

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

DEXCEL PHARMA TECHNOLOGIES LTD.,
and DEXCEL LTD.,

Plaintiffs,

v.

SUN PHARMA GLOBAL FZE, et al.,

Defendants.

DEXCEL PHARMA TECHNOLOGIES LTD.,
and DEXCEL LTD.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD., and
DR. REDDY'S LABORATORIES, INC.,

Defendants.

Civil Action No. 15-08017-SDW-
LDW

(Consolidated with
Civil Action No. 15-08042)

MARKMAN OPINION

March 13, 2017

WIGENTON, District Judge.

Before the Court are the briefs and supporting materials of Plaintiffs Dexcel Pharma Technologies Ltd. and Dexcel Ltd. (collectively, "Plaintiffs") and Defendants Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc., Sun Pharma Global Inc., Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. (the "DRL Defendants"), (collectively, "Defendants"), regarding the request for a patent claim construction pursuant to Local Patent Rule 4.5(a).

This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b). This Court held a Markman¹ hearing on February 22, 2017, regarding patent claims in Plaintiffs' U.S. Patent Nos. 7,255,878 ("the '878 patent") and 9,023,391 ("the '391 patent") (collectively, "the patents-in-suit"). After carefully considering the parties' written and oral arguments regarding five claim phrases in the patents-in-suit, this Court has construed the disputed claim phrases as discussed below.

I. PROCEDURAL AND FACTUAL HISTORY²

This matter involves two of Dexcel Ltd.'s patents relating to Omeprazole Delayed Release Tablets 20 mg, an over-the-counter ("OTC") drug indicated for the treatment of frequent heartburn ("Dexcel's Omeprazole OTC product"). Both of Dexcel Ltd.'s patents are titled "Stable Benzimidazole Formulation" and claim stable pharmaceutical formulations and methods of manufacturing delayed release tablets of benzimidazole derivatives, such as Omeprazole.

Defendants are generic pharmaceutical makers and have each filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration seeking approval to market generic versions of Dexcel's Omeprazole OTC product. Defendants contend that the products proposed in their ANDAs will not infringe asserted claims of the patents-in-suit because, *inter alia*, Dexcel's Omeprazole OTC product was designed to eliminate the need for, and actually excludes, an intermediate layer between the product's Omeprazole core and its enteric coating. In contrast, Defendants' proposed products include an intermediate layer.

Plaintiffs commenced this lawsuit on November 11, 2015. They assert two Counts in the Complaint: (I) infringement of the '391 patent and (II) infringement of the '878 patent. (Compl.

¹ *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

² Unless otherwise noted, the facts are taken from the parties' submissions.

¶¶ 41-59.) On May 10, 2016, U.S. Magistrate Judge Leda D. Wettre issued an Order consolidating this action with Plaintiffs’ action against the DRL Defendants.³

II. LEGAL STANDARD

Patent claim construction is a matter of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). During interpretation of a claim, courts should initially look to intrinsic evidence, namely “the patent claims, the specification and the prosecution history if in evidence.” *Bristol-Myers Squibb Co. v. Immunex Corp.*, 86 F. Supp. 2d 447, 448 (D.N.J. 2000). “[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “The court should presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms.” *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448. A person of ordinary skill in the art “is deemed to read the claim term . . . in the context of the entire patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); *see Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) (“We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.” (citation omitted)); *see also Markman*, 52 F.3d at 979.

If the intrinsic evidence alone will not resolve the ambiguity, the Court may rely on extrinsic evidence, which includes expert testimony, treatises, dictionaries and articles. *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448-49. Extrinsic evidence may not be used to vary or contradict the meaning established by the intrinsic evidence. *Phillips*, 415 F.3d at 1318-19, 1324.

³ The lead case is 15-cv-08017 and the member case is 15-cv-08042.

“The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be . . . the correct construction.” *Id.* at 1316.

