

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

)	
)	
UNITED THERAPEUTICS)	
CORPORATION,)	
)	Civil Action No. 3:14-cv-5499 (PGS)(LHG)
Plaintiffs,)	
)	
v.)	
)	
SANDOZ, INC.)	
)	
Defendant.)	
)	

**UNITED THERAPEUTICS CORP.’S AND SANDOZ INC.’S
JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT**

Pursuant to Local Patent Rule 4.3 and the Scheduling Order [Dkt. No. 22] as amended by the Court on April 24, 2015 [Dkt No. 31], Plaintiff United Therapeutics Corporation (“UTC”) and Defendant Sandoz, Inc. (“Sandoz”) jointly file this Joint Claim Construction and Prehearing Statement, and state as follows:

I. AGREED CLAIM CONSTRUCTIONS (LOCAL PATENT RULE 4.3(A), SCHEDULING ORDER ¶ 11(B))

The parties reached an agreement on the construction of the following terms in the asserted claims:

1. “pharmaceutically acceptable salt” (claims 1 and 9) should be construed as “[a] salt which is useful in preparing a pharmaceutical composition that is generally safe, non-toxic and neither biologically nor otherwise undesirable and includes being useful for veterinary use as well as human pharmaceutical use, and which possesses the desired pharmacological activity.”
2. “the product of step (h)” (claims 1 and 9) should be construed as “the product of step (b).”

II. DISPUTED CLAIM CONSTRUCTIONS (LOCAL PATENT RULE 4.3(B), SCHEDULING ORDER ¶ 11(C))

The parties propose the following constructions for each disputed claim term contained in the asserted claims of the identified patents-in-suit, and make the following identifications of evidence in support of their respective constructions. Each party reserves the right to rely upon evidence identified by the other party.

1. “product” (claims 1 and 9)

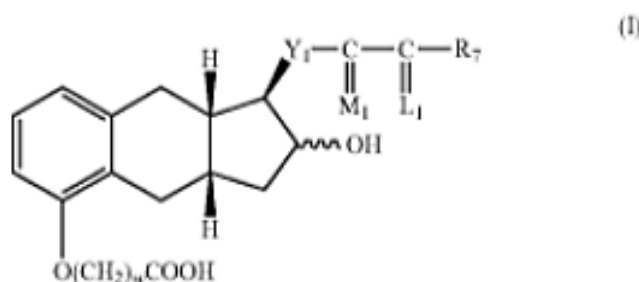
Plaintiff’s Construction	Defendant’s Construction
<p>Plain and ordinary meaning.</p> <p>To the extent the Court determines that this term requires construction, UTC proposes the following:</p> <p>“a substance resulting from a chemical reaction”</p>	<p>A chemical composition.</p>

Plaintiff’s Evidence	Defendant’s Evidence
<ul style="list-style-type: none"> U.S. Patent No. 8,497,393 claims 1-22; col. 7:16-20; col. 7:41-45; col. 17:37-40. UTC-Sand-Rem01170057, UTC-Sand-Rem01170059, UTC-Sand-Rem01170064-66. Amendment and Request for Reconsideration dated February 8, 2013. SDZ5499 0004846-56. Amendments and Reply dated June 5, 2013. SDZ5499 0004877-90. Notice of Allowance dated June 12, 2013. SDZ5499 0004894-99. Webster’s New Collegiate Dictionary (1981), Springfield, MA: G. & C. Merriam Co., p. 911. UTC_REM_II_000001787. Brown, et.al., CHEMISTRY: THE CENTRAL SCIENCE, (9th ed. 2003), p. 	<ul style="list-style-type: none"> U.S. Patent No. 8,497,393, SDZ5499 0004746-60, including but not limited to, claims 1-22; col. 7:14-15; col. 7:16-20; col. 7:41-45; col. 9:19-17:40. ’393 patent prosecution history, SDZ5499 0004761-932, including but not limited to 01/03/2013 Office Action at p. 2, SDZ 5499 0004835; Amendment and Request for Reconsideration dated February 8, 2013. SDZ54990004846-56; 5/5/2013 Office Action at pp. 2-3, SDZ5499 0004867-68; Amendments and Reply dated June 5, 2013. SDZ5499 0004877-90; Notice of Allowance dated June 12, 2013. SDZ5499 0004894-99. WEBSTER’S NEW COLLEGIATE DICTIONARY (1981), Springfield, MA: G. & C. Merriam Co., p. 911. UTC_REM_II_000001787.

