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Filed On Behalf Of:
Novartis Pharmaceuticals Corporation

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case IPR2017-01592[1]
Patent No. 8,410,131

PATENT OWNER'S MOTION TO EXCLUDE

[1] IPR2018-00507 has been joined to this proceeding (Paper 29, Apr. 3, 2018).

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I. INTRODUCTION

Patent Owner moves to exclude the following evidence:

a. All exhibits not cited in the Petition or Reply, *i.e.*, Exs. 1028-1038, 1040-1054, 1056-1068, 1070-1080, 1082-1084, 1086-1111 (*see* Paper 15 at 5, 7, 13, 15-16) and 1121-1126, 1128-1129, 1131-1132, 1135-1141, 1143-1146, 1148-1156, 1158 (*see* Paper 41 at 3, 5-7, 9, 11-12, 14, 16, 17, 19-20, 22-24, 27-29, 31-35, 37-39, 41-42, 45-49, 51, 53-55, 57-59, 61); the paragraphs of Dr. Pantuck's June 12, 2017 first Declaration not cited in the Petition or Reply, Ex. 1010 ¶¶ 1-18, 21-23, 25, 27-30, 66-67, 139, 148, 236-238, and 309 (*see* Paper 15 at 8-9); and the paragraphs of Dr. Pantuck's June 20, 2018 Reply Declaration not cited in the Petition or Reply, Ex. 1159 ¶¶ 1-71, 74, 76-82, 84-100, 104-109, 111-130, 147-225, 250-258, 263-269, 279-281, 288, 300-325, and 383 (*see* Paper 42 at 3).

b. The paragraphs of Dr. Pantuck's declarations not specifically identified or discussed in detail in the Petition or Reply, *i.e.*, Ex. 1010 ¶¶ 20, 24, 26, 31-65, 68-69, 71-73, 76-77, 79, 81-84, 87-88, 91-92, 94-132, 134, 136-138, 140-147, 151-157, 159-161, 164-166, 168-172, 174-176, 179-188, 190-192, 195-216, 219-222, 225-226, 228-233, 235, 244, 246-247, 280, 284, 290, 294-296, 306, and 308 (*see* Paper 15 at 3, 8-9), Ex. 1159 ¶¶ 134-146, 226-249, 326-340, 341-382 (*see* Paper 42 at 3).

c. Exhibits cited in the Petition or Reply that Petitioner failed to

demonstrate were prior art as of February 2001 and/or February 2002, *i.e.*, Exs. 1023, 1024 (*see* Paper 15 at 6-7) and 1147 (*see* Paper 41 at 44), and the paragraphs of Dr. Pantuck's declarations that rely on these exhibits, *i.e.*, Ex 1010 ¶ 63 (citing Exs. 1023 and 1024) (Paper 15 at 9-10) and Ex. 1159 ¶¶ 275, 299, 317 (citing Ex. 1147) (Paper 42 at 5). *See* Petition at 20, 59 (citing Exs. 1023 and 1024) and Reply at 18 (citing Ex. 1147).

Exhibits *not cited* in the Petition or Reply that Petitioner failed to demonstrate are prior art as of February 2001 and/or February 2002, *i.e.*, Exs. 1031, 1036, 1040, 1059-1061, 1076, 1092-1096 (*see* Paper 15 at 3-5, 6-7), 1140 and 1137 (*see* Paper 41 at 29, 33), and the paragraphs of Dr. Pantuck's declarations that rely on these exhibits, *i.e.*, Ex. 1010 ¶¶ 29 (Ex. 1031), 61-62 (Ex. 1036), 63 (Ex. 1040), 100 (Exs. 1059-1061), 110-111, (Ex. 1076), 113 (Ex. 1040), 114 (Ex. 1031), 116 (Ex. 1040), 117 (Exs. 1040, 1076), 119 (Ex. 1031), 120 (Ex. 1076), 121 (Ex. 1092), 122 (Exs. 1093-1096), 186 (Exs. 1093-1096) (*see* Paper 15 at 9-10), and Ex. 1159 ¶¶ 67 (Ex. 1031), 73 (Ex. 1140), 79 (Ex. 1031), 81 (Exs. 1040, 1092), 83 (Ex. 1040), 84-85 (Ex. 1092), 87-88, 92, 94-99, 101, and 113 (Ex. 1040), 149 (Ex. 1137), 152 (Ex. 1092), 215 (Exs. 1093-1096), 215 n.37 (Ex. 1140), 220 n.39 and 224 n.40 (Ex 1059) (*see* Paper 42 at 5).

d. Exhibits that should have been cited in the Petition as part of Petitioner's *prima facie* obviousness case, but that were not cited until the Reply,

i.e., Exs. 1039, 1055, 1069, 1081, 1085 (*see* Paper 15 at 5), and 1133, 1142, 1147, 1157, and 1160 (*see* Paper 41 at 64). *See* Reply at 10 (citing Exs. 1069, 1133, 1142, 1157), 11 (citing Exs. 1085 and 1160), 12 (citing Exs. 1039 and 1081), 18 (citing Ex. 1147), 24 (citing Ex. 1055).