A key aspect of claim construction is to assist the jury in understanding complicated language and concepts. *See Encap LLC v. Oldcastle Retail, Inc.*, No. 11-cv-808, 2012 WL 2339095, at *9 (E.D. Wis. June 19, 2012) (“Claim construction is not intended to allow for needless substitution of more complicated language for terms easily understood by a lay jury.”); *see also C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 863 (Fed. Cir. 2004) (“[M]erely rephrasing or paraphrasing the plain language of a claim by substituting synonyms does not represent genuine claim construction.”); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1247 (Fed. Cir. 2001) (“It is critical for trial courts to set forth an express construction of the material claim terms in dispute, in part because the claim construction becomes the basis of the jury instructions, should the case go to trial. It is also the necessary foundation of meaningful appellate review.” (citation omitted)).

III. CLAIM CONSTRUCTIONS

The parties dispute the meanings of five claim phrases: three in the ‘878 patent and two in the ‘391 patent. Defendants offer proposed constructions for each of the five phrases, whereas Plaintiffs argue that this Court need not construe any of the five phrases. Specifically, Defendants seek to construe each of the five phrases so as to specify that Plaintiffs’ claims preclude Dexcel’s Omeprazole OTC product from containing an intermediate layer between the benzimidazole derivative core and its enteric coating. Plaintiffs dispute Defendants’ proposed constructions but offer no proposed constructions of their own. The phrases-in-issue in the ‘878 patent and the related proposed constructions are as follows:

	Claim Phrase	Defendants' Proposed Construction	Plaintiff's Proposed Construction
Claim 1	applying a single layer of said neutralized solution directly to said substrate, without an intermediate layer between said substrate and said enteric coating	applying a single layer of said neutralized solution to said substrate, without applying an intermediate layer between said substrate and said single layer of said neutralized solution of said enteric polymer	No construction necessary
Claim 12	spraying a single layer of said neutralized solution directly over said substrate, without an intermediate layer between said substrate and said enteric coating	spraying a single layer of said neutralized solution to said substrate, without applying an intermediate layer between said substrate and said single layer of said neutralized solution of said enteric polymer	No construction necessary
Claim 23	directly coating said substrate with a single layer of said neutralized solution, without an intermediate layer between said substrate and said enteric coating	coating said substrate with a single layer of said neutralized solution, without applying an intermediate layer between said substrate and said single layer of said neutralized solution of said enteric polymer	No construction necessary

The phrases-in-issue in the '391 patent and the related proposed constructions are as follows:

	Claim Phrase	Defendants' Proposed Construction	Plaintiff's Proposed Construction
Claim 1	the enteric polymer having been layered directly onto the core	the enteric polymer having been applied in a layer onto the core, without an intermediate layer applied between the core and the enteric polymer layer	No construction necessary
Claim 13	the single layer layered directly over said single tablet core	the single layer applied onto the core, without an intermediate layer applied between said single tablet core and the single layer	No construction necessary

A. The '878 Patent Phrases-in-issue

Claims 1, 12, and 23 of the '878 patent each describe "A method for producing a stable tablet composition for a Benzimidazole derivative[.]" (Compl. Ex. B at 15:38-39, 16:9-10, 16:48-49.) "The method consist[s] essentially of" four steps. (*Id.* at 15:39-52, 16:9-24, 16:48-63.) The first three steps are (1) "forming a substrate with the benzimidazole derivate," (2) preparing an aqueous solution of an enteric polymer," and (3) "neutralizing said solution by addition of an alkalizing material[.]" (*Id.*) The fourth step, which is described in the '878 patent's phrases-in-issue, is either "applying a single layer of said neutralized solution directly to said substrate," (*Id.* at 15:50-51), "spraying a single layer of said neutralized solution directly over said substrate" (*Id.* at 16:22-23), or "directly coating said substrate with a single layer of said neutralized solution." (*Id.* at 16:61-62.) Each of the three claims also call for applying, spraying, or coating the neutralized solution onto the substrate "*without an intermediate layer between said substrate and said enteric coating.*" (*Id.* at 15:51-52, 16:23-24, 16:62-63 (emphasis added).)

In light of both the language of Claims 1, 12, and 23 of the '878 patent and the intrinsic record, Defendants propose that this Court construe these phrases “to exclude formulations made with an intermediate layer.” (Defs.’ Op. Br. at 15.) In contrast, Plaintiffs assert that no construction is necessary because the claims “are written in simple terms and easily understood and applied according to their plain and ordinary meaning.” (Pls.’ Op. Br. at 7.)

