IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIMA LABS, INC., JAZZ PHARMACEUTICALS IRELAND LIMITED and JAZZ PHARMACEUTICALS INTERNATIONAL III LIMITED,	)	**REDACTED PUBLIC VERSION RELEASED JUNE 18, 2015**
Plaintiffs,	)	
v.	)	C.A. No. 10-625-LPS
MYLAN PHARMACEUTICALS, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

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STARK, U.S. District Judge:

Pending before the Court is the issue of claim construction for the disputed terms in the claims of U.S. Patent Nos. 6,024,981 ("the '981 patent") and 6,221,392 ("the '392 patent") (collectively, "the patents-in-suit"). The '392 patent is a continuation of the '981 patent and the two patents-in-suit share a common specification. (C.A. No. 08-886 D.I. 124 at 6)[1] Both are entitled, "Rapidly Dissolving Robust Dosage Form."

I. BACKGROUND

The first of these Hatch-Waxman patent infringement actions was filed by Plaintiffs CIMA Labs, Inc., Azur Pharma Limited, and Azur Pharma International III Limited against Defendant Novel Laboratories, Inc., on November 25, 2008 (C.A. No. 08-886 D.I. 1), and another was filed on July 23, 2010 (C.A. 10-625 D.I. 1).[2] On December 29, 2014, the Novel action was dismissed without prejudice. (*See* D.I. 163)

The patents-in-suit claim an orally-disintegrable dosage form ("ODT") for the delivery of a pharmaceutical drug product. The product generally is comprised of an active ingredient and a matrix including a non-direct compression filler and a lubricant.[3] Claim 1 of the '981 patent is

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[1]Hereinafter, unless otherwise noted, all docket item (D.I.) references are to C.A. No. 08-886.

[2]Jazz Pharmaceuticals Ireland Limited and Jazz Pharmaceuticals International III Limited replaced the original Azur Pharma Plaintiffs by order of the Court on June 23, 2014. (*See* D.I. 82)

[3]"The hard, compressed, rapidly dissolvable dosage form claimed in the patents-in-suit allows delivery of active ingredients in a matrix that rapidly dissolves in saliva, allowing the patient to swallow the dissolved tablet as a solution or slurry, as opposed to an unpleasant or gritty mixture. The tablets also have friability and hardness characteristics which permit the tablets to be handled and packaged using conventional equipment, and which permit a plurality of tablets to be packaged together, as in a bottle." (D.I. 124 at 5) (internal citations omitted)

representative of the pertinent claims of the patents-in-suit:

> A hard, compressed, rapidly dissolvable dosage form adapted for direct oral dosing comprising: an active ingredient and a matrix including a non-direct compression filler and a lubricant, said dosage form being adapted to rapidly dissolve in the mouth of a patient and thereby liberate said active ingredient, and having a friability of about 2% or less when tested according to the U.S.P., said dosage form having a hardness of at least about 15 Newtons.

During reexamination of the '981 Patent, the Board of Patent Appeals and Interferences (the "Board") confirmed the original claims as patentable, and added new claims 41-70. (D.I. 116-1 Ex. D at CIMA-FAZ-0007079 - CIMA-FAZ-0007083) In those proceedings, the Board interpreted "non-direct compression filler" to mean:

> a filler material (i) which lacks adequate flow and compression characteristics to allow its use in direct compression processes and products absent physically modifying the filler, e.g., by granulation prior to compression, and has not been so modified prior to compression; and, (ii) which possesses adequate rapid dissolution/disintegration characteristics which allow the rapidly water soluble material in the product to dissolve sufficiently to allow ingestion as a non-gritty solution or slurry in 90 seconds or less.

(D.I. 116-8 Ex. K at CIMA-FAZ-00008251)[4]

The Board also construed "nondirect compression sugar or sugar alcohol" as follows:

> A sugar or sugar alcohol material having the following characteristics: (1) has not been physically modified to impart enhanced or improved flow and compression characteristics, as compared to the corresponding direct compression form; (2) of a particle size, which has not been modified as compared to the corresponding direct compression filler (e.g., which is neither granulated or agglomerated); and (3) dissolves sufficiently to allow

[4]The Board later amended its construction "by deleting the term 'disintegration' from the interpretation of non-direct compression filler." (D.I. 116-8 Ex. K at CIMA-FAZ-00008252)

ingestion as a non-gritty solution or slurry in 90 seconds or less.

