IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

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

DEFENDANTS, LUPIN LTD.'S, LUPIN PHARMACEUTICALS, INC.'S AND MYLAN PHARMACEUTICALS INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF ON INDEFINITENESS OF THE CLAIM TERM "QUINAPRIL MAGNESIUM"

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I. INTRODUCTION

Defendants, Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin") and Mylan Pharmaceuticals Inc. ("Mylan") (collectively, "Defendants") submit this responsive claim construction brief to further address the indefiniteness of the claim term "quinapril magnesium."

Apotex's Opening Claim Construction brief ("Apotex's Opening Brief") merely serves to confirm the ambiguity of the term "quinapril magnesium." In its Opening Brief, Apotex withdraws from a previously agreed upon construction of "quinapril magnesium," and proposes a materially different construction for the term. As explained below, Apotex's proposed construction of "quinapril magnesium," is contrary to the explicit language of the '486 patent specification and does not remedy the ambiguity of the term. Moreover, it is apparent that Apotex's construction of "quinapril magnesium" constitutes a thinly-veiled attempt to manipulate the claim construction process in order to support their infringement theory.

II. BACKGROUND

The major point of dispute between the parties regarding the proposed construction of the claim term "quinapril magnesium" is whether to include the word "the" prior to "magnesium salt of quinapril having the chemical formula, $Mg(C_{25}H_{29}N_2O_5)_2$."

Claim Term – "Quinapril magnesium"	
Defendants' Proposed Construction	**Apotex's Proposed Construction**
the magnesium salt of quinapril having the chemical formula, $Mg(C_{25}H_{29}N_2O_5)_2$	magnesium salt of quinapril having the chemical formula $Mg(C_{25}H_{29}N_2O_5)_2$

Defendants originally proposed that the term "quinapril magnesium" be construed as "the magnesium salt of quinapril having the chemical formula $Mg(C_{25}H_{29}N_2O_5)_2$." Exhibit ("Exh.") A, Defendants' Proposed Claim Construction. At the same time, Defendants expressly notified Apotex that their proposed construction of "quinapril magnesium" was based on the only

information provided in the patent and, since there is no accepted meaning for "quinapril magnesium" in the prior art and the '486 patent does not provide a chemical structure for "quinapril magnesium" or evidence that "quinapril magnesium" exists, the term is indefinite. *Id.* Apotex's original proposed construction was "magnesium salt of quinapril, *e.g.*, $Mg(C_{25}H_{29}N_2O_5)_2$." Exh. F, Apotex's Proposed Constructions of Claim Terms in the '486 Patent (emphasis added). At the December 5, 2012, "meet and confer" concerning claim construction Apotex agreed to adopt Defendants' proposed construction of "quinapril magnesium." Counsel for Apotex later circulated a document that they represented contained the "agreed" constructions; however, after review, Defendants noticed that the word "the" had been omitted before the words "magnesium salt" for the proposed construction of "quinapril magnesium." Exh. B, Proposed Constructions of Claim Terms in the '486 Patent. On December 10, 2012, Defendants informed Apotex that the word "the" should be inserted before "magnesium salt." Exh. C, Email from A. Stiefel to M. Masar. Plaintiffs did not respond or otherwise express disagreement with Defendants' December 10, 2012 email. In fact, on December 14, 2012, the deadline for opening claim construction briefs, Counsel for Apotex circulated an email in connection with the agreed claim constructions which clearly states that the parties' agreed construction of "quinapril magnesium" was "*the* magnesium salt of quinapril…" Exh. D, Email from M. Masar to A. Stiefel (emphasis added).

In view of the foregoing, Defendants were surprised to learn for the first time in Apotex's Opening Brief that the parties did not agree on the proposed construction of "quinapril magnesium." Apotex downplays the difference in the parties' proposed constructions and argues that they are "essentially the same;" however, if so, it is difficult to understand why Apotex has withdrawn from its agreement as to the construction of the claim term.

III. APOTEX'S PROPOSED CONSTRUCTION IS NOT SUPPORTED BY THE SPECIFICATION AND SHOULD NOT BE ADOPTED

Apotex's proposed construction of the claim term "quinapril magnesium" should not be adopted because it conflicts with the intrinsic evidence. Moreover, even if adopted, Apotex's proposed construction, like Defendants' proposed construction, does not resolve the ambiguity of the claim term "quinapril magnesium."

As explained in Defendants, Lupin Ltd.'s, Lupin Pharmaceuticals, Inc.'s and Mylan Pharmaceuticals, Inc.'s Opening Claim Construction Brief Regarding Indefiniteness of the Term "Quinapril Magnesium" ("Defendants' Opening Brief"), "quinapril magnesium" is repeatedly described in the '486 patent as "*the* magnesium salt of quinapril." '486 patent, Col. 1, ll. 7-8 and col. 2, ll. 46-47, DI 059-1 (emphasis added). As demonstrated above, Defendants' proposed construction adheres to the language of the specification. Given the use of the definite article with respect to "magnesium salt of quinapril" in the specification, a person of ordinary skill in the art faced with the '486 patent would understand "quinapril magnesium," whatever it is, refers to a single compound having a specified structure and properties. Rebuttal Expert Declaration of Dr. Zaworotko at ¶ 7 ("Exh. E"); *see In Girafa.com, Inc. v. IAC Search & Media, Inc*., No. 07–787–SLR, 2009 WL 3074712, at *2 (D. Del. Sept. 25, 2009) (holding that use of the article "the" preceding "home page" implies that any objective definition must identify just one page). Apotex's omission of the definite article from its proposed construction changes the meaning of the term so as potentially to allow for more than one compound to come within the ambit of "quinapril magnesium."

Apotex's intent in omission of the definite article from its proposed construction is revealed by its expert Dr. Moreton's discussion of "quinapril magnesium." Dr. Moreton refers to "quinapril magnesium" as "a" magnesium salt of quinapril that "can" have the structure provided

in his Declaration. Exhibit C to Apotex's Opening Brief, Expert Declaration of Dr. Moreton, DI 063-9 ("Moreton Decl.") at ¶¶ 11-12. Thus, Dr. Moreton appears to assert that "quinapril magnesium" can encompass more than one compound having various structures and properties, none of which are disclosed or even contemplated by the '486 patent.

Not only does Apotex's proposed construction for "quinapril magnesium" conflict with the intrinsic evidence, it further compounds the ambiguity of the claim term by expressly providing that it includes more than one compound, none of which are described in the '486 patent or disclosed in the prior art. *Id*. at ¶¶ 7-8. Defendants' proposed construction, while not remedying the ambiguity of the term "quinapril magnesium," is at least consistent with the language of the specification. Thus, Apotex's assertion that its construction is "essentially the same" as Defendants' proposed construction is misleading and is designed to leave open for later determination the identity of "quinapril magnesium."

IV. "QUINAPRIL MAGNESIUM" IS INDEFINITE UNDER EITHER PARTIES' CONSTRUCTION

As explained in Defendants' Opening Brief and accompanying Expert Declaration, the description of "quinapril magnesium" provided in the '486 patent, which Defendants have adopted as their proposed construction, does not resolve the ambiguity of the claim term. Apotex's argument that, because the parties independently reached proposed constructions that were similar, the term "quinapril magnesium" is not insolubly ambiguous, is inapposite. On the contrary, even if the parties agree on the words used in the '486 patent to describe "quinapril magnesium," neither of the parties' proposed constructions clarifies the scope of the claim term. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008) ("Even if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.");

see also Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 655 F.3d 1364, 1373 (Fed. Cir. 2011) ("[A] construed claim can be indefinite if the construction remains insolubly ambiguous, meaning it fails to provide sufficient clarity about the bounds of the claim to one skilled in the art."); *Girafa.com,* 2009 WL 3074712, at *2 (finding that because the court could define the term was not dispositive of indefiniteness). In fact, Apotex's proposed construction muddies the waters further in expressly allowing for multiple unknown compounds to come within the ambit of "quinapril magnesium." Exh. E at ¶¶ 7-8.

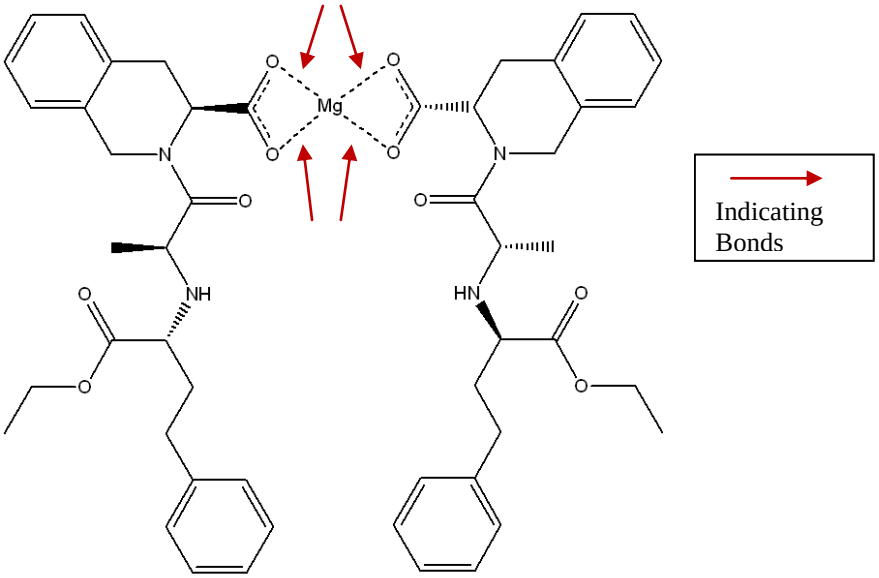
Tellingly, Apotex cites no legal authority for its position that the '486 patent's provision of a chemical formula, without more, is sufficient to render the meaning of a newly coined chemical term definite. Far from "readily identifiable," the lack of a structure or other characterization information for "quinapril magnesium" in the specification means that a person of ordinary skill in the art would have had no way of knowing whether they were performing the patented process and/or infringing the asserted claims. Moreover, although Apotex provides a possible structure for "quinapril magnesium" in its expert declaration, it provides no support in the specification or elsewhere for such a structure and omits the structure from its proposed construction. Exh. E at ¶ 8. In any case, as explained in Defendants' Opening Brief, the chemical structure suggested by Apotex is scientifically unsound and, thus, cannot be the structure of "quinapril magnesium." *Id*. at ¶ 5. Clearly, Apotex itself is uncertain of the structure of "quinapril magnesium."

V. DR. MORETON'S DECLARATION HIGHLIGHTS THE AMBIGUITY OF THE TERM "QUINAPRIL MAGNESIUM"

Far from clarifying the term "quinapril magnesium," Dr. Moreton's Declaration serves to underscore Apotex's uncertainty concerning the meaning of the term in that he allows for

"quinapril magnesium" to encompass more than one compound, a construction not contemplated by the '486 patent. Exh. E at ¶¶ 7-8.

Dr. Moreton states that "quinapril magnesium" is a "complex" and "a" magnesium salt that "can" have the following structure:



Moreton Decl. at ¶¶ 11-12. However, there is no support for Dr. Moreton's opinion in the patent or the prior art. Exh. E at ¶¶ 6-8. In fact, the '486 patent fails to even use the word "complex" and, as discussed above, does not assert or suggest that "quinapril magnesium" is an umbrella term that includes a number of different compounds having different structures and properties. *Id.* at ¶ 6. Furthermore, nothing in the prior art supports Dr. Moreton's opinion. *Id.* The fact that it was known that magnesium salts can form complexes is inapposite because there is no evidence in the '486 patent or the prior art that "quinapril magnesium" is a magnesium salt or that it forms a complex. *Id.* Regardless, the above structure Dr. Moreton proposes as one possibility for "quinapril magnesium" is scientifically unsound because, *inter alia,* it provides four, and not the required six, bonds for magnesium. *Id*. at ¶ 4.

Even if there were support for Dr. Moreton's opinion that "quinapril magnesium" is a "complex" and "a" magnesium salt of quinapril having the possible structure outlined above, such opinion fails to resolve the ambiguity of the claim term "quinapril magnesium." First, asserting that "quinapril magnesium" is a "complex" provides no information about the structure of that "complex." Exh. E at ¶ 6. Second, knowledge that "quinapril magnesium" is "a" magnesium salt of quinapril is similarly uninformative concerning the structure of that compound or compounds. Finally, stating that "quinapril magnesium" "can" have a particular structure, merely underlines the fact that, under Plaintiffs' construction, other chemical structures are possible. *Id.* at ¶¶ 7-8. Thus, Dr. Moreton's opinion concerning the meaning of "quinapril magnesium" amounts to a reiteration of its ambiguity because he implies that "quinapril magnesium" is any number of complexes or salts, having numerous chemical structures and concomitant properties, none of which are identified in the '486 patent or the prior art.

Furthermore, Dr. Moreton's use of the word "complex" to describe quinapril magnesium appears to leave open the possibility that "quinapril magnesium" may involve an association of more than two quinapril molecules and one magnesium ion. *Id.* at ¶ 7. This approach fits with Apotex's conclusion in its Technical Report that Defendants' product contains structurally undefined "quinapril-magnesium complexes" rather than "quinapril magnesium." Exh. F to Defendants' Opening Claim Construction Brief on Indefiniteness, DI 061-2 at 1 and 40-41. Thus, Apotex's approach to construction of the term "quinapril magnesium" is clearly calculated to support its infringement position rather than define the claim term in a manner consistent with the language in the patent.

VI. DEFINITION OF A PERSON OF ORDINARY SKILL IN THE ART

The parties have put forward their respective definitions of a person of ordinary skill in the art because a tenet of claim construction is that a "court construing a patent claim seeks to

accord a claim the meaning it would have to a person of ordinary skill in the art at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Apotex's definition of a person of ordinary skill in the art omits synthetic and analytical chemists and allows for a very low level of education, including an undergraduate degree. Defendants disagree with Apotex in terms of the type and level of skill attributed to a person of ordinary skill in the art with respect to the '486 patent.

The '486 patent is directed to processes involving a *reaction* between quinapril or an acid addition salt thereof and an alkaline magnesium compound to make a purportedly novel compound, "quinapril magnesium," and not merely a novel formulation of previously identified ingredients. Exh. E at ¶ 3. Moreover, the '486 patent provides very little detail as to how to perform the aforementioned processes to achieve "quinapril magnesium" or how to detect or quantify "quinapril magnesium" in a composition. *Id.* Thus, the '486 patent is aimed at individuals having synthetic and analytical skills necessary to determine the experimental conditions necessary for the reactions described therein and to analyze the resulting compositions to confirm the presence of "quinapril magnesium." *Id.* Accordingly, Defendants' definition of a person of ordinary skill in the art encompasses an individual who has skill and experience in chemical synthesis and/or analysis. In addition, given the dearth of information in the '486 patent concerning the reaction conditions needed to produce "quinapril magnesium" or the method to be used detect and quantify "quinapril magnesium," Defendants also assert that the '486 patent is aimed at an individual with a high level of education, such as a Masters Degree or a Ph.D. with a number of years experience. *Id.*

VII. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court adopt Defendants' proposed construction of the term "quinapril magnesium" and hold that the term "quinapril magnesium" as recited in the asserted claims of the '486 patent is indefinite.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 14th day of January, 2013, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record or pro se parties identified on the attached service list in the manner specified either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

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