UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 0:12-cv-60704-SEITZ/SIMONTON (consolidated)

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

CASE NO. 0:12-cv-60704-PAS

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

CASE NO. 0:12-cv-60705-PAS

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

CASE NO. 0:12-cv-60708-PAS

JOINT CLAIM CONSTRUCTION STATEMENT

Plaintiffs Apotex Inc. and Apotex Corp. (collectively "Plaintiffs" or "Apotex") and Defendants Lupin Ltd., Lupin Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Pfizer, Inc. and Greenstone, LLC (collectively, "Defendants") hereby provide their Joint Claim Construction Statement relating to U.S. Patent No. 6,531,486 ("the '486 patent") in accordance with the Order Setting Trial Date, Pretrial Deadlines and Referral to Magistrate ("Pretrial Scheduling Order") (D.E. 41) entered in the above-captioned case.[1]

I. BACKGROUND

Apotex asserts that each of the Defendants have infringed certain claims of the '486 patent by manufacturing solid pharmaceutical dosage forms (i.e. tablets) comprising quinapril magnesium. Defendants allege, among other things, that the asserted patent claims are invalid and/or not infringed.

On November 9, 2012, the parties exchanged a list of proposed terms for construction, and exchanged proposed constructions for those terms on November 30, 2012. During a "meet and confer" held on December 5, 2012, the parties reached agreement on the construction of a number of terms, as identified in Section II.A below. Having narrowed the remaining claim terms to be construed, the parties filed the following briefs in accordance with the schedule identified in the Pretrial Scheduling Order:

[1] The above-captioned cases have been consolidated for pre-trial purposes under Case No. 12-60704-CIV-SEITZ/SIMONTON. Accordingly all docket entries cited correspond to this case.

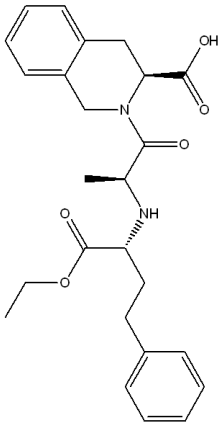
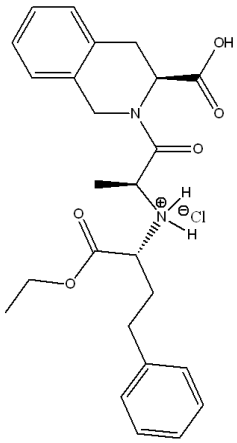
Opening Briefing	Responsive Briefing
Plaintiffs' Opening Claim Construction Brief (D.E. 63), with Exs. A-H, including Ex. C, Declaration of R.C. Moreton, Ph.D.	Plaintiffs' Responsive Brief to Defendants' Joint Claim Construction Brief (D.E. 77)
Defendants' Joint Opening Claim Construction Brief (D.E. 62), with Exs. A-N	Plaintiffs' Brief in Response to Mylan and Lupin Defendants' Indefiniteness Brief (D.E. 78), with Exs. I-NN, including Ex. KK, Declaration of M.J. Cima, Ph.D.
Mylan and Lupin Defendants' Opening Claim Construction Brief on Indefiniteness (D.E. 58), with Exs. A-G, including Ex. D, Declaration of M. Zaworotko, Ph.D.	Defendants' Joint Responsive Claim Construction Brief (D.E. 76), with Exs. O-T
	Mylan and Lupin Defendants' Responsive Claim Construction Brief On Indefiniteness (D.E. 75), with Ex. A-F

Claim construction discovery is scheduled to close on January 31, 2013. The parties are working together to take depositions of the three identified expert witnesses (Apotex's Drs. Cima and Moreton; Lupin and Mylan Defendants' Dr. Zaworotko) by this time. Having complied with the Court's order, the parties now submit this Joint Claim Construction Statement.

