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*Attorneys for Defendant  
Novartis Pharmaceuticals Corporation*

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION**

THE REGENTS OF THE UNIVERSITY OF  
MICHIGAN,  
and  
THE UNIVERSITY OF SOUTH FLORIDA  
BOARD OF TRUSTEES,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Defendant.

Case No. 3:22-cv-04913-AMO

**JOINT CLAIM CONSTRUCTION &  
PREHEARING STATEMENT**

[Patent L.R. 4-3]

Plaintiffs The Regents of the University of Michigan and The University of South Florida Board of Trustees (collectively, “Plaintiffs”) and Defendant Novartis Pharmaceuticals Corporation (“Defendant”) jointly submit this Joint Claim Construction and Prehearing Statement pursuant to Patent Local Rule 4-3 and the Joint Case Management Statement (Dkt. 69). The Parties have met and conferred as required.

**A. Patent L.R. 4-3(a): Proposed Construction of Each Agreed Term**

The parties’ agreed constructions are provided below.<sup>1</sup>

| Agreed Upon Terms                                                                                                            | Proposed Construction                                                                                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| “supramolecular synthon”                                                                                                     | The sum of the components of a multiple-component non-covalent interaction, wherein the non-covalent interaction contributes to the formation of a discrete supramolecular entity or polymeric structure, wherein each component is a chemical functionality |
| “carbonyl”                                                                                                                   | -C(=O)- (for clarity, “carbonyl” does not refer to the -C(=O)- portion of another functional group such as carboxylic acid or carboxamide)                                                                                                                   |
| “wherein the supramolecular synthons are non-covalently bonded to one another by non-covalent bonding to a solvent molecule” | Plain and ordinary meaning, which is wherein one or more solvent molecules are non-covalently bonded to two or more supramolecular synthons, linking the supramolecular synthons to one another                                                              |

**B. Patent L.R. 4-3(b): Proposed Construction of Each Disputed Term**

The parties’ proposed constructions and supporting evidence for the disputed terms are provided in Exhibit A. The parties reserve the rights to cite additional rebuttal intrinsic evidence in response to arguments raised by the opposing party during claim construction

<sup>1</sup> For clarity, while the parties agree that the terms “API homosynthons” and “heterosynthon dimer” are formed by “complementary” chemical functionalities, the parties dispute the proper construction of the claim term “compl[e]mentary.” See Exhibit A. Defendant believes that the Court’s construction of said “compl[e]mentary” chemical functionalities will resolve the disputes between the parties regarding the constructions of the terms “API homosynthons” and “heterosynthon dimer” listed in Exhibit A.

briefing. For each disputed term, the parties also reserve the rights to cite intrinsic or extrinsic evidence cited by the opposing party for that term in Exhibit A.

**C. Patent L.R. 4-3(c): Identification of Significant and Case or Claim Dispositive Terms**

Plaintiffs' Statements: Plaintiffs do not believe that construction of any of the disputed terms will be case or claim dispositive.

Defendant's Statements: Defendant believes that constructions of the disputed terms "co-crystal," "compl[e]mentary [chemical functionalities]" / "compl[e]mentary,"<sup>2</sup> "permits formation of," "active pharmaceutical ingredient (API)" / "the API," "co-former" / "the co-former" / "said co-former," "a second chemical functionality" / "the second chemical functionality," and "carboxamide" may be case dispositive if Defendant's proposed construction is adopted or if the Court holds one or more of these terms is indefinite.

**D. Patent L.R. 4-3(d): Anticipated Time for Claim Construction Hearing**

The parties anticipate that they will require at least (3) hours for the claim construction hearing.

**E. Patent L.R. 4-3(e): Witnesses at Claim Construction Hearing**

Neither party believes that live expert testimony is required at the *Markman* hearing.

**F. Patent L.R. 4-3(f): Requested Factual Findings**

Neither party requests any factual findings from the Court related to claim construction other than those submitted with any expert declaration that may be served by the parties in accordance with Patent Local Rule 4-3.

Dated: June 6, 2023

Respectfully Submitted,

FISH & RICHARDSON P.C.

