IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC., Plaintiff, v. SANDOZ, INC., Defendant.	C.A. No. 12-1011 (GMS) CONSOLIDATED
MILLENNIUM PHARMACEUTICALS, INC., Plaintiff, v. FRESENIUS KABI USA, LLC, *et al.*, Defendants.	C.A. No. 13-467 (GMS)

PLAINTIFF MILLENNIUM PHARMACEUTICALS, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Plaintiff Millennium Pharmaceuticals, Inc. ("Millennium") developed and sells VELCADE®, the potent boronic acid proteasome inhibitor bortezomib. VELCADE® is approved for treatment of patients with multiple myeloma and patients with mantle cell lymphoma who have received at least one prior therapy.

Millennium filed these patent infringement actions after receiving notice that Defendants Sandoz, Inc., Accord Healthcare, Inc., Actavis LLC, Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Pharmaceuticals Holding, Inc. (collectively, "Defendants") seek approval to market generic versions of VELCADE® before the expiration of two Orange Book listed patents.[1]

VELCADE® is an injectable drug product, manufactured in the form of the lyophilized[2] mannitol ester of bortezomib. Prior to the development of the claimed inventions of the patents-in-suit, bortezomib's prospects were limited because the compound itself was not sufficiently stable for use as a commercial product. The patents-in-suit – United States Patent Nos. 6,958,319 ("the '319 patent") and 6,713,446 ("the '446 patent") – are directed to the discovery that preparing bortezomib in the form of a sugar (*e.g.*, mannitol) ester affords a highly stable lyophilized product that can be quickly reconstituted for administration by injection. As stated in the common specification of the '319 and '446 patents,[3] the invention "provides the discovery that lyophilization of an aqueous mixture comprising a boronic acid compound and a compound

[1] These actions are brought pursuant to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act").

[2] "Lyophilization," or freeze-drying, refers to the use of vacuum pressure to remove water (or other solvents) from a frozen substance, leaving the desired components of the substance in solid form. Prior to administration for injection, a lyophilized substance is reconstituted into liquid form by addition of a solvent such as sterile water.

[3] The '319 patent is a continuation of the '446 patent.

having at least two hydroxyl groups produces a stable composition that readily releases the boronic acid compound upon dissolution in aqueous media." A-2,[4] '446 patent 2:8-13; A-16, '319 patent 2:11-16. The '319 patent claims, *inter alia*, lyophilized sugar esters of boronic acid compounds including bortezomib, and related methods and compositions. The '446 patent includes similar claims in which the sugar is mannitol.

The parties have agreed on certain claim constructions and have narrowed the claim terms to be construed by the Court to one: "sugar." Because Millennium's proposed construction of "sugar" is faithful to the disclosures in the patents-in-suit, whereas Defendants' proposal disregards certain important language, the Court should adopt Millennium's proposal.

II. THE INVENTION OF THE PATENTS-IN-SUIT

VELCADE® is a treatment for multiple myeloma, an incurable form of blood cancer. Multiple myeloma begins in the bone marrow and causes solid tumors that interfere with the production of red blood cells, white blood cells, and platelets, ultimately causing bone and kidney damage. VELCADE® is also a treatment for mantle cell lymphoma, a rare form of non-Hodgkins lymphoma, a cancer of the lymph nodes that affects the immune system. The active pharmaceutical ingredient of VELCADE® is bortezomib, a boronic acid compound. The compound itself is a potent proteasome inhibitor[5] but is highly unstable; it degrades significantly over relatively short periods of time, and is thus challenging to formulate.

Millennium's predecessor, ProScript, Inc. ("ProScript"), first synthesized bortezomib in the early 1990s and initiated the development that ultimately resulted in VELCADE®. ProScript

[4] Citations to "A-_" refer to pages of the parties' Joint Appendix of Intrinsic Evidence.

[5] "Proteasome" refers to a group of enzymes that facilitate cell growth by degrading unneeded or damaged proteins; inhibiting the operation of proteasome therefore inhibits cell growth. Bortezomib's effectiveness in treating certain cancers reflects its high degree of selectivity for inhibiting the growth of cancerous – rather than healthy – cells.

began developing an injectable liquid formulation for use in initial clinical trials. But a viable commercial drug product must be stable, ideally at ambient temperatures, for long periods so that the drug can be transported, stored, and administered without sacrificing safety or effectiveness, and ProScript's liquid formulation failed to overcome bortezomib's inherent instability sufficiently to meet these requirements.