Plaintiff's Evidence	Defendant's Evidence
<p>G-10. UTC_REM_II_000001762.</p> <ul style="list-style-type: none"> • Suchocki, et. al., CONCEPTUAL CHEMISTRY, (2001), p. G-6. UTC_REM_II_000001769. • Zumdahl, CHEMISTRY (1986), p. A36. UTC_REM_II_000001766. • Williams, et.al., <i>Asymmetric, Stereocontrolled Total Synthesis of Paraherquamide A</i>, J. Am. Chem. Soc. 2003, 125, 12172-178. UTC_REM_II_000001741-47. • Williams, et.al., <i>Stereocontrolled Total Synthesis of (+)-Paraherquamide B</i>, J. Am. Chem. Soc. 1996, 118, 557-579. UTC_REM_II_000001718-40. • Williams, et.al., <i>Synthetic Studies on Et-743. Assembly of the Pentacyclic Core and a Formal Total Synthesis</i>, J. Org. Chem. 73.24 (2008): 9594-9600. UTC_REM_II_000001748-54. • Heathcock, et.al., <i>Further Studies of the Daphniphyllum Alkaloid Polycyclization Cascade</i>, J. Org. Chem. 66 (2001): 450-454. UTC_REM_II_000001670-89. • Heathcock, et.al., <i>Daphniphyllum Alkaloids. 12. A Proposed Biosynthesis of the Pentacyclic Skeleton. Proto-Daphniphylline</i>, J. Org. Chem. 57 (1992): 2554-2566. UTC_REM_II_000001657-69. • Buchwald, et.al., <i>An Air-Stable Catalyst System for the Conversion of Esters to Alcohols</i>, J. Org. Chem. 57 (1992): 3753-3755. UTC_REM_II_000001648-50. • Buchwald, et.al., <i>A Practical Titanium-Catalyzed Synthesis of Bicyclic Cyclopentenones and Allylic Amines</i>, J. Org. Chem. 61 (1996): 2713-2718. UTC_REM_II_000001651-56. 	<ul style="list-style-type: none"> • Brown et al., CHEMISTRY: THE CENTRAL SCIENCE, (9th ed. 2003), p. G-10. UTC_REM_II_000001762. • Suchocki et al., CONCEPTUAL CHEMISTRY, (2001), p. G-6. UTC_REM_II_000001769. • Zumdahl, CHEMISTRY (1986), p. A36. UTC_REM_II_000001766. • Williams et al., <i>Asymmetric, Stereocontrolled Total Synthesis of Paraherquamide A</i>, J. AM. CHEM. SOC. 2003, 125, 12172-178. UTC_REM_II_000001741-47. • Williams et al., <i>Stereocontrolled Total Synthesis of (+)-Paraherquamide B</i>, J. AM. CHEM. SOC. 1996, 118, 557-579. UTC_REM_II_000001718-40. • Williams et al., <i>Synthetic Studies on Et-743. Assembly of the Pentacyclic Core and a Formal Total Synthesis</i>, J. ORG. CHEM. 73.24 (2008): 9594-9600. UTC_REM_II_000001748-54. • Heathcock et al., <i>Further Studies of the Daphniphyllum Alkaloid Polycyclization Cascade</i>, J. ORG. CHEM. 66 (2001): 450-454. UTC_REM_II_000001670-89. • Heathcock et al., <i>Daphniphyllum Alkaloids. 12. A Proposed Biosynthesis of the Pentacyclic Skeleton. Proto-Daphniphylline</i>, J. ORG. CHEM. 57 (1992): 2554-2566. UTC_REM_II_000001657-69. • Buchwald et al., <i>An Air-Stable Catalyst System for the Conversion of Esters to Alcohols</i>, J. ORG. CHEM. 57 (1992): 3753-3755. UTC_REM_II_000001648-50. • Buchwald et al., <i>A Practical Titanium-</i>