By: /s/ John M. Farrell

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<sup>2</sup> The parties identified alternative terms for construction: "compl[e]mentary [chemical functionalities]" (identified by Defendant) or "compl[e]mentary" (identified by Plaintiffs). These terms are separately listed in Exhibit A.

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SOUTH FLORIDA BOARD OF TRUSTEES**

Dated: June 6, 2023

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**ATTORNEYS FOR DEFENDANT  
NOVARTIS PHARMACEUTICALS  
CORPORATION**

# EXHIBIT A

Exhibit A

| Claim Term   | Plaintiff's Proposed Construction and Support                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Novartis's Proposed Construction and Support                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| "co-crystal" | <p>A multiple-component, single crystalline phase, having a fixed stoichiometry of its component compounds</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 1:44-67; 3:8-28; 4:50-5:13; 5:33-37, 5:48-7:15; 7:19-41; 8:32-62; 9:10-26; 10:40-50; 11:39-23:59.</p> <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on July 27, 2006; Amendment and Response to Office Action made on August 3, 2007 and accompanying Declaration of Michael J. Zaworotko, Nair Rodriguez-Hornedo, and Brian Moulton and related exhibits; Amendment and Response to Office Action made on March 5, 2010; Amendment and Response to Office Action made on October 22, 2010; Amendment and Response to Office Action made on January 14, 2014; Amendment and Response to Office Action made on January 15, 2015; Response to Office Action made on October 20, 2015; Amendment and Response to Office Action made on July 25, 2016.</p> <p>'344 Patent File History (UM00000019) including: Amendment and Response to Office Action made on July 10, 2014; Amendment and Response to Office Action made April 1, 2016; Appeal Brief filed August 10, 2017; Reply Brief filed February 7, 2018.</p> <p>Any intrinsic evidence relied upon by Defendant</p> <p><u>Extrinsic Evidence:</u></p> | <p>a crystalline solid containing more than one molecular component (at least one API and at least one co-former) comprising stoichiometric, non-covalent interactions between chemical functionalities of the molecular components, where the crystalline solid is not a salt (<i>i.e.</i>, a solid comprising cations and anions)</p> <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 10, col. 3, ll. 12-13, col. 5, ll. 4-11, col. 7, ll. 19-39, col. 8, ll. 47-54, col. 9, ll. 10-19, col. 11, l. 39 – col. 23, l. 59</li> <li>• '344 patent file history: <ul style="list-style-type: none"> <li>○ UM00000212-18 at 216-17 (April 11, 2014 Non-Final Office Action at 4-5)</li> <li>○ UM00000269-82 at 271-76, 278-81 (July 10, 2014 Amendment at 3-8, 10-13)</li> <li>○ UM00000372-85 at 374-76, 378-84 (October 5, 2015 Non-Final Office Action at 2-4, 6-12)</li> <li>○ UM00000393-407 at 394-99, 400-02, 404-06 (April 1, 2016 Amendment at 2-7, 8-10, 12-14)</li> </ul> </li> </ul> |

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|  | <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p> | <ul style="list-style-type: none"> <li>○ UM00000430-45 at 432-35, 437-43 (July 12, 2016 Final Office Action<sup>1</sup> at 2-5, 7-13)</li> <li>○ UM00000472-573 at 478-79, 481-82, 486-94, 496-501 (August 10, 2017 Appeal Brief at 7-8, 10-11, 15-23, 25-30)</li> <li>○ UM00000588-600 at 590-99 (December 8, 2017 Examiner's Answer at 3-12)</li> <li>○ UM00000603-609 at 604-09 (February 7, 2018 Reply Brief at 2-7)</li> <li>• '956 application file history: <ul style="list-style-type: none"> <li>○ NPC-UNIV-000000703-11 at 705-10 (March 22, 2006 Non-Final Office Action at 2-7)</li> <li>○ NPC-UNIV-000000717-29 at 718-29 (July 27, 2006 Amendment at 2-13)</li> <li>○ NPC-UNIV-000001725-35 at 1727-34 (November 15, 2006 Final Office Action at 2-9)</li> <li>○ NPC-UNIV-000001773-79 at 1774-78 (March 15, 2007 Amendment at 2-6)</li> <li>○ NPC-UNIV-000001786-88 at 1787-88 (April 24, 2007 Advisory Action at 1-2)</li> <li>○ NPC-UNIV-000001792-1800 at 1793-99 (August 3, 2007 Amendment at 2-8)</li> </ul> </li> </ul> |
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<sup>1</sup> While UM00000430-445 issued as a Non-Final Office Action, a July 21, 2016 Communication from the USPTO states that the July 12, 2016 Office Action is in fact a Final Office Action. UM00000452-54 at 454 (July 21, 2016 Communication).