In considering the parties’ arguments, this Court first notes that the purpose of claim construction is “to clarify and when necessary to explain what the patentee covered by the claims[.]” *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). However, claim terms with plain meanings “do not require additional construction.” *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1326 (Fed. Cir. 2012).

In this instance, Claims 1, 12, and 23 explicitly state that the enteric coating must be either applied, sprayed, or coated onto the substrate “without an intermediate layer between said substrate and said enteric coating.” (Compl. Ex. B at 15:51-52, 16:23-24, 16:62-63.) Although Defendants propose that Claims 1, 12, and 23 be construed to exclude an intermediate layer, the phrases-in-issue, without any alteration, plainly exclude an intermediate layer from the claimed invention. Moreover, the specification does not assign a special meaning to the phrase “without an intermediate layer between said substrate and said enteric coating.” (*Id.*) Thus, it is appropriate to give the “inventor’s claim terms . . . their ordinary meaning.” *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). Accordingly, this Court declines to construe the phrases-in-issue in Claims 1, 12, and 23 of the '878 patent and, instead, gives the phrases their plain and ordinary meaning.

B. The ‘391 Patent Phrases-in-issue

In contrast to the phrases-in-issue in the ‘878 patent, the phrases-in-issue in the ‘391 patent do not include the phrase “without an intermediate layer between said substrate and said enteric coating.” Instead, the relevant portions of Claims 1 and 13 of the ‘391 patent are as follows:

	Claim Phrase
Claim 1	the enteric polymer having been layered directly onto the core
Claim 13	the single layer layered directly over said single tablet core

(Compl. Ex. A at 20:36-37, 21:18-19.) As with the phrases-in-issue in the ‘878 patent, Defendants propose that this Court construe the ‘391 patent’s phrases-in-issue so as to clarify that they exclude an intermediate layer from Dexcel Ltd.’s claimed invention. Plaintiffs, on the other hand, argue that no construction is necessary for these phrases. However, holding that Claims 1 and 13 need no construction would not resolve the parties’ dispute as to whether the ‘391 patent excludes an intermediate layer from Dexcel Ltd.’s claimed invention. A determination that no construction is needed would therefore be inappropriate. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361–62 (Fed. Cir. 2008) (“A determination that a claim term ‘needs no construction’ or has the ‘plain and ordinary meaning’ may be inadequate . . . when reliance on a term’s ‘ordinary’ meaning does not resolve the parties’ dispute.”). Instead, in light of the intrinsic record and as discussed below, this Court construes the phrases-in-issue from the ‘391 patent as follows:

	Claim Phrase	Defendants' Proposed Construction	Court's Construction
Claim 1	the enteric polymer having been layered directly onto the core	the enteric polymer having been applied in a layer onto the core, without an intermediate layer applied between the core and the enteric polymer layer	the enteric polymer having been layered directly onto the core without an intermediate layer
Claim 13	the single layer layered directly over said single tablet core	the single layer applied onto the core, without an intermediate layer applied between said single tablet core and the single layer	the single layer layered directly over said single tablet core without an intermediate layer

In this instance, this Court must determine whether a person of ordinary skill in the art at the time of the invention would have understood the terms “layered directly onto the core” and “layered directly over” as used in the ‘391 patent to preclude the inclusion of an intermediate layer between the product’s enteric coating and its core. *See Phillips*, 415 F.3d at 1313. Here, such a construction—precluding an intermediate layer—is supported by the intrinsic evidence.

First, the Abstract to the ‘391 patent describes the product as “A stable composition with a benzimidazole derivative, such as Omeprazole, *which does not contain a separating layer between the active compound and an enteric coating layer.*” (Compl. Ex. A, Abstract (emphasis added).) This explicit exclusion of an intermediate layer is consistent with the language of both Claims 1 and 13 which describe the invention as “consisting essentially of” only two parts: “a single tablet core . . . and . . . a single layer comprising an enteric polymer” (*Id.* at 20:20-39, 21:6-22.) The exclusion of an intermediate layer is also consistent with the basis on which the ‘391 patent distinguishes Dexcel’s Ltd.’s invention from the prior art.