II. CONSTRUCTION OF TERMS

A. Construction of Terms on Which the Parties Agree

During a "meet and confer" held on December 5, 2012, the parties reached agreement on the construction of the following terms:

CLAIM	CLAIM TERM	CONSTRUCTION
1	"solid pharmaceutical composition"	finished solid dosage form capable of being administered as a drug product
1	"quinapril magnesium"	the magnesium salt of quinapril having the chemical formula $Mg(C_{25}H_{29}N_2O_5)_2$
1	"quinapril or an acid addition salt thereof"	chemical compound having the chemical formula $C_{25}H_{30}N_2O_5$ and the chemical structure shown below, or an acid addition salt thereof 
1	"alkaline magnesium compound"	magnesium compound that, when added to water, results in a pH greater than about 7
5-8	Whether the order of the steps is a limitation	the claimed method requires the steps to be performed in the order set forth in the claims
11	"quinapril hydrochloride"	hydrochloric acid addition salt of quinapril having the chemical formula $C_{25}H_{30}N_2O_5 \cdot HCl$ and the chemical structure shown below 

B. Each Party's Proposed Constructions of Disputed Claim Terms

The parties identify the following disputed claim terms and propose the following constructions for those terms:

CLAIM	CLAIM TERM	PLAINTIFFS' PROPOSED CONSTRUCTION	DEFENDANTS' PROPOSED CONSTRUCTION
1	"quinapril magnesium"	Parties' agreed upon construction	Pfizer Defs. – parties' agreed upon construction Mylan and Lupin Defs. – indefinite despite parties' agreed upon 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
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
6-8	"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
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

16	"at least about 80%"	approximately 80% or more	more than 75%

C. Relative Priority of Disputed Terms

In view of the issues presented by each side in this case, the parties agree that they would like to address the disputed claim terms in the following order at the *Markman* hearing. This order reflects the relative priority of the terms, leading with the most contentious and/or dispositive terms and ending with terms that are less contentious and/or likely to lesser effects on resolving the issues between the parties.

PRIORITY	CLAIM TERM
1	"quinapril magnesium"
2	"reacting ... so as to convert ... to quinapril magnesium"
3	"in the presence of a solvent"
4	"at least about 80%"
5	"wet mass"
6	"dry mass" and "dried mass"

Accordingly, the parties suggest that the Claim Construction Hearing scheduled for March 8, 2013 be conducted in the order set forth above.

D. Anticipated Length of Time Necessary for Tutorial and Claim Construction Hearing

Pursuant to the Scheduling Order Entered in this case (D.E. 41), and as requested during the Scheduling Conference held on September 6, 2012, Apotex intends to provide the Court with a tutorial regarding the science and technology behind the inventions of the '486 patent. Defendants intend to provide a tutorial regarding the science and technology behind the

inventions of the '486 patent as well as overviews of the methodology that each Defendant uses to make its quinapril products. The parties anticipate this hearing lasting approximately four (4) hours, with Plaintiffs and Defendants each presenting for two (2) hours. Depending on the Court's preference, Apotex is willing to present the tutorial through its attorneys or through Dr. Michael J. Cima, Ph.D. Defendants are likewise willing to present their tutorial through counsel or through experts.

For the *Markman* Hearing currently scheduled for March 8, 2013, Plaintiffs s anticipate that approximately six (6) hours, with Plaintiffs and Defendants each presenting for three (3) hours, will be sufficient to complete oral arguments. Defendants anticipate that the *Markman* hearing can be completed in less than four hours. While their experts may be in attendance at this hearing, the parties expect to present their arguments through attorneys only, unless the Court desires otherwise.

E. Identification of Witnesses

The parties identify the witnesses to be present at the tutorial as follows:

Plaintiffs' Witnesses: Dr. Michael J. Cima, unless the Court prefers attorney presentations.

Defendants' Witnesses: Dr. Michael Zaworotko, Dr. Michael Crowley, Dr. William Stagner, Dr. Paul Chirik and/or Dr. Christopher Rhodes. Defendants' identification of tutorial witnesses is subject to change depending on their availability. At the time of this submission, Mylan was notified that its expert Dr. Christopher Rhodes is unavailable for the tutorial in this case due to a family medical matter. In light of Dr. Rhodes' predicament, Mylan expects to provide an alternative expert for use in the tutorial and will disclose such expert in advance thereof.

The parties identify the witnesses to be called at the March 8, 2013 *Markman* hearing:

Plaintiffs' Witnesses: None, unless requested by the Court.

Defendants' Witnesses: None, unless requested by the Court.

DATED: January 22, 2013

Respectfully submitted,

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