UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 12-60704-CIV-SEITZ/SIMONTON (consolidated)

APOTEX, INC. and APOTEX CORP.,
Plaintiffs,
v.
MYLAN PHARMACEUTICALS INC.,
Defendant.
_____/

CASE NO. 12-60704-CIV
SEITZ/SIMONTON

APOTEX, INC. and APOTEX CORP.,
Plaintiffs,
v.
PFIZER INC., and GREENSTONE LLC,
Defendants.
_____/

CASE NO. 12-60705-CIV
SEITZ/SIMONTON

APOTEX, INC. and APOTEX CORP.,
Plaintiffs,
v.
LUPIN PHARMACEUTICALS, INC. and LUPIN LTD.,
Defendants.
_____/

CASE NO. 12-60708-CIV
SEITZ/SIMONTON

PLAINTIFFS' BRIEF IN RESPONSE TO
DEFENDANTS' JOINT CLAIM CONSTRUCTION BRIEF (D.E. 62)

I. INTRODUCTION

Plaintiffs Apotex Inc. and Apotex Corp. (collectively, "Apotex") submit this brief in response to the claim construction arguments presented in Defendants Lupin Ltd., Lupin Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Pfizer, Inc. and Greenstone, LLC (collectively, "Defendants") Joint Opening Claim Construction Brief (D.E. 62) filed on December 14, 2012 ("Defendants' Opening Brief").

The '486 patent claims, specification and file history clearly and unambiguously frame the invention based on the reaction to form quinapril magnesium in an amount sufficient to increase the stability of the resulting tablets. This was Dr. Sherman's invention and he (through his patent counsel) repeatedly distinguished his invention from the prior art on this ground alone.

For example, each method claim of the '486 patent requires "the step of reacting .. so as to convert quinapril … to quinapril magnesium." The specification states that "the purpose of the invention is to eliminate the unstable quinapril or acid addition salt thereof and replace it with stable quinapril magnesium" to a degree wherein "the remaining quantity of quinapril or acid addition salt thereof … will be small enough that any degradation thereof will not be significant to the stability of the final product." (emphasis added). In contrast, the specification states that the stable products made in accordance with the prior art '450 patent and Gu article "result[] entirely or primarily not from conversion to" quinapril magnesium, but from "the presence of the … alkaline stabilizing compound in the final product," even though a small "uncertain and probably variable" amount of quinapril magnesium possibly forms "at the outer surface of the granules." In other words, the prior art taught tablets containing quinapril and a separate component (the stabilizer), not ones containing quinapril magnesium formed from the reaction claimed in the

'486 patent. This distinction is repeated throughout the file history. There was no other clear and unambiguous way that the claims of the '486 patent were distinguished from the prior art.

Following well-established claim construction principles, Apotex's constructions are fully supported by the '486 patent's claims, specification, and prosecution history (i.e. the intrinsic evidence), as well as the extrinsic evidence (to the extent the Court deems it necessary to consider it). In contrast, the Defendants' constructions ignore the clear meanings of the claim terms in an attempt to avoid the legitimate coverage of the claims of the '486 patent. Further, Defendants' constructions violate numerous black-letter claim construction principles by incorporating limitations from ambiguous statements in the specification or the prosecution history, relying on dictionary definitions, and/or ignoring the intrinsic evidence in favor of inconsistent extrinsic evidence.

Accordingly, Apotex's constructions should be adopted and Defendants' constructions should be rejected.

II. PERSON OF ORDINARY SKILL IN THE ART ("POSA")

Apotex set for the its definition of a person of ordinary skill in the art (POSA) in its opening brief (D.E. 63 at 8). In summary, the POSA would be a pharmaceutical formulator with at least one to five years of experience in drug development and formulation related to industrial application, specifically including wet granulation processes (depending on his/her education level). *Id.*; Ex. C, Moreton Decl. at ¶ 8; Ex. KK, Cima Decl. at ¶ 18.[1] Based on Federal Circuit case law, this is an appropriate definition of the POSA based on the factors that may be considered including the type of problems encountered in art; prior art solutions to those

[1] Exhibits A-H referred to herein were filed with Apotex's Opening Brief (D.E. 63). Exhibits I-NN were filed with Apotex's Brief in Response to Mylan and Lupin Defendants' Indefiniteness Brief, which was filed concurrently.

problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field. *See Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1376 (Fed. Cir. 2012).

In contrast, Defendants ignore, *inter alia*, the nature of the problem that the '486 patent inventor (Dr. Sherman, a formulator with 30+ years' experience)[2] faced and the sophistication of the technology. The '486 patent concerns methods of making stable solid pharmaceutical compositions of quinapril magnesium. *See, e.g.*, Ex. A, '486 patent at col. 1:5-2:44. It is clear from the '486 patent and other references that there was a need for methods of making stable pharmaceutical compositions containing quinapril. *See, e.g., id.* at col. 1:5-9; 2:41-67. As such, the most relevant art in this case is pharmaceutical formulation, not analytical or synthetic chemistry. *See* Ex. KK, Cima Decl. at ¶¶ 17-19. Defendants' definition of the POSA (D.E. 62 at 6, n.5; *see also* Zaworotko Decl. (D.E. 60-1) at ¶ 24) overemphasizes the need for analytical and synthetic chemical expertise. *See* Ex. KK, Cima Decl. at ¶¶ 17-19. In fact, it appears Defendants' POSA would need to have a masters or a Ph.D. degree in three disparate disciplines. (D.E. 62 at 6, n.5) ("masters or Ph.D. in pharmaceutical sciences, organic chemistry, and analytical chemistry") (emphasis added). Defendants' POSA would not be able to appreciate or understand the complexity and nuance of pharmaceutical formulation, especially composition manufacturing techniques, like wet granulation. *See* Ex. KK, Cima Decl. at ¶¶ 17-19.

Accordingly, Apotex's definition of the POSA should be adopted and Defendants' POSA definition should be rejected.

[2] Defendants assert that "Apotex was, in effect, the applicant" because Dr. Sherman was listed as the inventor. (D.E. 62 at 3, n.3.) However, this has no basis in fact or law – Apotex had no legal interest in this patent until Dr. Sherman assigned it to them in 2012. The only applicant was Dr. Sherman, Defendants' unsupported and incorrect conjecture notwithstanding.

III. "QUINAPRIL MAGNESIUM"

The parties' agreed to the definition of the term "quinapril magnesium." However, despite agreeing the term can be construed and not challenging the actual construction, Lupin and Mylan have provided a separate brief (D.E. 62) regarding the alleged indefiniteness of this term. Pfizer and Greenstone do not join Mylan and Lupin's brief nor have they contested the agreed upon construction. Apotex has submitted concurrently a separate opposition brief (with supporting declaration and exhibits) that demonstrate why Mylan and Lupin's arguments are legally and factually unfounded. As set forth therein, Mylan and Lupin cannot meet the difficult burden of proving this term is insolubly ambiguous by clear and convincing evidence.

IV. "REACTING … SO AS TO CONVERT … TO QUINAPRIL MAGNESIUM"

CLAIM	CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION	DEFENDANTS' PROPOSED CONSTRUCTION
1	"reacting ... so as to convert ... to quinapril magnesium"	chemically changing a significant portion of the quinapril or acid addition salt thereof to quinapril magnesium	Performing a process, different from standard wet granulation, which chemically changes quinapril or an acid addition salt thereof and an alkaline magnesium compound to produce quinapril magnesium

A. Apotex's Construction Is Consistent With the Purpose of The Invention

As detailed in its Opening Brief, Apotex's proposed construction is correct because it captures the invention described and claimed in the '486 patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) ("The 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."). Apotex's construction reflects the stated purpose of the '486

invention, i.e., to eliminate the unstable quinapril or acid addition salt thereof, by converting a significant portion thereof to the stable quinapril magnesium. *See* Ex. A, '486 patent at Col. 2:56-67; Apotex Opening Brief at 16.

Defendants' construction is wrong because it arguably would cover even the slightest, *de minimis* amount of a conversion. But that is clearly not the invention described in the '486 patent. One of ordinary skill would not read the specification and prosecution history, which specifically states that just a small amount of conversion is not being claimed as the invention (*see, e.g.*, Ex. A, '486 patent at col. 1:57-2:32; Ex. B, Pros. Hist. at AI0012088-12089) and then conclude that the claimed invention covers such a small amount of conversion. *See* Ex. C, Moreton Decl. at ¶ 21 ("one of ordinary skill in the art would understand that the invention described … is not directed to processes wherein a nominal amount of conversion to quinapril magnesium occurs."). Thus, Apotex's construction merely clarifies that which is already described in the specification, i.e., the present invention is directed to chemically changing a significant portion of quinapril or acid addition salt to quinapril magnesium.

Defendants also misapply the holding in *Phillips* to support their position that Claim 1 should be construed to capture **any** conversion to quinapril magnesium. *See* Defendants' Op. Br. at 14 (citing *Phillips*, 415 F.3d at 1314-15). *Phillips* states "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." *Phillips*, 415 F.3d at 1315 (emphasis added). Here, Defendants are arguing that the express quantitative limitations in Claims 16-19 somehow bar Apotex from claiming **any** quantitative conversion of quinapril magnesium in Claim 1. This goes too far. While *Phillips* arguably creates a presumption that claim 1 is not specifically limited to the express numerical ranges contained in Claims 16-19, it does not give Defendants a

license to broaden the scope of Claim 1 and ignore the clearly stated purpose of the invention by including *de minimis* conversions to quinapril magnesium. As described above, such a construction contradicts the purpose of the present invention.

Additionally, Apotex is not interpreting claim 1 to include the conversions identified in Claims 16-19. Indeed, *Phillips* holds that an independent claim should be given a broader scope than a dependent claim to avoid rendering the claim redundant. *Phillips,* 415 F.3d at 1324-25 . Thus, Apotex's construction of Claim 1 is consistent with that principle because its construction is broader than what is described in Claims 16-19.

B. Apotex's Statements During Prosecution Were Not A Clear and Unmistakable Disavowal Of Claim Scope

Defendants' claim construction arguments are nothing more than a thinly veiled attempt to bolster their non-infringement positions. If the Defendants' construction is adopted, there is little doubt they will later argue they do not infringe the claims of the '486 patent because they practice only "standard wet granulation" processes. However, Defendants have not offered any evidence to demonstrate that one of skill in the art would readily understand the meaning of this term to unequivocally show Apotex's disavowal. Thus, Defendants cannot argue that Apotex made a "clear and unmistakable" disavowal of claim scope when they are in no position to offer any clarity the boundaries of their imported limitation.[3]

Defendants' Brief correctly points out that in order to constitute a disavowal, an applicant's statements during prosecution must be "both clear and unmistakable." Defendants Opening Brief at 7. The Federal Circuit has also recognized an important distinction between

[3] Notably, Apotex's statement during prosecution contained the phrase "more or less standard wet granulation," yet, Defendants Opening Brief fails to explain why their construction is limited to just "standard wet granulation." *See, e.g.,* Ex. B, *Pros. History* at AI0000408-409. As such, Defendants inclusion of only a portion of Apotex's actual statement appears to be arbitrary in nature, and thus, not fully supported by the intrinsic evidence.

statements that describe the prior art, which are not a disavowal, and statements that describe the claimed invention, which can result in a disavowal. *See Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281, 1293-1294 (Fed. Cir. 2000). In *Northern Telecom*, the patentee made statements during prosecution that described the teachings of a prior art reference as, *inter alia*, "concerned with a totally different process." *Id.* In determining whether these statements were an express disavowal of claim scope, the court focused on both the contextual circumstances in which the statements were made and how the statements should be interpreted in view of the patent disclosure. *Id.* The Court ultimately found that statements did not contain the "clarity and deliberateness" required to raise to the level of express disavowal. *Id.*

The Federal Circuit's holding in *Northern Telecom* is wholly consistent with the positions presented in Apotex's Opening Brief, i.e., Apotex's statements do not clearly and deliberately exclude "standard wet granulation" processes from the claimed invention. Apotex's Opening Brief at 18, *cf. Northern Telecom* at 1293-94 (finding that a patentee's statement describing a prior art process did not amount to an exclusion of the prior art process from the invention). Instead, Apotex argued that the '450 patent merely describes "a more or less standard wet granulation" and does not provide any parameters for doing the wet granulation and does not disclose a wet granulation technique that matches Apotex's claimed process. This is important because not all wet granulation techniques would result in converting a significant portion of the quinapril hydrochloride to quinapril magnesium. *See* Apotex's Opening Brief at 18-19.

C. Defendants Rely On Irrelevant Evidence

Defendants seek to introduce evidence relating to statements made by Apotex to the European Patent Office during prosecution of the European counterpart to the '486 patent. Defendants Opening Brief at 10. However, the Federal Circuit has held that statements made during prosecution of foreign counterparts "are irrelevant to claim construction because they

were made in response to patentability requirements unique to … European law." *Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006). Thus, Defendants reliance on this evidence is improper, and it should not be considered in determining the proper meaning of the claims.

Similarly, Defendants' reliance on a statement made by counsel for Apotex during the September 6, 2012 scheduling hearing before the Court is solely meant to confuse the issues in an attempt to prejudice Apotex. *Phillips* makes clear that "the ordinary and customary meaning of a claim term 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." Phillips 415 F.3d at 1313 (emphasis added). Therefore, the identified statement is irrelevant to the issue of claim construction.

For the reasons above, and the arguments raised in Apotex's Opening Brief, the Court should adopt Apotex's construction because it most comports with the stated purpose of the invention and Apotex's statements were not a clear and unmistakable disavowal of claim scope.

V. "IN THE PRESENCE OF A SOLVENT"

CLAIM	CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION	DEFENDANTS' PROPOSED CONSTRUCTION
1	"in the presence of a solvent"	With a sufficient amount of a liquid to at least moisten the quinapril or acid addition salt thereof and the alkaline magnesium compound to permit the reaction to occur	A liquid of a type and in an amount sufficient to dissolve the quinapril or an acid addition salt thereof and the alkaline magnesium compound to enable the reaction

The parties agree that this term requires a chemical change of the quinapril to quinapril magnesium. The major differences between the two proposals lies in (a) the degree of conversion

to quinapril magnesium and (b) whether "standard" wet granulation techniques (to the extent they exist) are excluded from the claims.

A. Apotex's Construction Is Consistent With the Purpose of The Invention

As detailed in Apotex's Opening Brief (D.E. 63 at 16-17), Apotex's proposed construction is correct because it captures the invention described and claimed in the '486 patent claims, specification and file history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) ("The 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."). The '486 patent claims, specification and file history clearly and unambiguously frame the invention based on the reaction to form quinapril magnesium in an amount sufficient to increase the stability of resulting tablets. This was Dr. Sherman's invention and he (through his patent counsel) repeatedly distinguished his invention from the prior art on this ground alone.

For example, each method claim of the '486 patent requires "the step of reacting .. so as to convert quinapril … to quinapril magnesium. Ex. A, '486 patent at Claims 1-12, 16-19. Also, the specification states that "the purpose of the invention is to eliminate the unstable quinapril or acid addition salt thereof and replace it with stable quinapril magnesium" to a degree wherein "the remaining quantity of quinapril or acid addition salt thereof … will be small enough that any degradation thereof will not be significant to the stability of the final product." (emphasis added). In contrast, the specification states that the stable products made in accordance with the prior art '450 patent and Gu article "result[] entirely or primarily not from conversion to" quinapril magnesium, but from "the presence of the … alkaline stabilizing compound in the final product," even though a small "uncertain and probably variable" amount of quinapril magnesium possibly forms "at the outer surface of the granules." *Id.* at col. 1:48-2:15. In other words, the prior art taught tablets containing quinapril and a separate component (the stabilizer), not ones containing

quinapril magnesium formed from the reaction claimed in the '486 patent (to any appreciable degree). This distinction was repeated in the file history. Ex. B, Pros. History at AI0000456 ("quinapril magnesium may be present in small unpredictable amounts in the prior art formulation taught in [the '450 patent].")

Apotex's construction reflects the stated purpose of the '486 invention, i.e., to eliminate the unstable quinapril or acid addition salt thereof, by converting a significant portion thereof to the stable quinapril magnesium. *See* Apotex Op. Br. (D.E. 63) at 16.

Defendants' construction is wrong because it is overly broad, inconsistent with the intrinsic evidence, and arguably would cover methods that results in tablets with even a *de minimis* amount of quinapril magnesium. But that is clearly not the invention described in the '486 patent. One of ordinary skill would not read the clear statements above that recognize small, unpredictable amounts of conversion were in the prior art methods and understand the claims to cover such small amounts of conversion. *See, e.g.,* Ex. C, Moreton Decl. at ¶ 21 ("one of ordinary skill in the art would understand that the invention described … is not directed to processes wherein a nominal amount of conversion to quinapril magnesium occurs."). Defendants' construction calls for the illogical conclusion that Dr. Sherman knowingly amended his claims so that they would be invalid.

Defendants' arguments (D.E. 62 at 12-15) against Apotex's construction are incorrect. First, they argue that Claim 1 has no "mention of the amount that is converted." While there is no explicit amount, the claim must be read in light of the specification, which clearly indicates that "the remaining quantity of quinapril or acid addition salt thereof … will be small enough that any degradation thereof will not be significant to the stability of the final product." It is of no consequence that Dr. Sherman amended the claim (without conceding the examiner was right) to remove "all or substantially all." Removal of this limitation does not mean that the rest of the

specification and file history can be ignored. Thus, the correct construction cannot broaden the scope of Claim 1 to ignore the clearly stated purpose of the invention by including *de minimis* conversions to quinapril magnesium.

Defendants' argument (D.E. 62 at 13-14) regarding the splitting of Claim 17 is a misapplication of the law as Defendants turn the holding in *Phillips* on its head. Essentially, Defendants argue that because Dr. Sherman did not add a limitation that was present in dependent claims that Claim 1 should be construed to capture any conversion to quinapril magnesium. *Phillips* stands for the unremarkable position that an independent claim must be as broad or broader than its dependent claims. In other words, Apotex cannot now say that Claim 1 requires 99% conversion because dependent Claims 16-19 all require less than that. arguably creates a presumption that Claim 1 is not any narrower than "about 80%" *Phillips* also states "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." *Phillips*, ?? F.3d at 1315 (emphasis added). Again, this is nothing surprising – Apotex cannot argue that Claim 1 should be construed to mean, e.g., "about 80%" conversion because then Claim 16 would be redundant. Defendants take these straightforward principles and stretch then to unprecedented lengths. There is no case law that stands for the proposition that would allow the express quantitative limitations in Claims 16-19 to somehow mean that one would disregard the clear teaching of the specification and file history to bar Apotex from claiming **any** quantitative conversion of quinapril magnesium. As described above, such a construction contradicts the purpose of the present invention.

Defendant's argument (D.E. 62 at 15) that "significant portion" is vague is inapt in this case. Defendants' entire basis for its position is attorney argument, unsupported by evidence.

Defendants did not provide any evidence in its opening brief demonstrating that one of ordinary skill would understand the term differently than in Apotex's expert, Dr. Moreton opined. One of ordinary skill would understand that a process that resulted in enough conversion to quinapril magnesium would fall within the scope of Claim 1 so long as the compositions were more stable than compositions containing unconverted or unstabilized quinapril hydrochloride. *See* Ex. C, *Moreton Decl.* at ¶¶ 35-36. One of ordinary skill would know that the specific amount would vary upon numerous conditions and thus, a more specific numerical limitation would be improper. *Abbott Labs.*, 334 F.3d at 1277-1280 (reversing district court's construction that limited the "effective amount" of an degradation inhibitor to a specific number, when the amount would vary "depend[ing] on many environmental considerations."). Similar to *Abbott*, an ordinary formulator knew that too little conversion to quinapril magnesium would not provide a stable tablet. *See* Ex. C, Moreton Decl. at ¶ 21.

As such, Apotex's construction including "significant conversion" is more in line with the intrinsic and extrinsic evidence than Defendants' construction that would require the illogical thought that the inventor purposefully invalidated his broadest independent claim during prosecution of the patent.

B. Dr. Sherman's Statements During Prosecution Were Not A Clear and Unmistakable Disavowal Of "Standard Wet Granulations" that Result in Significant Conversion of Quinapril to Quinapril Magnesium

As set forth in Apotex's opening brief (D.E. 63 at 17-19), Defendants' are seeking to import a vague and unsupported limitation of "different from standard wet granulation" into the claims. Defendants correctly point out that in order to constitute a disavowal, an applicant's statements during prosecution must be "both clear and unmistakable." Defs. Op. Br. (D.E. 62) at 7.

Here, the only way that Dr. Sherman clearly and unmistakably distinguished the prior art was, as described above, on the basis that the prior art taught tablets containing quinapril and a separate component (the stabilizer), not ones containing quinapril magnesium formed from the reaction claimed in the '486 patent (to any appreciable degree).

This distinction is repeated throughout the file history. For example, the '450 patent is repeatedly distinguished because it does not teach a reaction. *See, e.g.*, Ex. B, Pros. History at AI0000412 ("Example A [in the '450 patent] refers to a wet granulation method for the manufacture of tablets from the listed materials … which **are not reacted** but combined. The Examiner has stated incorrectly that the materials allegedly **react** when this is contrary to the disclosure of [the '450 patent]"); AI0000426 (same); AI000414 ("Clearly therefore, it is impossible to conclude as the Examiner has that [the '450 patent] discloses in view of reference D2, a process comprising the step of 'reacting'."); AI0000427-28 (same); AI0000427 ("**No where in the ['450 patent] reference is there discussed any reactions** …."); AI0000428 ("[The '450 patent] is silent with respect to a reaction as this would be contrary to the teachings" in that patent); AI000429 ("without pointing out any specific disclosure in the specification of [the '450 patent] which discuss **the end result being quinapril magnesium**.") (underlines emphases added; bold emphases in original). As clearly stated, "with Applicant's Claim 1 the quinapril or quinapril acid addition salt is converted to quinapril magnesium. The teachings of [the '450 patent] point in a different direction …." *Id.* at AI000430 (emphasis added). Further, reading the '450 patent to disclose reacting "would again be a misreading of the reference, as it teaches combining and contacting but in no way discusses reacting." *Id.* In fact, the '450 patent teaches "that a reaction is not desirable …" *Id.* Ultimately, the examiner allowed the patent to issue because of this distinction: "The difference between the Harris ['450 patent] process and

the instantly claimed process is the salt formed of the quinapril compound. In the instant process, quinapril magnesium is formed. In the Harris process, a composition containing quinapril hydrochloride and magnesium carbonate is formed." *Id.* at AI0000468.

There was no other clear and unambiguous way that the claims of the '486 patent were distinguished from the prior art. Unlike the numerous and varied statements concerning the lack of reaction in the '450 patent, Defendants rely (D.E. 63 at 9-10) on a single statement (repeated less than five times) that the '450 patent 'is silent in relation to anything but the use of a more or less standard wet granulation process." However, Defendants ignore the fact that these statements are followed up two sentences later with "[c]learly therefore, it is impossible to conclude that [the '450 patent] discloses a process comprising the step of reacting" in each instance. Defendants incorrectly read this statement as disavowing all "standard wet granulations." However, when read in the context of the paragraph it appears in (let alone the larger context of the entire file history), this statement means that not all wet granulations lead to the reaction and that Dr. Sherman was only claiming the ones that do. Thus, Defendants cannot argue that Dr. Sherman made a "clear and unmistakable" disavowal of claim scope, especially when they offer no clarity as to what they define as the boundaries of their imported limitation.[4]

This case is analogous to *Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281 (Fed. Cir. 2000). In *Northern Telecom*, the patentee made statements during prosecution that described the teachings of a prior art reference as, *inter alia*, "concerned with a totally different process." *Id.* In determining whether these statements were an express

[4] Notably, Apotex's statement during prosecution contained the phrase "more or less standard wet granulation," yet, Defendants Opening Brief fails to explain why their construction is limited to just "standard wet granulation." *See, e.g.*, Ex. B, *Pros. History* at AI0000408-409. As such, Defendants inclusion of only a portion of Apotex's actual statement appears to be arbitrary in nature, and thus, not fully supported by the intrinsic evidence.

disavowal of claim scope, the court focused on both the contextual circumstances in which the statements were made and how the statements should be interpreted in view of the patent disclosure. *Id.* The Court ultimately found that statements did not contain the "clarity and deliberateness" required to raise to the level of express disavowal. *Id.*

Also, the Federal Circuit recognized an important distinction between statements that describe the prior art, which are not a disavowal, and statements that describe the claimed invention, which can result in a disavowal. *See Northern Telecom*, 215 F.3d at 1293-94. This holding is wholly consistent with the positions presented in Apotex's Opening Brief (D.E. 63 at 18) that Dr. Sherman's statements do not clearly and deliberately exclude "standard wet granulation" processes from the claimed invention. Instead, Dr. Sherman described the prior art '450 patent as "a more or less standard wet granulation," which did not provide any parameters to determine that a significant reaction occurred in the disclosed "wet granulation" technique. This lead Dr. Sherman to distinguish his invention based on the '450 patent's failure to disclose the reaction to form quinapril magnesium.

As such, Defendants construction is improper and should be rejected because it incorporates a limitation based on an ambiguous description of the prior art, when the clearly stated difference between the prior art and the claimed invention was the reaction of quinapril magnesium.

C. Defendants Rely On Irrelevant Evidence

Defendants' reliance on a statement made by counsel for Apotex during the September 6, 2012 scheduling hearing before the Court is solely meant to confuse the issues in an attempt to prejudice Apotex. *Phillips* makes clear that "the ordinary and customary meaning of a claim term 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." *Phillips*,

415 F.3d at 1313 (emphasis added). Therefore, the identified statement is irrelevant to the issue of claim construction. Even if considered, this statement is not clearly unambiguous as Apotex's counsel was intending to convey the idea that wet granulation is typically not done to cause a reaction, not that the claims exclude "typical wet granulations" (whatever Defendants contend that means).

For the reasons above, and the arguments raised in Apotex's Opening Brief, the Court should adopt Apotex's construction because it most comports with the stated purpose of the invention and Apotex's statements were not a clear and unmistakable disavowal of claim scope.

VI. "WET MASS"

CLAIM	CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION	DEFENDANTS' PROPOSED CONSTRUCTION
5-8	"wet mass"	material that is sufficiently wetted with solvent to form lumps or granules and to permit the reaction to occur	The material resulting from the wet granulation (as described in the '486 patent) of at least quinapril or an acid addition salt thereof, an alkaline magnesium compound and the solvent

Based on the briefs, the parties agree that the term "wet mass" requires the material (a) to be created during wet granulation (D.E. 63 at 20; D.E. 62 at 18-19) and (b) to be sufficiently wetted to permit the reaction to occur (D.E. 63 at 19-21; D.E. 62 at 19).

The two remaining disputes are (1) whether the wet granulation must be "as described in the '486 patent" as Defendants' proposed or any wet granulation and (2) whether the wet mass has to be "sufficiently wetted .. to form lumps or granules" as proposed by Apotex.

As to the first issue, Defendants' proposed limitation is a classic example of improperly limiting the claims to the specific embodiments in the specification. *See, e.g., Phillips*, 415 F.3d

at 1315; *Abbott Labs.*, 334 F.3d at 1280. Furthermore, the '486 patent specification explicitly states that the Examples "are intended to be illustrative but not limiting of the invention." Ex. A, *'486 patent* at col. 4:65-67 (emphasis added). Furthermore, Defendants appear to have waived at least this part of their construction as they do not mention it or cite to any evidence, intrinsic or extrinsic, in support of adding this limitation in their opening brief. To be clear, Claims 5-8 should not be limited to any particular method or set of conditions.

Regarding the second issue, Defendants' argument (D.E. 19) that "the specification never refers to sufficient wetting to form lumps or granules" is legally and factually deficient. First, information that is well known in the art need not be described in detail in the specification. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, (Fed. Cir. 1986). As described in its opening brief (D.E. 63 at 19-21), the ordinary formulator would understand "wet mass" in a wet granulation would form lumps and granules. *See, e.g.*, Ex. C, Moreton Decl. at ¶¶ 25-31. In its opening brief, Defendants submitted no evidence to contradict Dr. Moreton's testimony. Second, Defendants admit that the wet mass results from "wet granulation." Logically, the results of wet granulation is the formation of lumps or granules. Thus, if the wet mass is not "sufficiently wetted … to form lumps or granules," then it cannot achieve the agreed upon purpose of this step.

For the reasons above and in Apotex's Opening Brief, the Court should adopt Apotex's construction.

VII. "DRY MASS" OR "DRIED MASS"

CLAIM	CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION	DEFENDANTS' PROPOSED CONSTRUCTION
5-8	"dry mass" "dried mass"	Material that results from removing a sufficient amount of solvent from the wet mass to allow further processing	The material that results upon removing the solvent from the wet mass

As stated in Apotex's opening brief (D.E. 63 at 21-22), the claim language itself and the specification (i.e. the intrinsic evidence), as well as Dr. Moreton's uncontroverted testimony, show that a sufficient amount, but not necessarily all, of the wet granulation solvent needs to be removed for further processing.

Defendants' argument (D.E. 62 at 21) regarding the supposed vagueness of Apotex's proposed inclusion of "further processing" and "sufficient amount" miss the mark. The term "further processing" is explicitly found in Claims 5-8, yet Defendants have never asked or proposed that further construction was needed. This belies their current position that the term is vague. Also, this term clearly means taking the dry mass and making it into a pharmaceutical dosage form, such as a tablet. As for the "sufficient amount" to allow for further processing, one of ordinary skill would know that the specific amount would vary upon numerous conditions and thus, a more specific numerical limitation would be improper. *Abbott Labs.*, 334 F.3d at 1277-1280 (reversing district court's construction that limited the "effective amount" of an degradation inhibitor to a specific number, when the amount would vary "depend[ing] on many environmental considerations."). Similar to *Abbott*, an ordinary formulator knew that removal of too little or too much solvent from the wet mass can adversely impact further processing of tablets. *See* Ex. C, Moreton Decl. at ¶¶ 32-

34. The ordinary pharmaceutical formulator would know that all of the solvent does not have to be removed to allow for further processing. *See id.*

Further, Defendants' construction is vague because it can mean that (a) all of the solvent must be removed, (b) any amount of solvent can be removed, or (c) a sufficient amount of solvent can be removed to allow for further processing, and thus should be rejected. *See Bone Care*, 2010 WL 2266518 at *8. Furthermore, Defendants' brief makes no effort to clarify what level of drying it is intended to cover.

For the reasons above in Apotex's Opening Brief, the Court should adopt Apotex's construction because it is most consistent with the meaning of this term to one of skill in the art.

VIII. "AT LEAST ABOUT 80%"

CLAIM	CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION	DEFENDANTS' PROPOSED CONSTRUCTION
16	"at least about 80%"	Approximately 80% or more	More than 75%

As described in Apotex's opening brief (D.E. 63 at 23-24), Apotex's construction follows to the principles laid out by the Federal Circuit regarding this term, i.e., "about" should be given its ordinary and accepted meaning of "approximately" when the patentees fail to clearly redefine the term in the specification. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). The '486 specification does not redefine "about" in this specification, and thus, adopting a construction having an exact numerical limitation would ignore Apotex's deliberate imprecision in the claims. *See Cohesive*, 543 F.3d at 1370; *Abbott Labs.*, 334 F.3d at 1277-1280 (reversing district court's construction that limited the "effective amount" of an degradation inhibitor to a specific number, when the amount would vary "depend[ing] on many

environmental considerations."). Also, Apotex's construction is further supported by the intrinsic and extrinsic evidence as described in Apotex's opening brief.

In contrast, Defendants' sole basis (D.E. 62 at 21-23) for their construction lies in the difference in claim scope between dependent Claims 18 and 19. This reliance is misplaced. First, the term "at least about" does not appear in those claims, nor do those claims depend from claims containing this language. Thus, Defendants' arbitrary revision of the claims to support their construction has no logical or legal underpinnings. Notably, Defendants have not cited to any case law that directly supports the mental gymnastics required by their construction.

Defendants' entire construction rests on attorney argument. Defendants did not provide any evidence in its opening brief demonstrating that one of skill in the art would understand the term differently than Dr. Moreton's opinion. As Dr. Moreton opined, one of ordinary skill would understand that a process that resulted in less than 75% conversion to quinapril magnesium would fall within the scope of Claim 16 so long as the compositions were more stable than compositions containing unconverted or unstabilized quinapril hydrochloride. *See* Ex. C, *Moreton Decl.* at ¶¶ 35-36.

For the reasons above and in Apotex's Opening Brief, the Court should adopt Apotex's construction because it is most consistent with the accepted claim construction principles and the understanding of one of ordinary skill in the art.

IX. CONCLUSION

For all the above reasons, Apotex respectfully requests that the Court construe the claims of the '486 patent as proposed by Apotex or as agreed to by the parties.[5]

[5] Defendants' Opening Brief omits the parties' agreed upon construction that "the claimed method requires the steps to be performed in the order set forth in the claims." *See* D.E. 63, Appx. A, Claims 5-8. Defendants do not dispute this construction in their opening brief. Thus, the Court should adopt the agreed upon construction.

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