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|  |  | <ul style="list-style-type: none"> <li>○ NPC-UNIV-000001826-36 at 1829-35 (August 10, 2007 Non-Final Office Action at 3-9)</li> <li>○ NPC-UNIV-000001985-92 at 1987-90 (June 24, 2010 Final Office Action at 2-5)</li> <li>○ NPC-UNIV-000002014-23 at 2015-19, 2022-23 (October 22, 2010 Amendment at 2-6, 9-10)</li> <li>○ NPC-UNIV-000003981-87 at 3983-85 (August 2, 2013 Non-Final Office Action at 2-4)</li> <li>○ NPC-UNIV-000004020-31 at 4021-30 (January 14, 2014 Amendment at 2-11)</li> <li>○ NPC-UNIV-000004070-76 at 4072-74 (July 15, 2014 Final Office Action at 2-4)</li> <li>○ NPC-UNIV-000004084-92 at 4085-91 (January 15, 2015 Amendment at 2-8)</li> <li>○ NPC-UNIV-000004103-15 at 4107-14 (June 16, 2015 Non-Final Office Action at 4-11)</li> <li>○ NPC-UNIV-000004162-76 at 4163-4174 (October 20, 2015 Response at 2-13)</li> <li>○ NPC-UNIV-000004197-212 at 4199-201, 4204-10 (February 25, 2016 Non-Final Office Action at 2-4, 7-13)</li> <li>○ NPC-UNIV-000004218-30 at 4219-28 (July 25, 2016 Amendment in Response at 2-11)</li> </ul> |
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|  |  | <ul style="list-style-type: none"> <li>• UM00000527-30 (U.S. Patent No. 3,664,858 (“Huffman”), col. 1, l. 57 – col. 2, l. 22, col. 2, ll. 50-67, col. 3, ll. 1 – col. 5, l. 47)</li> <li>• NPC-UNIV-028066993-7023 (U.S. Patent No. 6,559,293 (“Almarsson”), col. 1, ll. 15-65, col. 6, ll. 1-12, col. 14, l. 14 – col. 15, l. 20, col. 33, l. 17 – col. 34, l. 15)</li> <li>• NPC-UNIV-028067024-72 at 7038-39 (U.S. Provisional Application No. 60/356,764 at 14-15)</li> <li>• NPC-UNIV-028067073-130 at 7088-89, 7110 (U.S. Provisional Application No. 60/380,288 at 15-16, 37)</li> <li>• NPC-UNIV-028067131-90 at 7146-47 (U.S. Provisional Application No. 60/406,974 at 15-16)</li> <li>• NPC-UNIV-028066410-27 at 6413-18 (Aakeröy, <i>Crystal Engineering: Strategies and Architectures</i>, ACTA CRYST., B53, 1997, at 572-77)</li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-028066573-75 at 6575 (<i>Compendium of Chemical Terminology, IUPAC Recommendations</i>, International Union of Pure and Applied Chemistry (2nd ed., 1997) at 363)</li> <li>• NPC-UNIV-028066837-39 at 6839 (<i>Nomenclature of Inorganic Chemistry Recommendations 1990</i>, International Union of Pure and Applied Chemistry (G.J. Leigh ed., 1990) at 118)</li> </ul> |
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|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <ul style="list-style-type: none"> <li>• NPC-UNIV-028066840-905 at 6862-64, 6867 (John Olmsted <i>et al.</i>, Chemistry: The Molecular Science (1997) (2nd ed.) at 468-70, 473)</li> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul>                                                                                                                                                                                                                                        |
| “co-former” / “the co-former” / “said co-former” | <p>A co-crystal former i.e. a component compound of a co-crystal</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 3:12-5:3; 8:32-46; 9:27-65; 11:39-23:59.</p> <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on July 27, 2006; Amendment and Response to Office Action made on January 14, 2009; Amendment and Response to Office Action made on March 5, 2010; Amendment and Response to Office Action made on October 22, 2010; Amendment and Response to Office Action made on October 20, 2015; Amendment and Response to Office Action made on July 25, 2016.</p> <p>'344 Patent File History (UM00000019) including: Amendment and Response to Office Action made on April 1, 2016; Appeal Brief filed August 10, 2017; Reply Brief filed February 7, 2018.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> | <p>molecular component of the co-crystal; for clarity, the terms “co-former,” “the co-former” and “said co-former” describe the same molecular component having the same chemical formula</p> <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 10</li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul> |