(D.I. 116-66 Ex. QQQ at CIMA-FAZ-00010271)

The action was stayed during the pendency of the reexamination proceedings, from April 18, 2011 (C.A. No. 10-625 D.I. 53) until March 21, 2014 (C.A. No. 10-625 D.I. 82). The parties completed claim construction briefing on the disputed terms in November 2014. (D.I. 124, 125, 140, 142, 160) The Court held a claim construction hearing on November 10, 2014. (C.A. No. 10-625 D.I. 108)

II. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the

claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[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." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from

bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

III. CONSTRUCTION OF THE DISPUTED TERMS[5]

[5]Because of the similarity and overlap of the issues presented, the Court discusses both disputed terms together. Where pertinent – such as when considering whether the terms each require their own construction – the Court notes this in its discussion.

A. "non-direct compression filler"

Plaintiff's Proposed Construction: A filler material assessed immediately prior to compression: (i) which lacks enhanced or improved flow and compression characteristics, as compared to the corresponding direct compression form; and, (ii) which possesses adequate rapid dissolution characteristics which allow the rapidly water soluble materials in the product to dissolve sufficiently to allow ingestion as a non-gritty solution or slurry in 90 seconds or less.
Defendant's Proposed Construction: A rapidly water soluble filler that is not fit for direct compression because of its poor flow or compressibility properties, and which is not a direct compression filler.
Court's Construction: A filler material assessed immediately prior to compression: (i) which lacks enhanced or improved flow and compression characteristics, as compared to the corresponding direct compression form; and, (ii) which possesses adequate rapid dissolution characteristics which allow the rapidly water soluble materials in the product to dissolve sufficiently to allow ingestion as a non-gritty solution or slurry in 90 seconds or less.

B. "non-direct compression sugar" or "non-direct compression sugar alcohol"

Plaintiff's Proposed Construction: A sugar or sugar alcohol material assessed immediately prior to compression having the following characteristics: (1) which lacks enhanced or improved flow and compression characteristics, as compared to the corresponding direct compression form; (2) of a smaller particle size, as compared to the corresponding direct compression filler; and (3) dissolves sufficiently to allow ingestion as a nongritty solution or slurry in 90 seconds or less.
Defendant's Proposed Construction: A rapidly water soluble [sugar/sugar alcohol] that is not fit for direct compression because of its poor flow or compressibility properties, and which is not a direct compression [sugar/sugar alcohol].

Court's Construction:

> A sugar or sugar alcohol material assessed immediately prior to compression having the following characteristics: (1) which lacks enhanced or improved flow and compression characteristics, as compared to the corresponding direct compression form; (2) of a smaller particle size, as compared to the corresponding direct compression filler; and (3) dissolves sufficiently to allow ingestion as a nongritty solution or slurry in 90 seconds or less.

The parties principally dispute: (i) whether the filler/sugar/sugar alcohol material must be assessed for whether it is direct or non-direct ***immediately prior*** to the compression of the tablet, (ii) whether the constructions of "non-direct compression filler" and "non-direct compression sugar/sugar alcohol" should be distinct from each other (i.e., whether the "non-direct compression filler" is required to dissolve in the same way that the "non-direct compression sugar/sugar alcohol" is required to dissolve), and (iii) whether CIMA should be held to the construction position it advocated in another infringement action.

In regard to the first issue, Mylan's position hinges on its assertion that its product uses a starting ingredient which is classified as [redacted] (*See* D.I. 116-57 Ex. HHH at CIMA-FAZ-00005045) Mylan contends that because Plaintiffs expressly stated during reexamination that [redacted] "any construction of a nondirect compression filler that would include a direct compression filler such [redacted] cannot be correct because it would encompass an ingredient that the patentee specifically stated was outside the patent's scope." (D.I. 125 at 11)

Plaintiffs' position is that, regardless of the classification of the starting ingredient, "the relevant point of assessment was immediately prior to the compression molding process." (D.I. 124 at 12) Under Plaintiffs' proposed construction, then, the claims may encompass filler

material initially classified as "direct" when the material has been modified to become a non-direct compression filler prior to the compression process.

During reexamination, the Board concluded that the sugar or sugar alcohol material must be assessed immediately prior to compression, since the claims specifically require that the ***compressed*** tablet is comprised of a non-direct compression filler/sugar/sugar alcohol:

> The claims specifically list components which are included in the tablet, such as an active ingredient, lubricant, and a "nondirect compression" sugar or sugar alcohol. Persons of ordinary skill in the art would have understood that the recited list is a recipe specifying what components are added together to make the tablet. The recitation of a "nondirect compression" sugar or sugar alcohol would therefore reasonably be understood to mean that this particular form was included in the tablet immediately prior to the compression molding process. To read it otherwise would essentially be reading the "nondirect compression" limitation out of the claim. How the sugar changes during compression is pertinent only to the extent that the ***tablet*** is required by the claim to have certain properties. . . .

(D.I. 116-70 Ex. UUU at CIMA-FAZ-00010846) (emphasis added) This focus on when the material is assessed is due to the fact that non-direct and direct fillers are readily modifiable.