ProScript received assistance from the National Cancer Institute ("NCI") to develop a viable formulation of bortezomib. Dr. Shankar Gupta, an NCI project leader who specializes in drug formulations, worked on the bortezomib formulation project with Dr. Valentino Stella and Ms. Wanda Waugh at the University of Kansas. Dr. Gupta, Dr. Stella, and Ms. Waugh – the inventors of the patents-in-suit – discovered that lyophilizing bortezomib with mannitol produces a solid that is highly stable, showing no degradation over many months. Furthermore, this solid lyophilized mannitol-bortezomib ester reconstitutes easily in a pharmaceutically-active form in aqueous solution (for example, by adding sterile water for injection).

The invention of the patents-in-suit made possible the creation of a highly stable bortezomib formulation that reconstituted readily for treatment, and was critical to the continued development and commercialization of VELCADE®. Because the clinical studies of VELCADE® were highly successful, authorities quickly recognized that bortezomib was a breakthrough drug needed by patients. The approval process was fast-tracked by the FDA, and VELCADE® was ultimately approved in approximately half the usual time. VELCADE® was the first-ever proteasome inhibitor to be approved.

In keeping with its promising beginning, VELCADE® has proven to be a great success. VELCADE® has won numerous awards, has been publicly praised by specialists in the field, and has been used to treat over 400,000 patients in 90 countries. The inventors' discovery of the

stable, commercially viable mannitol ester formulation of bortezomib, has dramatically improved the lives of cancer patients around the world.

III. THE LAW OF CLAIM CONSTRUCTION

In *Phillips v. AWH Corp.*, the Federal Circuit explained that claim terms should be interpreted in the context of a patent's "intrinsic evidence," including (1) the claim language, (2) the specification, and (3) the prosecution history. 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005); *see also Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc) ("To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history.") (quotation omitted); *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).

"[T]he words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) and citing *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999)). "Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321.

The claims do not stand alone, but rather are part of "a fully integrated written instrument." *Markman*, 52 F.3d at 978. Accordingly, the claims must be read in view of the patent specification for appropriate context. *Phillips*, 415 F.3d at 1315; *Markman*, 52 F.3d at 979 (the specification "may act as a sort of dictionary, which explains the invention and may define terms used in the claims"). The claim 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." *Phillips*, 415 F.3d at 1316 (internal quotation omitted).

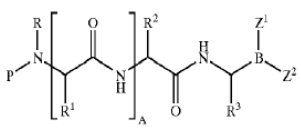
"[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics*, 90 F.3d at 1582. Nevertheless, the Federal Circuit has "authorized district courts to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (citing *Markman*, 52 F.3d at 980); *see also id.* at 1318 ("Within the class of extrinsic evidence, the court has observed that dictionaries and treatises can be useful in claim construction.") (citing *Renishaw PLC v. Marposs Societa Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

IV. THE DISPUTED CLAIM TERM

Term	Asserted Claims[6]	Millennium's Proposed Construction	Defendants' Proposed Construction
"sugar"	'446 patent: 19-20, 31-32, 53, 57, 61 '319 patent: 25-26, 40, 54, 57, 62, 66, 70	glucose, sucrose, fructose, trehalose, xylitol, mannitol, sorbitol, or similar saccharide	saccharides including monosaccharides, disaccharides, and reduced sugars

A. Millennium's Proposed Construction is Consistent with the Claim Language

The term "sugar" is important in the patents-in-suit, appearing (either directly or by dependence) in numerous claims. For example, claim 1 of the '319 patent recites as follows:

> A compound of the formula (1):
>
> 
> (1)
>
> wherein
>
> P is hydrogen or an amino-group protecting moiety;

[6] In its Preliminary Infringement Contentions, Millennium asserted the same 17 claims against each Defendant. In 14 of those 17 claims, the term "sugar" appears either directly or by dependence. The remaining three claims recite the specific sugar mannitol.