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|                    | <p><u>Extrinsic Evidence:</u></p> <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant’s invalidity contentions and documents cited therein.</p> <p>Plaintiffs’ infringement contentions and documents cited therein.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                              |
| “API homosynthons” | <p>Synthons formed between identical and complementary chemical functionalities of the API</p> <p><u>Intrinsic Evidence:</u></p> <p>’344 Patent (UM00000773): Abstract; Figures 1-24; 1:44-67; 3:29-5:13; 5:21-7:15; 7:42-8:15; 8:62-64; 9:10-10:5; 10:40-50; 11:22-31; 11:39-58; 11:60- 23:59.</p> <p>’956 Application File History (UM00009710) including: Amendment and Response to Office Action made on July 24, 2006; Amendment and Response to Office Action made on August 3, 2007 and accompanying Declaration by Michael J. Zaworotko, Nair Rodriguez-Hornedo, and Brian Moulton and related exhibits; Amendment and Response to Office Action made on March 5, 2010; Amendment and Response to Office Action made on October 22, 2010; Amendment and Response to Office Action made on January 14, 2014; Amendment and</p> | <p>synthons formed between identical and complementary chemical functionalities of the API<sup>2</sup></p> <p><u>Intrinsic &amp; Extrinsic Evidence:</u></p> <p><i>See the intrinsic and extrinsic evidence identified by Novartis below for “permits formation of” and “compl[e]mentary [chemical functionalities]”</i></p> |

<sup>2</sup> Novartis understands that the only dispute between the parties with respect to the claim construction of “API homosynthons” is the proper meaning of “complementary” that appears therein. Novartis further understands that the Court’s construction of the term “compl[e]mentary [chemical functionalities]” / “compl[e]mentary” will resolve the dispute regarding the construction of “API homosynthons.”

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|                                | <p>Response to Office Action made on January 15, 2015;<br/>Response to Office Action made on October 20, 2015.</p> <p>'344 Patent File History (UM00000019) including:<br/>Amendment and Response to Office Action made on July 10, 2014; Amendment and Response to Office Action made on April 1, 2016; Appeal Brief filed August 10, 2017; Reply Brief filed February 7, 2018; Decision on Appeal filed August 6, 2019.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> <p><u>Extrinsic Evidence:</u></p> <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p> |                                                                                                                                                                                                                                                           |
| "compl[e]mentary" <sup>3</sup> | <p>Plain and ordinary meaning of complementary, which is corresponding geometry/shape and molecular recognition that allows for interaction</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 3:29-59; 4:13-33; 4:50-5:3; 5:21-7:15; 7:62-8:31; 8:62-9:9; 9:27-10:5; 11:39-23:59.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>[chemical functionalities] that, from the perspectives of geometry/shape and molecular recognition, can and do in fact interact [with one another] under certain conditions</p> <p>OR indefinite</p> <p><u>Intrinsic &amp; Extrinsic Evidence:</u></p> |

<sup>3</sup> The parties agree that the spelling of the term "complimentary" was a typographical error, and "complementary" was intended.