Omeprazole is “known to be susceptible to degradation and transformation in acid media.” (*Id.* at 1:19-23.) Accordingly, Omeprazole must be protected from “the acidic environment of the stomach” when administered orally. (*Id.* at 1:34-36.) The background art addressed this issue by, for example, “directly coat[ing] the solid core containing Omeprazole . . . with an enteric coating layer.” (*Id.* at 1:54-57 (citing European Patent No. 237,200).) However, coating the Omeprazole core with an enteric coating, while limiting the core’s exposure to stomach acid, caused another issue: “the alkaline core containing Omeprazole was found to react with the enteric coating, thereby causing the enteric coating to degrade.” (Compl. Ex. A at 1:58-61.) The prior art solved this secondary problem by including an intermediate layer between the enteric coating and the Omeprazole core which would eliminate the interaction between the core and the enteric coating. (*See id.* at 2:3-20.)

In the ‘391 patent, Plaintiffs identify an additional shortfall of the prior art. Although the prior art limits the interaction between the enteric coating and the Omeprazole core through the inclusion of an intermediate layer, the intermediate layer “is a disadvantage in that it complicates the manufacturing process and increases the expense and difficulty of manufacture.” (*Id.* at 2:20-23.) The ‘391 patent goes on to note that “A formulation of a benzimidazole derivative, such as Omeprazole, which lacks an intermediate coating layer and yet which is stable both during storage and during the passage through the stomach, would be highly desirable.” (*Id.* at 2:62-65; *see also id.* at 3:5-9.) In light of this desire to limit the manufacturing difficulties and costs associated with using an intermediate layer to protect the core from the enteric coating, the ‘391 patent’s Summary of the Invention describes a change to the formulation of the enteric coating which allows the invention “to maintain the stability of [the] active ingredient without a separating layer.” (*Id.* at 3:13-16.) “*Instead*, the enteric coating layer is applied as a solution with a pH value of at least 6.5

. . . *directly to the benzimidazole derivative substrate.*” (*Id.* at 3:16-20 (emphasis added).) In light of this description of the invention and the basis on which it is distinguished from the prior art, it appears the specific purpose of the invention was to eliminate the need for the intermediate layer. Thus, it follows that a person of ordinary skill in the art would read “layered directly onto the core” and “layered directly over” as excluding an intermediate layer from Claims 1 and 13. This construction is further supported by both the complete absence of an intermediate layer in any of the invention examples listed throughout the ‘391 patent, (*see id.* at 6:60-20:17), and also, by the prosecution history to the ‘391 patent in which the inventors repeatedly distinguish the prior art on the basis that Dexcel Ltd.’s invention lacks an intermediate layer. For example, in an April 17, 2007 response to an August 26, 2014 Office Action, the inventors state:

Many enteric formulations have been made to increase stability during passage through the gut. Most require at least two coatings to keep the benzimidazole derivative stable. This application defines another approach, which achieves the same stability at the multiple coating formulations *but only has a single enteric coat, so costs associated with manufacture are less.*

(Wang Decl. Ex. 16, at 5 (emphasis added).)

Although Plaintiffs argue that the ‘391 patent permits the inclusion of an intermediate layer, the intrinsic evidence contradicts this assertion. The phrases-in-issue in the ‘391 patent may only reasonably be construed so as to exclude an intermediate layer.⁴

⁴ It bears noting that although Plaintiffs contest Defendants’ proposed construction of the phrases-in-issue in the ‘391 patent on the ground that it would render the phrases-in-issue in the ‘878 patent redundant, “claim differentiation does not serve to broaden claims beyond their meaning in light of the patent as a whole, and it cannot override clear statements of claim scope found in the specification and prosecution history.” *Poly-America, L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1137 (Fed. Cir. 2016) (citing *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999)).

IV. CONCLUSION

For the reasons stated above, this Court orders that the disputed claims in the patents-in-suit be construed as set forth in this Opinion. A summary of this Court's construction of the disputed claims is provided in the corresponding Order.

s/ Susan D. Wigenton

Susan D. Wigenton, U.S.D.J.

Orig: Clerk
cc: Leda Dunn Wettre, U.S.M.J.
Parties