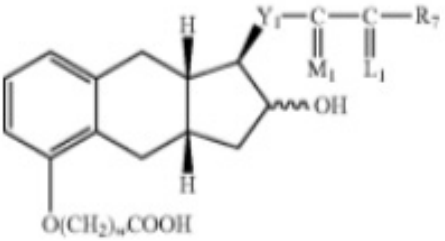
Plaintiff's Evidence	Defendant's Evidence
<ul style="list-style-type: none"> All intrinsic and extrinsic evidence cited for this term by Sandoz. Dr. Williams will offer testimony that a person of ordinary skill in the art reading the term "product" in the context of the '393 patent would understand it is used according to its plain and ordinary meaning or "a substance resulting from a chemical reaction." Dr. Williams will also explain why Sandoz's construction of this term is not consistent with the understanding of a person of ordinary skill in the art and will rebut the testimony of Dr. Heathcock regarding this term. 	<p><i>Catalyzed Synthesis of Bicyclic Cyclopentenones and Allylic Amines</i>, J. ORG. CHEM. 61 (1996): 2713-2718. UTC_REM_II_000001651-56.</p> <ul style="list-style-type: none"> Dr. Clayton Heathcock will testify that Sandoz's proposed claim construction for "product" is consistent with the way this term is used in the '393 patent and is consistent with the ordinary and customary meaning, as understood by a person of ordinary skill in the art around 2007. Dr. Heathcock will also rebut the testimony of Dr. Williams regarding this term.

2. "A product comprising a compound of formula I:



or a pharmaceutically acceptable salt thereof" (claim 1)

Plaintiff's Construction	Defendant's Construction
<p>Plain and ordinary meaning.</p> <p>To the extent the Court determines that this term requires construction, UTC proposes the following:</p> <p>"a substance resulting from a chemical reaction constituted primarily of formula I:</p>	<p>A chemical composition that includes, but is not limited to, a compound of formula I, or a pharmaceutically acceptable salt thereof, and that may also include other non-mentioned substances (including impurities), additives, or carriers, without limitation as to the types or relative amounts thereof.</p>

Plaintiff's Construction	Defendant's Construction
 <p>(i)</p> <p>or a pharmaceutically acceptable salt thereof”</p>	

Plaintiff's Evidence	Defendant's Evidence
<ul style="list-style-type: none"> • U.S. Patent No. 8,497,393 claims 1-22; col. 4:22-26; col. 4:60-col. 5:36; col. 7:16-20; col. 7:41-45; col. 17:37-40. UTC-Sand-Rem01170057-59, UTC-Sand-Rem01170064-66; Abstract; col. 5:38-49; col. 7:14-15; col. 8:66-67; col. 14:50-17:36 at UTC_REM_II_000003354; UTC_REM_II_000003358; UTC_REM_II_000003359; UTC_REM_II_000003362-64; UTC_REM_II_000003365. • Amendment and Request for Reconsideration dated February 8, 2013. SDZ5499 0004846-56. • Amendments and Reply dated June 5, 2013. SDZ5499 0004877-90. • Notice of Allowance dated June 12, 2013. SDZ5499 0004894-99. • '305 Patent File History, Amendments and Reply dated July 7, 2011, at UTC_REM_II_000002032. • Webster's New Collegiate Dictionary (1981), Springfield, MA: G. & C. Merriam Co., p. 911. UTC_REM_II_000001787. • Brown, et.al., CHEMISTRY: THE CENTRAL SCIENCE, (9th ed. 2003), p. G-10. UTC_REM_II_000001762. • Suchocki, et. al., CONCEPTUAL 	<ul style="list-style-type: none"> • U.S. Patent No. 8,497,393, SDZ5499 0004746-60, including but not limited to, claims 1-22; col. 4:22-26; col. 4:60- 5:36; col. 7:14-15; col. 7:16-20; col. 7:41-45; col. 9:20-23; col. 11:42-13:17; col. 17:26-32; col. 17:37-40. • '393 patent prosecution history, SDZ5499 0004761-932, including but not limited to Amendment and Request for Reconsideration dated February 8, 2013. SDZ54990004846-56; Amendments and Reply dated June 5, 2013. SDZ5499 0004877-90; Notice of Allowance dated June 12, 2013. SDZ5499 0004894-99. • WEBSTER'S NEW COLLEGIATE DICTIONARY (1981), Springfield, MA: G. & C. Merriam Co., p. 911. UTC_REM_II_000001787. • Brown et al., CHEMISTRY: THE CENTRAL SCIENCE, (9th ed. 2003), p. G-10. UTC_REM_II_000001762. • Suchocki et al., CONCEPTUAL CHEMISTRY, (2001), p. G-6. UTC_REM_II_000001769. • Zumdahl, CHEMISTRY (1986), p. A36. UTC_REM_II_000001766. • Williams et al., <i>Asymmetric, Stereocontrolled Total Synthesis of</i>

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