|                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                             |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                           | <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on August 3, 2007 and accompanying Declaration of Michael J. Zaworotko, Brian Moulton, and Nair Rodriguez-Hornedo and related exhibits; Amendment and Response to Office Action made on October 20, 2015; Amendment and Response to Office Action made on July 25, 2016.</p> <p>'344 Patent File History (UM00000019) including: Amendment and Response to Office Action made on April 1, 2016.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> <p><u>Extrinsic Evidence:</u></p> <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p> | <p><i>See the intrinsic and extrinsic evidence identified by Novartis below for "compl[e]mentary [chemical functionalities]"</i></p>                                        |
| "compl[e]mentary [chemical functionalities]" <sup>4</sup> | No additional construction necessary, beyond the construction of "compl[e]mentary" discussed above.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | [chemical functionalities] that, from the perspectives of geometry/shape and molecular recognition, can and do in fact interact [with one another] under certain conditions |

<sup>4</sup> Plaintiffs believe it is improper to construe the term "compl[e]mentary [chemical functionalities]" because it is not a claim term.

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|                       |                                                                                                                        | <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 10, col. 1, ll. 55-67, col. 3, ll. 29-34, col. 3, l. 60 – col. 4, l. 49, col. 7, ll. 13-15, col. 7, l. 42 – col. 8, l. 31, Fig. 24</li> <li>• '344 patent file history: <ul style="list-style-type: none"> <li>◦ UM00000472-573 at 478-79, 481, 486-88, 496-501 (August 10, 2017 Appeal Brief at 7-8, 10, 15-17, 25-30)</li> </ul> </li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-028066840-905 at 6862-64, 6867 (John Olmsted <i>et al.</i>, Chemistry: The Molecular Science (1997) (2nd ed.) at 468-70, 473)</li> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul> |
| “heterosynthon dimer” | <p>A synthon formed by two different, yet complementary chemical functionalities</p> <p><u>Intrinsic Evidence:</u></p> | synthon formed by two different, yet complementary chemical functionalities <sup>5</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

<sup>5</sup> Novartis understands that the only dispute between the parties with respect to the claim construction of “heterosynthon dimer” is the proper meaning of “complementary” that appears therein. Novartis further understands that the Court’s construction of the term “compl[e]mentary [chemical functionalities]” / “compl[e]mentary” will resolve the dispute regarding the construction of “heterosynthon dimer.”

