents

1. The term "core" is construed to mean "a composition which achieves controlled release of the active compound in the intestinal tract without the aid of a coating."[1]

[1] "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005); *see also Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1327 (Fed. Cir. 2003) ("By insisting that its invention directs energy in a way that does not affect temperature measurement, the patentee has rejected the examiner's broad assessment of the claim scope and stated in a public record what his invention could not be. That statement is a deliberate surrender of claim scope, unmistakable in its effect because it is not suitable to multiple interpretations . . . .").

The court is convinced that the patentee expressly surrendered the full scope of the term "core" during prosecution. In particular, to overcome a prior art rejection in a related patent application, the patentee stated:

> In all prior art compositions cited by the Examiner, the release control is achieved either by providing a matrix which slowly dissolves (or disintegrates) in the intestinal tract and during this process releases the active ingredient or by providing a specific coating around the core which controls the release of the active ingredient. Contrary thereto, in the present application *the release control*

The '688 Patent

2. The term "without food" is construed to have its plain and ordinary meaning.[2]

> *is achieved by an insoluble core and not by a coating*, and the core is not dissolved or destroyed during the release of the active ingredient but remains intact.

(D.I. 86 at JA0078 (emphasis added). In other words, prior art compositions achieved controlled released either by using a soluble, disintegrating matrix or a coating; the patentee's invention, however, employs an insoluble matrix core *and* does not use a coating. In the court's view, such a statement—"with reasonable clarity and deliberateness"—disclaimed cores that work in conjunction with coatings to achieve controlled release in the intestines. *See N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1294 (Fed. Cir. 2000).

To be clear, the '620, '886, and '965 Patents all allow the use of coatings for their claimed pellet formulations in other capacities. In fact, each explicitly claims formulations having an enteric coating—sometimes described as a component of the core or as a separate element. *See* '620 Patent, claim 1 ("An orally administrable pharmaceutical pellet formulation having a controlled release profile for the treatment of the intestinal tract, which comprises a core and an enteric coating . . ."); '886 Patent, claim 1 ("A controlled release pellet formulation for treatment of the intestinal tract, said formulation comprising a core comprising: 1) a homogeneously dispersed pharmaceutically active compound in a non gel-forming polymer matrix and 2) an enteric coating . . ."); '965 Patent, claim 1 ("A controlled release pellet formulation, comprising 1) homogeneously dispersed 5-aminosalicylic acid in a core comprising a polymer matrix . . . ; and 2) an enteric coating . . ."). But the enteric coating does not play a role in the controlled release of the active compound in the intestinal tract. *See, e.g.*, '620 Patent, col. 2 ll. 46–51 ("In order to achieve the necessary local active compound concentration, the active compound must in this case be released at the site of inflammation within a relatively short time (up to a few hours) without, however, it being released virtually immediately, in order that its action does not wear off too rapidly."). Rather, delays the release altogether until the pellet has passed through the stomach; once the pellet reaches the intestines, the enteric coating dissolves, and the core itself then serves to control the release of the active compound. *See, e.g.*, '620 Patent, col. 1 ll. 49–51 ("In the prior art, tablets and pellets are known which are coated with an enteric coating in order to thus prevent a premature release of the active compounds."); col. 4 ll. 15–16 ("The enteric coating should only dissolve after the formulation has left the stomach.").

The court's construction is intended to hold the patentee to its prosecution disclaimer. *See Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013) ("Prosecution history disclaimer plays an important role in the patent system. It promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." (internal quotation marks omitted)). But the construction does not exclude from the scope of the claims all formulations having coatings, which would be at odds with the plain language of the claims and the specification. *See* '620 Patent, col. 4 ll. 33–35 ("The pellet formulation can comprise one or more coatings, however [sic] pellet formulations in which the pellet only comprises one coating are preferred.").

The court does not understand the plaintiffs' argument that, "[t]o the extent Novel is arguing that the claims do not cover a composition that uses a coating to control release, that is an infringement inquiry and is not properly before this Court at this time." (D.I. 89 at 2.) Claim construction is where the court decides the meaning—and therefore the scope—of the claims. It is inextricably tied to and a part of the infringement inquiry. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581–82 (Fed. Cir. 1996) ("A literal patent infringement analysis involves two steps: the proper construction of the asserted claim and a determination as to whether the accused method or product infringes the asserted claim as properly construed." (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996)). When, if not now, would the court decide the scope of the term "core"?

[2] The court can find nothing in the intrinsic record to suggest that the claim term should receive less than the full scope of its ordinary meaning. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). The defendant's proposal—"on an empty stomach"—is no more illuminating than the claim term itself; rather, the colloquialism injects uncertainty and vagueness into the claims.

While the term is given its plain and ordinary meaning, the court will offer some additional guidance. First, the plain and ordinary meaning of "without food" is not the same, as the plaintiffs argue, as "without the need for

3. The term "remission is defined as a DAI score of 0 or 1" is construed to mean "remission is a DAI score of 0 or 1 as calculated by the sum of the four subscores based on stool frequency, bleeding, mucosal appearance on endoscopy, and physician's rating of disease activity.[3]

Dated: July 10, 2015

UNITED STATES DISTRICT JUDGE

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food." Such an understanding would essentially rewrite "without food" to mean "*with or* without food," which obviously cannot be the plain and ordinary meaning.

Second, the parties appear to agree that, at the very least, the plain meaning of "without food" requires that the subject cannot take the drug *at the same time as* food. (D.I. 89 at 9, 11.)

Finally, based on the prosecution history, the court is convinced that "without food" also includes some period of time prior to administering the drug. In a summary of an interview between the examiner and the prosecuting attorney, the examiner wrote: "Applicant's representative . . . proposed amending the claims to limit the patient population to those who *had not eaten prior to administration* of the granulated mesalamine formulation, so that the formulation is *administered 'without food.'*" (D.I. 86 at JA0167 (emphasis added).) In other words, "without food" is more than the simultaneous ingestion of food and drug. But the length of this preceding period is within the purview of one skilled in the art.

[3] Patents drafters rarely make claim construction so easy. This claim term is, itself, an express definition. It tells the court exactly how to construe "remission." In relevant part, Claim 1 claims: "A method of maintaining the remission of ulcerative colitis in a subject . . . wherein: . . . remission is defined as a DAI score of 0 or 1." '688 Patent, claim 1. Oddly enough, the plaintiffs ask the court to construe the definition itself by examining how "remission" is used through the intrinsic record. But, effectively, they seek to entirely rewrite the claim. They take an explicit instruction from the claims and try to twist it to say something it does not. The plaintiffs appear to forget that "the name of the game is the claim." *See Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1298 (Fed. Cir. 2014) (quoting *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)).

Thus, the court need only reference the specification to determine how a DAI score is calculated. The specification provides:

> Ulcerative colitis disease activity was assessed using a modified Sutherland Disease Activity Index[] (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. 6–12. The court applies this exact definition to its construction. While the plaintiffs are correct that the specification oftentimes describes remission in terms of only two of the four subscores, nowhere does the specification define the total DAI score in a different manner.