Exhibits *not cited* in the Petition or Reply that should have been cited as part of Petitioner's *prima facie* obviousness case, but that were not cited until Dr. Pantuck's Reply Declaration, *i.e.*, Exs. 1136 (Paper 41 at 28), 1137 (Paper 41 at 29-30), 1138 (Paper 41 at 31), 1140 (Paper 41 at 33-34), 1145 (Paper 41 at 41), 1148 (Paper 41 at 45-46), 1149 (Paper 41 at 46-47), 1152 (Paper 41 at 51).

e. The paragraphs of Dr. Pantuck's Reply Declaration that rely on incomplete and misleading citations to the testimony of Patent Owner's expert Dr. Burris, *i.e.*, Ex. 1159 ¶¶ 110, 134, 135, 347 (citing Ex. 1126) (*see* Paper 42 at 6), 344 and 345 (citing Ex. 1130) (*see* Paper 42 at 6-7). *See* Reply at 12 (citing Ex. 1159 ¶ 110), 13 (citing Ex. 1159 ¶¶ 134-146), 23 (citing Ex. 1159 ¶¶ 341-376).

f. Dr. Pantuck's opinions concerning a "SciFinder" search, *i.e.*, Ex. 1159 ¶¶ 72-75, 185, 214, 240, 261, and 302 (*see* Paper 42 at 2). *See* Reply 8-9.

g. Unauthenticated Exs. 1011 (*see* Paper 15 at 12), 1060 (*see* Paper 15 at 3, 5) and 1147 (*see* Paper 41 at 43), and the paragraphs of Dr. Pantuck's declarations that rely on these exhibits, *i.e.*, Ex. 1010 ¶¶ 24, 95, and 99 (citing Ex. 1011), 100 (citing Ex. 1060) (*see* Paper 15 at 9-10), and Ex. 1159 ¶¶ 62 (citing Ex.

1011), 275, 299, and 317 (citing Ex. 1147) (*see* Paper 42 at 5). *See* Petition at 7 (citing Ex. 1011), Reply at 18 (citing Ex. 1147).

II. ARGUMENT

a. Materials Not Cited In The Petition Or Reply Should Be Excluded

Numerous materials submitted by the Petitioner (identified *supra* at § I.a.) are nowhere cited in its Petition or Reply. Petitioner's failure to cite this material violates 35 U.S.C. § 312(a)(3), 37 C.F.R. §§ 42.22(a)(2) and 42.104(b), and F.R.E. 402, which require that a petition or reply not only cite, but also explain the relevance of, the material submitted therewith. Such violations warrant the exclusion of the uncited material. *See SK Innovation Co., Ltd. v. Celgard, LLC*, IPR2014-00679, Paper 58 at 49 (P.T.A.B. Sep. 25, 2015) (granting motion to exclude exhibits under F.R.E. 401 and 402, because patent owner did not cite them or rely on them "with any particularity during this proceeding").

b. Paragraphs Of Expert Declarations Not Specifically Identified Or Discussed In Detail In The Petition Or Reply Should Be Excluded

Numerous paragraphs from Dr. Pantuck's declarations (identified *supra* at § I.b.) are not specifically identified or discussed in any detail in the Petition or Reply. Instead, the Petition and Reply include improper block citations to those paragraphs with barely any description of their substance. For example, Petition at 18 cites Ex. 1010 ¶¶ 94-138 (spanning 30 pages of Dr. Pantuck's first Declaration) as a "*see also*" citation without any explanation. Reply at 10 cites Ex. 1010 ¶¶ 178-

189 (spanning 8 pages of Dr. Pantuck's first Declaration) in one sentence that begins "The evidence of record shows …," without identifying that evidence. Reply at 13 cites Ex. 1159 ¶¶ 134-146 (spanning 9 pages of Dr. Pantuck's Reply Declaration) and ¶¶ 226-249 (spanning 15 pages of Dr. Pantuck's Reply Declaration) in connection with just two sentences. And Reply at 23 cites Ex. 1159 ¶¶ 131-133, 273-274, and 341-376 (collectively spanning over 20 pages of Dr. Pantuck's Reply Declaration) in connection with just one sentence and referencing only two exhibits without pin-cites.

Petitioner's failure in its Petition or Reply to adequately explain the relevance of those paragraphs, and the other paragraphs identified *supra* at § I.b., violates 35 U.S.C. § 312(a)(3), 37 C.F.R. §§ 42.22(a)(2) and 42.104(b), and F.R.E. 402, discussed above. Petitioner's failure also violates 37 C.F.R. § 42.6(a)(3), which forbids the incorporation by reference of content from one paper in another, and 37 C.F.R. § 42.24(a) and (c), which establish word limits for petitions and replies that cannot be circumvented through incorporation by reference. Such violations warrant the exclusion of the inadequately identified and discussed paragraphs of Dr. Pantuck's declarations. *See Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, IPR2013-00517, Paper 87 at 14-16 (P.T.A.B. Feb. 11, 2015) (finding that reply improperly incorporated by reference arguments from expert declaration where "[n]one of the extensive reasoning or analysis or evidence

cited in paragraphs 25 and 26 of the Branchaud Reply Declaration appears in the Reply"), *aff'd*, 821 F.3d 1359 (Fed. Cir. 2016); *Fidelity Nat'l Information Servs., Inc. v. Datatreasury Corp.*, IPR2014-00490, Paper 9 at 11 (P.T.A.B. Aug. 13, 2014) (declining to consider information found only in an expert declaration where petition cited to the declaration "in lieu of [citing] to the references themselves amount[ing] to an incorporation by reference of arguments").

c. <u>Non-Prior Art References Should Be Excluded</u>

The parties dispute whether the priority date for the '131 patent is February 19, 2001 or February 18, 2002. Regardless, Exs. 1023-1024, 1060, 1137, 1140, and 1147 and the paragraphs of Dr. Pantuck's declarations that rely upon those exhibits (identified *supra* at § I.c.) should be excluded under F.R.E. 402 as irrelevant, because Petitioner has failed to show that these exhibits are prior art as of either February 2001 or February 2002.

Ex. 1023 ("Gibbons US '239") issued from an application filed April 5, 2002. Ex. 1024 ("Dukart US '923") issued from an application filed on May 29, 2002. Gibbons US '239 and Dukart US '923 qualify as prior art to the '131 patent under pre-AIA 35 U.S.C. § 102(e) ***only if*** February 18, 2002 is the relevant priority date for the '131 patent ***and*** Gibbons US '239 and Dukart US '923 are entitled to their respective April 6, 2001 and June 1, 2001 priority dates. Petitioner, however, has done nothing to satisfy its burden of production to show that either reference is

entitled to its priority date. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1380 (Fed. Cir. 2015) (challenger bears burden of production to show that prior art patent invalidates challenged claims under § 102(e)). Petitioner thus has not shown that Exs. 1023 or 1024 are prior art as of February 2001 or February 2002.

Exs. 1060 and 1147 contain no publication date, and Petitioner has failed to show that they are prior art as of February 2001 or February 2002.

Exs. 1137 and 1140 on their face are dated after February 18, 2002 and thus are not prior art as of February 2001 or February 2002.

Additionally, if the Board determines that February 19, 2001 is the relevant priority date, Exs. 1031, 1036, 1040, 1059, 1061, 1076, and 1092-1096, and the portions of the Petition and Reply and the paragraphs of Dr. Pantuck's declarations that rely on them, should be excluded under F.R.E. 402 as irrelevant because Petitioner has failed to show that these exhibits are prior art as of February 2001.

Exs. 1031, 1059, 1061, and 1093-1096 on their face are dated after February 19, 2001 and are not prior art as of that date. Ex. 1076 indicates that it was published in 2001 but contains no publication month or day, and thus Petitioner has failed to show it is prior art as of February 2001.

Ex. 1036 ("Dukart WO '000") was filed on November 13, 2001 and claims priority to a U.S. provisional application. However, Dukart WO '000 does not

designate the U.S., and thus qualifies as prior art to the ’131 patent under pre-AIA 35 U.S.C. § 102(e) only as of its November 13, 2001 filing date. Ex. 1036 thus is not prior art as of February 2001.

Ex. 1040 (“Dukart ’446”) is a continuation of a U.S. application filed on November 13, 2001, and claims priority to a U.S. provisional application. Petitioner, however, has done nothing to satisfy its burden to show that Dukart ’446 is entitled to its provisional filing date. Ex. 1040 thus has not been shown to be prior art as of February 2001.

Ex. 1092 (“Zhu ’973”) issued from a U.S. application filed on September 18, 2001. Petitioner has done nothing to satisfy its burden to show that Zhu ’973 is entitled to claim priority to an earlier provisional date, and thus has not shown that Zhu ’973 is prior art as of February 2001.

d. Late-Identified *Prima Facie* Obviousness References Should Be Excluded

Several exhibits submitted by the Petitioner in this proceeding (identified *supra* at § I.d.) were not cited in connection with any of Petitioner’s *prima facie* obviousness grounds set forth in its June 12, 2017 Petition. Instead, Petitioner waited until over a year to cite them for the first time in its June 21, 2018 Reply. Each of these exhibits was publicly available well before June 12, 2017, and is cited by the Petitioner in connection with a basic aspect of Petitioner’s *prima facie* case, *e.g.*, Exs. 1039, 1085 (allegedly concerning preclinical testing), 1069, 1081

(allegedly concerning clinical testing), 1055, 1133, 1142 (allegedly concerning mTOR molecular biology), 1157 (allegedly concerning development of everolimus for transplant patients), 1160 (allegedly concerning the conversion of temsirolimus to rapamycin in the body).

Petitioner has not explained why it delayed citing these exhibits until its Reply. Such a prolonged and unexplained delay warrants the exclusion of the belatedly cited reply evidence. *See Intelligent Bio-Systems*, IPR2013-00517, Paper 87 at 14-16 (reply violated 37 C.F.R. §§ 42.23(b) (improper scope) and 42.6(a)(3) (improper incorporation by reference) where it cited "a number of … references" that were not included in the petition); *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00052, Paper 88 at 11-16 (P.T.A.B. May 1, 2014) (declining to consider evidence and argument relying on such evidence that exceeded the proper scope of a reply).

Petitioner's belatedly cited reply evidence also violates 35 U.S.C. § 312(a)(3) (***petition*** must identify "with particularity" the evidence that supports a petitioner's challenges) and 37 C.F.R. § 42.104(b) (***petition*** must identify specific portions of the evidence that support a petitioner's challenges; "[t]he Board may exclude or give no weight to the evidence where a party has failed to state its relevance or to identify specific portions of the evidence that support the challenge"). For this additional reason, the exhibits identified *supra* at § I.d. should

be excluded.

e. Incomplete And Misleading Citations To Dr. Burris's Testimony Should Be Excluded

Several paragraphs of Dr. Pantuck's Reply Declaration (identified *supra* at § I.e.)—as well as the Reply itself at pages 11-12—rely on incomplete and misleading citations to the testimony of Patent Owner's expert Dr. Burris. These incomplete and misleading citations should be excluded under F.R.E. 106 ("If a party introduces all or part of a writing or recorded statement, an adverse party may require the introduction, at that time, of any other part—or any other writing or recorded statement—that in fairness ought to be considered at the same time").

Alternately, Patent Owner asks that the Board in fairness under F.R.E. 106 consider the following portions of Exs. 1126 and 1130.

For Ex. 1159 ¶ 110 (citing Ex. 1126 at 97:16-20), consider Ex. 1126 at 81:8-23 (agreeing with the statement in Creaven (Ex. 2056 at 94) that "unless the toxicity from a phase I trial is prohibitive or truly unpredictable and dangerous, the new agent automatically proceeds to phase II testing"); 88:8-89:10 (explaining that temsirolimus's advancement to Phase II studies in RCC "reflected the desperate need that existed for treatments for this cancer as of 2001, and it did not reasonably suggest that temsirolimus would be therapeutically effective against advanced RCC"); and 97:1-98:1 (providing Dr. Burris's complete answer where he explained "A phase I trial simply tells you, do you have a dose that can be given with

reasonable safety to a patient? And therefore there's not a go/no-go decision on a phase I trial unless there's unpredictable, unmanageable toxicity.")

For Ex. 1159 ¶¶ 134, 135, and 347 (citing Ex. 1126 at 33:3-25, 31:1-9, and 28:17-20), consider Ex. 1126 at 24:2-25:17 (explaining how a person of ordinary skill ("POSA") would understand the standard error reported in Weckbecker, Ex. 1021); 27:10-24 (explaining that, due to the overlap in standard errors between the everolimus and control groups, "there might not be any shrinkage with everolimus alone"); 28:1-9 (explaining that there is no statistical difference in tumor volume between the Weckbecker control group and everolimus group); and 31:11-32:18 (explaining that, from the data reported in Weckbecker, a POSA would have concluded that everolimus alone was not effective).

For Ex. 1159 ¶¶ 344 and 345 (citing Ex. 1130 at 576:18-577:6), consider Ex. 1130 at 520:11-23 (explaining that everolimus, rapamycin, and temsirolimus are different compounds with different biological properties, including binding parameters, pharmacologic parameters, and half-lives); 520:24-523:7 (explaining that, although everolimus, rapamycin, and temsirolimus are mTOR inhibitors, it was not known whether their mechanisms of action were superimposable or how rapamycin would work in different cancer cells); 523:18-524:4, 524:20-526:22 (explaining the differences in AUC and binding affinities to FKBP-12 of mTOR inhibitors, which could lead to different anti-tumor activity); and 526:24-527:20,

529:19-531:4 (explaining that everolimus, rapamycin, and temsirolimus had different half-lives, which could lead to different anti-tumor activity).

f. Dr. Pantuck's Opinions Concerning A "SciFinder" Literature Search Should Be Excluded

Several paragraphs of Dr. Pantuck's Reply Declaration (identified *supra* at § I.f.) concern a "SciFinder" literature search (Ex. 1150), that Dr. Pantuck in his Reply Declaration alleges identified "rapamycin-tumor-related references." Ex. 1159 ¶ 72. At his July 27, 2018 deposition in this proceeding, however, it became abundantly clear that Dr. Pantuck did not himself conduct the "SciFinder' search, did not understand how the search was conducted, and did not even review the results of the search to verify that the results constituted "rapamycin-tumor-related references." *See* Ex. 2113 at 78:12-23, 81:1-13, 82:5-16, 83:5-8, 83:21-24, 84:11-86:1414, 87:11-88:17, 89:7-90:1, 91:14-93:13, 94:5-18, and 235:3-13.

The failure by an expert to clearly identify the specific information on which the expert allegedly relied constitutes violations of F.R.E. 702 (expert testimony must be based upon sufficient facts or data) and 703 (expert's opinion must be based on "facts or data in the case that the expert has been made aware of or personally observed"). Such violations warrant exclusion. *See, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1373-74 (Fed. Cir. 2013) (district court abused discretion in admitting expert's testimony where expert could not clearly identify the source of the data on which he relied).

g. Unauthenticated Exhibits Should Be Excluded

Petitioner alleges Exs. 1011, 1060, and 1147 were publicly available as of February 19, 2001 and/or February 18, 2002. However, none of these exhibits includes any indication that the information upon which Petitioner relies in these exhibits is authentic or was publicly available as of these dates.

Petitioner alleges that Ex. 1011 is an FDA approval letter for Rapamune®. There is no indication on the face of the letter, however, to show that it was publicly available as of February 2001 or February 2002.

Petitioner alleges that Ex. 1060 is a 2001 article published in the American Journal of Transplantation. This exhibit on its face fails to demonstrate that the information was published in this journal, or that it was publicly available as of February 2001 or February 2002.

As discussed *supra* at § II.c., Ex. 1147 on its face fails to demonstrate that the information relied upon therein by the Petitioner was publicly available as of February 2001 or February 2002.

F.R.E. 901(a) requires that, "[t]o satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Exs. 1011, 1060 and 1147 clearly do not meet this requirement with respect to the purposes for which Petitioner intends and therefore should be excluded for lack of

authentication. *See TRW Auto. U.S. LLC v. Magna Elecs. Inc.*, IPR2014-01348, Paper 25 at 10 (P.T.A.B. Jan. 15, 2016) (excluding reference where petitioner failed to demonstrate it was published as of alleged date; mere attorney argument that the reference was published on that date did not suffice).

h. Any Other Evidence Not Included In The Instituted Grounds Should Be Excluded

Patent Owner provisionally moves to exclude under F.R.E. 402, 35 U.S.C. § 312(a)(3) and 37 C.F.R. § 42.104(b) any evidence that does not appear in the instituted grounds, other than evidence used for the limited purposes of describing the state of the art or reinforcing the meaning of a prior art reference included in the instituted grounds. *See In re NuVasive, Inc.*, 841 F.3d 966, 972-973 (Fed. Cir. 2016) (Board abused its discretion by relying on portion of prior art reference first identified by petitioner in its reply, which portion did not merely describe the state of the art, but instead was the sole prior art disclosure of disputed claim elements relied upon by the Board); *Genzyme Therapeutic Prods. Ltd. P'Ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1368 (Fed. Cir. 2016) (parties should move to exclude a reference not cited in instituted grounds).

III. CONCLUSION

For the foregoing reasons, the materials identified above should be excluded.

Date: August 8, 2018

Respectfully submitted,

/s/ Nicholas N. Kallas
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Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing PATENT OWNER'S MOTION TO EXCLUDE was served on August 8, 2018 by causing it to be sent by email to counsel for Petitioner at the following email addresses:

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Dated: August 8, 2018

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