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|  | <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 1:44-67; 3:29-5:13; 5:25-7:15; 7:42-8:15; 9:10-10:5; 10:40-50; 11:22-31; 11:39-58; 11:60-23:59.</p> <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on July 24, 2006; Amendment and Response to Office Action made on August 3, 2007 and accompanying Declaration of Michael J. Zaworotko, Brian Moulton, and Nair Rodriguez-Hornedo and related exhibits; Amendment and Response to Office Action made on March 5, 2010; Amendment and Response to Office Action made on October 22, 2010; Amendment and Response to Office Action made on January 14, 2014; Amendment and Response to Office Action made on January 15, 2015; Amendment and Response to Office Action made on October 20, 2015.</p> <p>'344 Patent File History (UM00000019) including: Amendment and Response to Office Action made on July 10, 2014; Amendment and Response to Office Action made on April 1, 2016; Appeal Brief filed August 10, 2017; Reply Brief filed February 7, 2018; Decision on Appeal filed August 6, 2019.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> <p><u>Extrinsic Evidence:</u></p> <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> | <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 11, col. 3, ll. 51-59, col. 4, ll. 50-55, col. 5, l. 54 – col. 6, l. 49, col. 6, ll. 52-54, col. 6, ll. 63-64, col. 7, ll. 3-4, col. 7, ll. 7-12, col. 9, ll. 57 – col. 10, l. 5, col. 13, l. 10 – col. 16, l. 54, col. 17, l. 43 – col. 18, l. 32, col. 19, l. 51 – col. 20, l. 14, col. 21, ll. 16-49, col. 22, l. 18 – col. 23, l. 59, Figs. 6C, 6D, 7C, 7D, 8C, 8D, 9B, 10B, 12, 16B, 19B, 21B, 22B, 23B</li> <li>• '344 patent file history <ul style="list-style-type: none"> <li>◦ UM00000472-573 at 481, 496-97 (August 10, 2017 Appeal Brief at 10, 25-26)</li> </ul> </li> <li>• <i>See also the intrinsic evidence identified by Novartis above for “compl[e]mentary [chemical functionalities]”</i></li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• Plaintiffs' Infringement Contentions at 20-23</li> <li>• <i>See also the extrinsic evidence identified by Novartis above for “compl[e]mentary [chemical functionalities]”</i></li> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul> |
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|                               | <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p>"permits formation of"</p> | <p>can form</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 1:44-67; 3:29-5:13; 5:21-7:15; 7:42-8:15; 8:62-64; 9:10-10:5; 10:40-50; 11:22-31; 11:39-58; 11:60- 23:59.</p> <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on July 24, 2006; Amendment and Response to Office Action made on August 3, 2007 and accompanying Declaration by Michael J. Zaworotko, Nair Rodriguez-Hornedo, and Brian Moulton and related exhibits; Amendment and Response to Office Action made on March 5, 2010; Amendment and Response to Office Action made on October 22, 2010; Amendment and Response to Office Action made on January 14, 2014; Amendment and Response to Office Action made on January 15, 2015; Response to Office Action made on October 20, 2015.</p> <p>'344 Patent File History (UM00000019) including: Amendment and Response to Office Action made on July 10, 2014; Amendment and Response to Office Action made April 1, 2016; Appeal Brief filed August 10, 2017; Reply Brief filed February 7, 2018; Decision on Appeal filed August 6, 2019.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> <p><u>Extrinsic Evidence:</u></p> | <p>can and does in fact form under certain conditions</p> <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 10, col. 1, ll. 55-67, col. 3, ll. 41-56, col. 3, l. 60 – col. 4, l. 33, col. 4, ll. 50-55, col. 5, l. 38 – col. 6, l. 30, col. 6, ll. 35-49, col. 6, l. 57 – col. 7, l. 15, col. 7, l. 42 – col. 8, l. 15, col. 9, ll. 47-62, col. 11, ll. 48-54, Figs. 4A, 5A, 6B, 7B, 8B, 10A, 14A, 15A, 16A, 17A, 18A, 19A, 20A, 21A, 22A, 23A, and 24</li> <li>• '344 patent file history: <ul style="list-style-type: none"> <li>○ UM00000472-573 at 478-79, 481, 486-88, 496-501 (August 10, 2017 Appeal Brief at 7-8, 10, 15-17, 25-30)</li> </ul> </li> <li>• '956 application file history: <ul style="list-style-type: none"> <li>○ NPC-UNIV-000001985-92 at 1987-88 (June 24, 2010 Final Office Action at 2-3)</li> <li>○ NPC-UNIV-000002014-23 at 2015-19, 2021-22 (October 22, 2010 Amendment at 2-6, 8-9)</li> <li>○ NPC-UNIV-000003981-87 at 3985 (August 2, 2013 Non-Final Office Action at 4)</li> </ul> </li> </ul> |

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|                                                             | <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p>                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>○ NPC-UNIV-000004020-31 at 4021-22, 4030 (January 14, 2014 Amendment at 2-3, 11)</li> <li>• NPC-UNIV-028069543-547 (Freemont <i>et al.</i>, <i>Cocrystal structure of an editing complex of Klenow fragment with DNA</i>, 85 PROC. NATL. ACAD. SCI. USA 8924-28 (1988))</li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul> |
| <p>"active pharmaceutical ingredient (API)" / "the API"</p> | <p>No construction necessary; plain and ordinary meaning.</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 3:12-28; 9:27-65; 10:51-11:5.</p> <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on January 14, 2009.</p> <p>'344 Patent File History (UM00000019) including: Appeal Brief filed August 10, 2017; Decision on Appeal filed August 6, 2019.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> <p><u>Extrinsic Evidence:</u></p> | <p>biologically active moiety having a therapeutic effect on a human or animal suffering from a given pathological condition, when administered in a given concentration; for clarity, the terms "active pharmaceutical ingredient (API)" and "the API" describe the same molecular component having the same chemical formula</p> <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 10, col. 9, ll. 27-34</li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as</li> </ul>                |