The Court agrees with Plaintiffs and the Board that, to properly construe "nondirect sugar or sugar alcohol," it is necessary to look to the time immediately prior to compression, rather than looking to a list of ingredients with which the process is started.

The same approach is appropriate for the contested term non-direct compression filler. One of skill in the art would read the claim language to require the ***tablet*** to contain a nondirect compression filler, sugar, or sugar alcohol. The patents-in-suit do not simply teach a compression process, but claim a "tablet" or "dosage form" which contains the filler/sugar/sugar alcohol – so it is proper to assess the materials which are actually ***in the tablet***. To the extent a

direct compression filler, sugar, or sugar alcohol is modified so that immediately prior to compression it would be classified as a ***nondirect*** compression filler, sugar, or sugar alcohol, it is within the meaning of nondirect compression filler, sugar, or sugar alcohol as claimed. Accordingly, the Court will adopt Plaintiffs' constructions.

The second dispute is whether there is any distinction between filler and sugar/sugar alcohol, and whether the terms need to be construed with any such distinction in mind. Plaintiffs assert that while a non-direct compression filler is not required to dissolve, the "nondirect compression sugar/sugar alcohol must itself be water soluble, i.e., dissolve." (D.I. 124 at 16) Plaintiffs assert further that "[a] non-direct compression sugar/sugar alcohol is a species of the non-direct compression filler genus. As a result, the construction of a non-direct compression sugar/sugar alcohol must be more narrow than genus term." (*Id.*) (internal citations omitted) Defendant maintains that "the difference between a filler, sugar and sugar alcohol is not material to the issues in this case." (D.I. 125 at 10)[6]

The prosecution history indicates that there is a difference between the filler and the sugar/sugar alcohol. "The '392 patent claims involve compressed tablets comprising a non-direct compression sugar or sugar alcohol. The claims of the '981 patent are broader, involving a non-direct compression filler – a broader genus that includes the sugar and sugar alcohols of the '392 claims." (D.I. 116-8 Ex. K at CIMA-FAX-00008254) Based on this, the Court concludes that it is appropriate to construe the terms "non-direct compression filler" and "non-direct compression sugar/sugar alcohol" distinctly.

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[6]Regardless of whether issues will arise in this action relating to this dispute, it was represented at the claim construction hearing that litigation in other courts may be implicated.

The '981 specification states:

> Any conventional material can be used as a filler in accordance with the present invention, so long as it meets the overall objectives hereof. The filler must be rapidly dissolvable when a tablet produced from the same is placed in the mouth. This means that the material must be significantly rapidly water soluble.

('981 Patent, col. 9 ll. 35-40) The Board said of this statement, "According to the 981 specification, 'any conventional material' can be a non-direct compression filler so long as it can be compressed into a rapidly dissolvable form." (D.I. 116-9 Ex. L at CIMA-FAZ-00001350) The patent describes "rapidly dissolvable" as meaning "the rapidly water soluble ingredients will dissolve sufficiently to allow ingestion as a non-gritty solution or slurry in 90 seconds or less." ('981 Patent, col. 3 ll. 36-39) Moreover, the specification states:

> [T]o further improve the organoleptic qualities of the dosage forms of the present invention, the amount of non-rapidly dissolvable, i.e., non-rapidly water soluble materials used is minimized as much as possible. Ideally, the only non-rapidly dissolving species would be the active ingredient, particularly when in protected particle form, and the lubricant.

('981 patent, col. 4 ll. 7-13) The specification discloses a preferred embodiment in which both the filler and the sugar/sugar alcohol would be rapidly dissolvable, but it does not limit the invention to this embodiment. The sugar/sugar alcohol "may be used as a filler" ('981 Patent, col. 3 l. 51), but other materials may be used as well. The relationship between fillers and sugar/sugar alcohols is reflected in Plaintiffs' proposed constructions.

Defendant contends that the positions Plaintiffs are advocating here are inconsistent with those Plaintiffs have taken in prior litigation in the United States District Court for the District of Minnesota. (*See* D.I. 116-43, Ex. T (Plaintiffs' *Markman* Brief with Respect to the Term "Non-

Direct Compression Filler," *CIMA Labs Inc. v. KV Pharm., Co.*, C.A. No. 03-2477-JNE-JSM D.I. 575 (D. Minn. Sept. 23, 2005)) However, Defendants have not identified any inconsistent statements by Plaintiffs. Additionally, in the intervening years after the Minnesota action and the filing of claim construction briefs here, the Board concluded the reexaminations, and that additional prosecution history has had a substantial impact on the Court's determination of the proper constructions. Therefore, while the Court has considered the arguments which were made in the Minnesota action, the prior statements are not inconsistent with the record before the Court.

Accordingly, for the reasons stated above the Court will adopt Plaintiffs' proposed constructions.

IV. CONCLUSION

An appropriate Order follows.