R is hydrogen or alkyl;
A is 0, 1, or 2;
R^1, R^2, and R^3 are each independently hydrogen, alkyl, cycloalkyl, aryl, or $–CH_2–R^5$;
R^5, in each instance, is aryl, aralkyl, alkaryl, cycloalkyl, heterocyclyl, heteroaryl, or $–W–R^6$, where W is a chalcogen and R^6 is alkyl;
wherein the ring portion of any said aryl, aralkyl, alkaryl, cycloalkyl, heterocyclyl, or heteroaryl in R^1, R^2, R^3, or R^5 can be optionally substituted; and
Z^1 and Z^2 together form a moiety derived from a ***sugar***, wherein the atom attached to boron in each case is an oxygen atom.[7]

A-24. Formula (1) above represents a boronic acid, such as bortezomib, in which the boron has been attached through oxygen atoms at Z^1 and Z^2 to a sugar moiety.[8] This composition – referred to in some claims as a sugar ester – provides the increased stability that made commercial formulation of VELCADE® possible.

Millennium's proposed construction, including only sugars, is consistent with the plain language of the claims. Defendants' proposal, in contrast, effectively rewrites the claims to recite the broader term "saccharide" rather than "sugar." There is no basis in any claim for such a construction.[9]

[7] Claim 1 of the '446 patent includes the additional phrase "and wherein the sugar is mannitol," but is otherwise identical. A-9.

[8] The parties have agreed that "moiety derived from a sugar" means "moiety formed by removing the hydrogen atoms from two hydroxyl groups of any sugar moiety," and that "Z^1 and Z^2 together form a moiety derived from a sugar" means "Z^1 and Z^2 together form a moiety formed by removing the hydrogen atoms from two hydroxyl groups of any sugar moiety." "Sugar" is the only remaining disputed term.

[9] Because Millennium's proposed construction includes examples from the categories of monosaccharides, disaccharides, and reduced sugars, as well as similar saccharides, it is consistent not only with claims that recite "sugar" but also claims that explicitly refer to those categories. *See, e.g.*, A-24, '319 patent cl. 2 (". . . wherein the sugar is a monosaccharide or disaccharide").

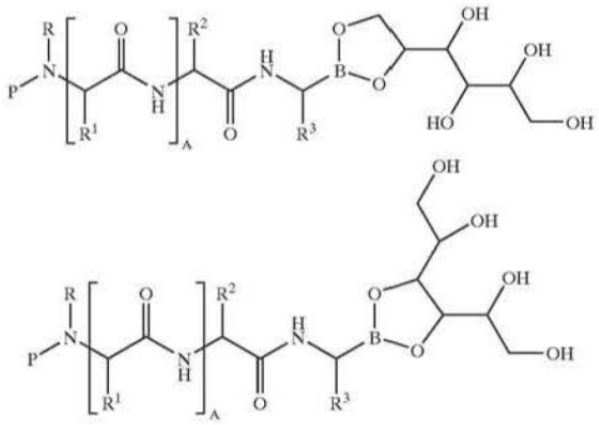
B. Millennium's Proposed Construction is Consistent with the Specification

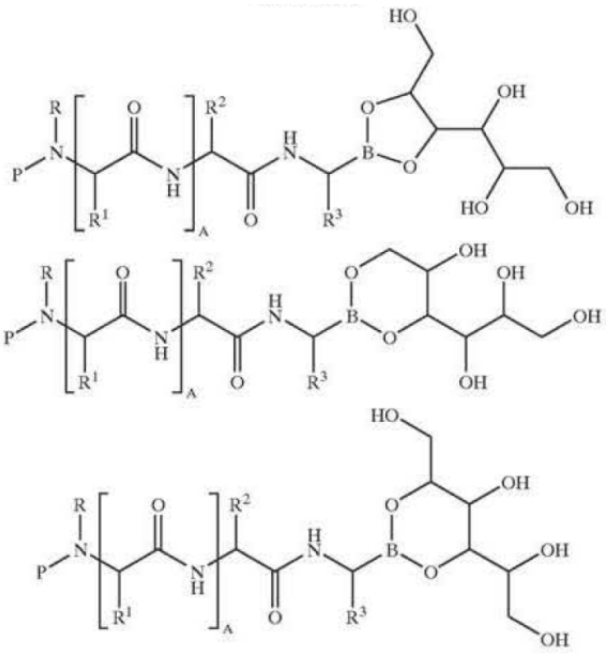
Millennium's proposed construction of the term "sugar" – "glucose, sucrose, fructose, trehalose, xylitol, mannitol, sorbitol, or similar saccharide" – directly reflects the description in the specification. The specification of the patents-in-suit states as follows:

> As used herein, the term 'moiety derived from a sugar' refers to a moiety formed by removing the hydrogen atoms from two hydroxyl groups of any sugar moiety. The moiety derived from a sugar may be attached to boron by any two of the hydroxyl groups of the sugar. . . .
>
> The sugar is preferably a monosaccharide or disaccharide. Non-limiting examples of suitable sugars include, glucose, sucrose, fructose, trehalose, xylitol, mannitol, and sorbitol. In certain preferred embodiments, the sugar is a reduced sugar, more preferably mannitol or sorbitol.

A-4, '446 patent 6:30-42; A-18, '319 patent 6:39-52. The specification further exemplifies for one skilled in the art sugar ester structures that are contemplated as part of the invention by providing multiple preferred examples of chemical structures for mannitol and sorbitol esters of boronic acid compounds:

> Preferably, the mannitol or sorbitol boronate ester compound has one of the following structures:





However, structures with larger boronate ester ring sizes are also possible.

A-4, ’446 patent 6:48-7:28; A-18, ’319 patent 6:58-7:40; *see also* A-5, ’446 patent 7:29-8:40; A-19, ’319 patent 7:41-8:58 (providing seven additional exemplary structures).

The textual and diagrammatic elements of the specification thus disclose that a “sugar” may be a monosaccharide, a disaccharide, or a reduced sugar. They further provide examples of suitable “sugars,” including glucose and fructose (which are monosaccharides), sucrose and trehalose (which are disaccharides), and xylitol, mannitol, and sorbitol (which are reduced sugars). A-4, ’446 patent 6:38-42; A-18, ’319 patent 6:48-52. Millennium’s proposed construction incorporates these teachings.

The description of the claimed invention in the specification cannot be ignored, as it is “entirely proper to consider the functions of an invention in seeking to determine the meaning of particular claim language,” *Medrad*, 401 F.3d at 1319; *see also Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1388 (Fed. Cir. 2010) (“claim terms must be construed in light of the entirety of the patent, including its specification”). Accordingly, where the specification

provides specific examples expressing the scope of a claim term, those examples must be taken into account. In *Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, for example, the Federal Circuit considered the proper construction of the term "wound." 554 F.3d 1010, 1019 (Fed. Cir. 2009). Because "[a]ll of the examples described in the specification involve skin wounds," the Court concluded that "[t]o construe 'wound' to include fistulae and 'pus pockets' would . . . expand the scope of the claims far beyond anything described in the specification." *Id.* Likewise, in *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, the Federal Circuit held that the district court erred in construing "body" to encompass "bodies composed of multiple pieces" because, among other things, "each figure that depicts a syringe shows a one-piece body." 653 F.3d 1296, 1305 (Fed. Cir. 2011) cert. denied, 133 S. Ct. 833 (2013) ("a construction of 'body' that limits the term to a one-piece body is required to tether the claims to what the specifications indicate the inventor actually invented").[10] *See also Medrad*, 401 F.3d at 1317 (affirming construction of "region of interest" as "as referring to the 'portion of the body being scanned'" based in part on examples in the specification that "strongly point to the 'region of interest' as being the portion of the anatomy being imaged"). In the '446 and '319 patents, the specification not only describes "sugar" as including monosaccharides, disaccharides, and reduced sugars but also provides specific examples.

The specification's second discussion of "sugar" reinforces this conclusion:

> In some preferred embodiments, the dihydroxy compound is a sugar, ***as described above***, preferably a monosaccharide or disaccharide, more preferably a reduced sugar, and most preferably sorbitol or mannitol.

[10] Defendants may argue that Millennium's proposal improperly imports a limitation from the specification into the claims. But as the Federal Circuit explained in *Retractable Technologies*, in construing claims courts must not "allow the claim language to become divorced from what the specification conveys is the invention." 653 F.3d at 1305. The specification here does not disclose any examples of sugars other than those it describes as "suitable."

A-6, '446 patent 10:32-35; A-20, '319 patent 10:53-56 (emphasis added). If the specific examples provided earlier in the specification were not intended to contribute meaningfully to the understanding of "sugar," there would be no need to incorporate those examples by referring to sugar as having been "described above."

C. Defendants' Proposed Construction is Inconsistent with the Claims and the Specification

Defendants propose a construction that is overbroad and inconsistent with the specification. Defendants' proposed construction effectively replaces the term "sugar" with the term "saccharide," a broad generic term that the patents-in-suit do not use. Defendants include the categories of sugars referenced in the specification – "monosaccharides, disaccharides, and reduced sugars" – in their construction. But by framing their construction as "saccharides *including*" these categories, Defendants essentially construe the term "sugar" to encompass *all* saccharides. As an initial matter, this construction does not advance the analysis; it simply substitutes the word "saccharide" for the word "sugar." But even more importantly, the two terms are not synonymous, and Defendants' construction would improperly expand the term "sugar" to include molecules that are neither claimed nor described in the specification.

For example, Defendants' interpretation of "sugar" as "saccharides" would also encompass polysaccharides. Ex. A,[11] WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE: UNABRIDGED (Merriam-Webster Inc., 1993) at 1995 (defining "saccharide" to include "polymerized sugars" with reference to the definition of "polysaccharides.") But polysaccharides – such as starch, glycogen, and cellulose – have molecular weights up to several million and often have highly branched structures,[12] whereas

[11] Citations to "Ex. _" refer to Exhibits attached hereto.

[12] Ex. B, A Dictionary of Chemistry (Oxford University Press, 4th ed. 2000) at 442.

sugars are of low molecular weight.[13] And in contrast to sugar, "cellulose cannot be digested by man," *id.* at 689, and starch granules (unlike "water-soluble" sugars[14]), "are insoluble in cold water but disrupt if heated to form a gelatinous solution."[15] Polysaccharides such as starch and cellulose are thus a very different class of molecules from the sugars described in the specification, and one skilled in the art would appreciate the distinction between large polysaccharides (such as starch, glycogen, and cellulose) and sugars (such as glucose, sucrose, and mannitol).[16] There is no basis to interpret the claim term "sugar" to include such large polymers, but Defendants' proposed construction would lump together these distinct categories.

Defendants' proposal should be rejected because it broadens the claims in a way that is unsupported by either the claims or the specification. *See Retractable Techs.*, 653 F.3d at 1305 (proper construction must "tether the claims to what the specifications indicate the inventor actually invented"); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1342 (Fed. Cir. 2010) (rejecting proposed construction that would encompass "direct detection" in part because the specification "contains no disclosure whatsoever of direct detection"). Defendants' proposal improperly "allow[s] the claim language to become divorced from what the specification conveys is the invention." *Retractable Techs.*, 653 F.3d at 1305. The Federal Circuit has "repeatedly rejected that approach." *Medrad*, 401 F.3d at 1319.

[13] Ex. B, A Dictionary of Chemistry (Oxford University Press, 4th ed. 2000) at 521.

[14] Ex. A, Webster's Third New International Dictionary of the English Language: Unabridged (Merriam-Webster Inc., 1993) at 2285.

[15] Ex. B, A Dictionary of Chemistry (Oxford University Press, 4th ed. 2000) at 514.

[16] See, e.g., Ex. C, Charles E. Mortimer, Chemistry: A Conceptual Approach (3d ed. 1975) at 687-89 ("Sugars, starches, and cellulose belong to a group of organic compounds called carbohydrates . . ."; "Glucose and fructose are known as monosaccharides. Sucrose, which is cane sugar, is a disaccharide."; "Cellulose and starch are polysaccharides that yield only D-glucose upon hydrolysis. It is estimated that the number of D-glucose units in the molecular structures of these substances may be as high as several thousand.")

V. CONCLUSION

For the foregoing reasons, Millennium requests that the Court adopt Millennium's proposed construction of "sugar" as "glucose, sucrose, fructose, trehalose, xylitol, mannitol, sorbitol, or similar saccharide."

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I hereby certify that on August 30, 2013, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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