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|                                                                                | <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p>"a second chemical functionality" / "the second chemical functionality"</p> | <p>No construction necessary; plain and ordinary meaning.</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 1:44-67; 3:29-59; 4:13-33; 4:50-5:3; 5:21-7:15; 7:62-8:31; 8:62-9:9; 9:27-10:5; 11:39-23:59.</p> <p>'956 Application File History (UM00009710) including: Amendment and Response to Office Action made on August 3, 2007 and accompanying Declaration by Michael J. Zaworotko, Nair Rodriguez-Hornedo, and Brian Moulton and related exhibits; Amendment and Response to Office Action made on October 22, 2010; Amendment and Response to Office Action made on January 15, 2015; Amendment and Response to Office Action made on October 20, 2015.</p> <p>'344 Patent File History (UM00000019) including: Amendment and Response to Office Action made on July 10, 2014; Amendment and Response to Office Action made on April 1, 2016.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> | <p>for clarity, the terms "a second chemical functionality" and "the second chemical functionality" describe the same chemical functionality having the same chemical formula</p> <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000004305-54 ('344 patent), claim 10</li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul> |

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|               | <p><u>Extrinsic Evidence:</u></p> <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p>                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| "carboxamide" | <p>No construction necessary; plain and ordinary meaning</p> <p><u>Intrinsic Evidence:</u></p> <p>'344 Patent (UM00000773): Abstract; Figures 1-24; 6:35-49; 11:60-23:59.</p> <p>Any intrinsic evidence relied upon by Defendant.</p> <p><u>Extrinsic Evidence:</u></p> <p>Expert testimony regarding the term at issue from the perspective of one of skill in the art based on intrinsic record and extrinsic evidence.</p> <p>Any extrinsic evidence relied upon by Defendant.</p> <p>Defendant's invalidity contentions and documents cited therein.</p> <p>Plaintiffs' infringement contentions and documents cited therein.</p> | <p>-C(=O)NH<sub>2</sub></p> <p>OR indefinite</p> <p><u>Intrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>NPC-UNIV-000004305-54 ('344 patent), claims 10, 18, col. 6, ll. 35-54, col. 6, ll. 57-59, col. 6, ll. 63-64, col. 7, ll. 1-8, col. 16, l. 4 – col. 18, l. 67, col. 19, l. 50 – col. 20, l. 14, col. 20, l. 51 – col. 22, l. 54, Figs. 10A-10B, 11, 12, 14A-14B, 16A-16B, 18A-18B, 19A-19B, 20A-20B, 21A-21B</li> </ul> <p><u>Extrinsic Evidence:</u></p> <ul style="list-style-type: none"> <li>NPC-UNIV-028066711-16 at 715 (1995 IUPAC Glossary at 1326)</li> <li>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions and Document Production Pursuant to Patent L.R. 3-1 and 3-2 dated February 14, 2023 ("Plaintiffs' Infringement Contentions") at 11 (citing UM00004012 (CHEMICAL ENTITIES OF</li> </ul> |

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|  |  | <p>BIOLOGICAL INTEREST (CHEBI), <i>Carboxamide</i>, <a href="http://www.ebi.ac.uk/chebi/searchId.do?chebiId=37622">http://www.ebi.ac.uk/chebi/searchId.do?chebiId=37622</a> (last visited Feb. 6, 2023)); UM00004016 (IUPAC GOLD BOOK, <i>Carboxamide</i>, <a href="http://goldbook.iupac.org/terms/view/C00850">http://goldbook.iupac.org/terms/view/C00850</a> (last visited Feb. 6, 2023))</p> <ul style="list-style-type: none"> <li>• NPC-UNIV-000006760-63 at 763 (2001 Merck Index at 298 (entry 1788))</li> <li>• Novartis intends to offer expert testimony concerning: 1) the technical background of the '344 patent; 2) the qualifications of a person of ordinary skill in the art as of March 1, 2002 and/or March 3, 2003; and 3) the understanding of a person of ordinary skill in the art concerning the meaning of this claim term in view of the intrinsic and extrinsic evidence.</li> </ul> |
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