

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDA PHARMACEUTICALS INC.,
and CIPLA LTD.,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

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C.A. No. 14-1453-LPS

Steven J. Balick, John G. Day, and Andrew C. Mayo, ASHBY & GEDDES, Wilmington, DE

H. Keeto Sabharwal, Dennies Varughese, Uma N. Everett, Rami Bardenstein, Dallin G. Glenn,
Josh I. Miller, and Josephine J. Kim, STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.,
Washington, DC

Attorneys for Plaintiffs Meda Pharmaceuticals and Cipla Ltd.

Dominick T. Gattuso, PROCTOR HEYMAN ENERIO LLP, Wilmington, DE

Charles B. Klein and Ilan Wurman, WINSTON & STRAWN LLP, Washington, DC

George C. Lombardi, Samuel S. Park, and Kevin E. Warner, WINSTON & STRAWN LLP,
Chicago, IL

Attorneys for Defendants Apotex Inc. and Apotex Corp.

MEMORANDUM OPINION

May 12, 2016
Wilmington, Delaware



STARK, U.S. District Judge:

On December 2, 2014, Plaintiffs Meda Pharmaceuticals and Cipla Ltd. (“Plaintiffs”) filed suit against Defendants Apotex Inc. and Apotex Corp (“Apotex” or “Defendants”) alleging infringement of U.S. Patent Nos. 8,163,723 (the “’723 patent”), 8,168,620 (the “’620 patent”), and 9,259,428 (the “’428 patent”). The patents are directed to a single-dosage formulation for the simultaneous administration of two active pharmaceutical ingredients: azelastine (an antihistamine) and fluticasone (a corticosteroid).

The parties submitted technology tutorials (D.I. 44 and 45) and claim construction briefs (D.I. 46, 47, 61, 63, and 96). The Court held a claim construction hearing on April 29, 2016. (*See* D.I. 113 (“Tr.”))

I. 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.” *Id.* 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.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

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 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) (quoting *Modine Mfg. Co. v. U.S. Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERM¹

“conditions”²

Plaintiffs “diseases or illnesses resulting in or causing allergic reaction(s)”
Defendants Plain and ordinary meaning. To the extent the Court determines that this term requires construction, Apotex proposes the following construction: “disease(s) or illness(es)”
Court “disease(s) or illness(es)”

A patent’s claims “define and circumscribe” the scope of a patentee’s right to exclude. *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1366, 1347 (Fed. Cir. 2010) (*en banc*). The Court, thus, begins its claim construction analysis with the language of the claims themselves.

The asserted patents here claim a method for treating a “condition for which administration of one or more antihistamines and/or one or more steroids is indicated.” *See, e.g.* ’723 pat. col. 11:52-53; ’620 pat. col. 12:42-44. Given this context, the Court finds that the plain and ordinary meaning of the term “condition,” to a person of ordinary skill in the art (“POSA”), is “disease or illness.”³

Claim language must be construed in the context of the claim as a whole. *See IGT v.*

¹The parties have agreed to certain constructions, all of which the Court has adopted or will adopt.

² This term appears in claims 1-4, 7, 8, 10-18, and 20-28 of the ’723 patent and claims 16, 17, and 24 of the of the ’620 patent.

³The parties do not dispute that what Defendants have proposed as their construction is, in fact, the plain and ordinary meaning of “conditions” to a POSA. (*See Tr.* at 25-26, 36-37)

Bally Gaming Int'l, Inc., 659 F.3d 1109, 1117 (Fed. Cir. 2011). “Extracting a single word from a claim divorced from the surrounding limitations can lead construction astray.” *Id.* Here, to the extent the claims of the patents-in-suit are concerned principally (or, for certain dependent claims, exclusively) with allergic reactions, it is not the word “conditions” that narrows the claim scope. Rather, it is the other limitations that establish the classes of disease or illnesses included within the scope of the claims: i.e., those conditions for which administration of an antihistamine or steroid is indicated.

For instance, independent claim 1 of the '723 patent is limited to methods relating to conditions typically treated by “antihistamines and/or . . . steroids.” Undoubtedly, a POSA would understand that not every disease or illness can be treated in this manner. But just because the overall scope of the claim does not reach every disease or illness does not mean that the claim term “condition” is being used in a manner narrower than its full plain and ordinary meaning.⁴

Plaintiffs argue that a person of ordinary skill in the art, having read the patent specification, would understand that “condition” is limited to conditions that “result in or cause an allergic reaction.” (D.I. 47 at 14) The “person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1314. Therefore, “[t]he customary meaning of a claim term is not determined in a vacuum and should be harmonized, to the extent possible, with the intrinsic record, as understood in the field of the invention.” *Lexion Med., LLC v. Northgate Techs., Inc.*, 641 F.3d 1352, 1356 (Fed. Cir. 2011).

⁴Thus, Plaintiffs’ concern that Defendants’ construction would encompass methods of treating anything from snake bites to cancer is unfounded. The claims would encompass these conditions *if, but only if*, these conditions meet the other claim limitations.

Neither the intrinsic nor extrinsic evidence supports a narrower construction of “conditions.” A court may depart from the ordinary meaning of a claim term in only two circumstances. *See Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015). First, a patentee may “act as a lexicographer” by assigning his own definition to a patent claim term. *Id.* Second, a patentee may intentionally disclaim, or “disavow,” claim scope. *Id.* A disclaimer or disavowal requires either “words or expressions of manifest exclusion or restriction,” *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 719, 190 L. Ed. 2d 463 (2014) (internal quotation marks omitted), or an implicit definition “so clear that it equates to an explicit one,” *Thorner*, 669 F.3d at 1368.

The intrinsic evidence Plaintiffs cite does not meet this exacting standard. Plaintiffs suggest that the patentees “defined” their invention as a method “useful for preventing or minimizing allergic reactions.” (D.I. 47 at 13) (citing ’723 pat. col. 1:20-22; ’620 pat. col. 1:11-13) Plaintiffs further note that the specification states that “the present invention relates [to treatments for] allergic reactions,” that the treatment of allergy symptoms was the purpose of the invention, and that the prosecution history shows the patentee and examiner were focused on the treatment of allergies. (D.I. 47 at 13-15) (citing ’723 pat. col. 1:20-22; ’620 pat. col. 1:11-13) While this evidence is probative of the “problem to be solved” by the invention, it is insufficient here to limit the scope of the claim term “condition.” *See, e.g., E-Pass Technologies, Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 (Fed. Cir. 2003). Rather, a disclaimer or disavowal is typically justified only if the text of the disputed patent **requires** the conclusion that the patentee disavowed claim scope, because to conclude otherwise would be **inconsistent with** its specification or claims. This is especially true here, where: (i) the specification does not include

explicitly narrowing language such as “the present invention requires,” “the present invention is,” or “all embodiments of the present invention are,” *Hill-Rom*, 755 F.3d at 1372; (ii) the specification contains at least six broader phrases that include “the present invention” (*see, e.g.*, ’723 pat. col. 4:41-53, 5:47-58, 6:46-57, 7:19-27, 7:35-41, 7:42-48), including one use that tracks the broad language of claim 1 (*see* ’723 patent 7:28-34 (“The present invention also provides a method for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more antihistamine and/or one or more steroid is indicated”));⁵ and (iii) the patent contains claims depending from independent claim 1 that are expressly limited to “allergic rhinitis” (’723 patent claim 8) or “allergic conjunctivitis” (’723 patent claim 9), which Defendant concedes are preferred embodiments.⁶

Other problems plague Plaintiffs’ proposed construction. First, Plaintiffs rely on a specification “definition” of “allergic reactions” that is not clearly a definition. (*See* Tr. at 32-36; D.I. 47 at 4 (citing ’723 patent 1:26-28) (“Such allergic reactions commonly comprise the allergy-related and vasomotor-related symptoms and the rhinovirus-related symptoms.”)) Second, the purported “definition” would confusingly include within “allergic reactions” conditions that Plaintiffs admit can be non-allergic. (*See* Tr. 35-36; D.I. 46 at 18 (citing D.I. 43-

⁵*See also Absolute Software v. Stealth Signal*, 659 F.3d 1121, 1136 (Fed. Cir. 2011) (“[W]e have found that use of the phrase ‘present invention’ or ‘this invention’ is not always . . . limiting, such as where the references to a certain limitation as being the ‘invention’ are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent.”).

⁶*See Liebel-Flarsheim v. Medrad*, 358 F.3d 898, 913 (Fed. Cir. 2004) (“[I]t is improper to read limitations from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.”).

10 at 5)) Third, relatedly, the prosecution history includes references to non-allergic conditions, such as types of asthma. (*See* D.I. 46 at 19)

Because Plaintiffs have not shown that a person of ordinary skill in the art would understand “conditions” to be limited to conditions causing allergic reactions, nor demonstrated that the patent itself so defined the term, the Court adopts Defendants’ construction.

III. CONCLUSION

The Court will construe the disputed term as described above. An appropriate Order follows.

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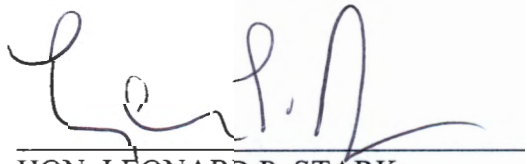
ORDER

At Wilmington, this **12th** day of **May, 2016**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the disputed claim term of U.S. Patent Nos. 8,163,723 (the "'723 patent") 8,168,620 (the "'620 patent"), and 9,259,428 (the "'428 patent") is construed as follows:

"Conditions," as used in claims 1-4, 7, 8, 10-18, and 20-28 of the '723 patent and claims 16, 17, and 24 of the of the '620 patent, means **"disease(s) or illness(es)."**



HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE