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#### UNITED STATES PATENT AND TRADEMARK OFFICE

### **BEFORE THE PATENT TRIAL AND APPEAL BOARD**

HOSPIRA, INC., Petitioner,

v.

GENENTECH, INC., Patent Owner.

Case IPR2017-00739 Patent 7,892,549

### PATENT OWNER'S PRELIMINARY RESPONSE

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## I. INTRODUCTION

The Patent Office has already decided the dispositive issue for this petition. During prosecution, the examiner determined that the challenged claims are entitled to priority to the provisional application filed on December 12, 1997, and therefore withdrew a rejection based upon the same Nabholtz reference (Ex. 1114) that Petitioner asserts in Ground 1. Neither Nabholtz nor any of the other references relied upon in this petition are prior art under that previous priority determination, and Petitioner has not presented any legitimate basis for reaching a different conclusion.

Under these circumstances, the Board should exercise its discretion to deny institution pursuant to 35 U.S.C. § 325(d). The purpose of these *inter partes* review proceedings is to allow parties to present issues not considered during the original prosecution, and it would waste administrative and party resources to institute this petition simply to address an issue that the Patent Office has already considered and decided. Nor would denial of institution under § 325(d) prejudice Petitioner, which has filed a separate petition (IPR2017-00737) challenging the same claims of U.S. Patent No. 7,892,549 ("the '549 patent") on different grounds.

Petitioner's priority challenge also fails on the merits because Petitioner has not offered proof under the correct legal standard to demonstrate that the provisional application lacks enablement and written description support for the

challenged claims. For example, the petition does not apply the *Wands* factors or even address whether a person of ordinary skill could make and use the invention without undue experimentation based upon the disclosure of the provisional application. The petition also does not present evidence as to whether the provisional application's disclosure would indicate to a person of ordinary skill whether the applicants were in possession of the claimed invention. Instead, it concludes that there is inadequate written description support simply because the provisional application contains no experimental examples involving the claimed three-drug combination—contrary to the established legal standard for written description. Because the petition on its face fails to offer sufficient proof under the correct legal standard for determining priority, Petitioner cannot carry its burden to demonstrate a reasonable likelihood of success.

The Board should deny institution.

#### **II. PROSECUTION HISTORY**

#### A. The '549 Patent

The '549 patent issued from U.S. Patent Application No. 10/356,824 ("the '824 application"), filed on February 3, 2003. (Ex. 1101 at 1.) The '824 application is a continuation of U.S. Patent Application No. 09/208,649 ("the '649 application"), filed on December 10, 1998, which later issued as U.S. Patent No.

7,846,441.<sup>1</sup> (*Id.*) The '649 application claims priority to U.S. Provisional Application No. 60/069,346 ("the provisional application"), filed December 12, 1997. (*Id.*)

The specification of the '549 patent is substantively identical to the provisional application filed on December 12, 1997. Indeed, Petitioner does not identify any new matter supposedly added to the '549 specification. The only differences between the '549 specification and the provisional application are the updated priority information (*compare* Ex. 1120 at 2, *with* Ex. 1119-1 at 7 (1:8-9)) and the correction of typographical errors (*e.g., compare* Ex. 1120 at 2 (1:12) ("the ErbB2 proto-oncogen"), *with* Ex. 1119-1 at 7 (1:14) ("ErbB2")).

The challenged claims recite a method of treatment for a particular type of breast cancer ("that overexpresses ErbB2 receptor" (claim 1), "characterized by overexpression of ErbB2 receptor" (claim 5), or "ErbB2 overexpressing" (claim 16)). (Ex. 1101 at 24.) That method of treatment involves administering a combination of three drugs: (1) an anti-ErbB2 antibody; (2) a particular class of

<sup>&</sup>lt;sup>1</sup> Hospira has filed a separate petition challenging the '441 patent (IPR2017-00731). Petitioner has also failed to demonstrate a reasonable likelihood of success for the grounds asserted in that petition for the reasons explained in Patent Owner's preliminary response in that proceeding.

chemotherapeutic agent called a "taxoid"; and (3) "a further growth inhibitory agent" (claims 1 and 16) or "a further therapeutic agent" (claim 5). (*Id.*)

#### **B.** The Examiner's Priority Determination

During prosecution, the examiner thoroughly assessed the priority of the pending claims. The examiner recognized in her initial office action that Patent Owner could claim priority back to the parent application for claims reciting a three-drug combination with an anti-ErbB2 antibody, a taxoid, and a "further growth inhibitory agent":

> Parent application 09/208,649 provides support for the combination of a[n] anti-erbB2 antibody and a taxoid, and appears to provide support for the combination of an anti-erbB2 antibody and any chemotherapeutic agent and further a [sic] another antibody that may bind to EGFR, ErbB3, ErbB4 or VEGF; or further a cytokine or a growth inhibitory agent.

(Ex. 1119-5 at 41.)<sup>2</sup> The examiner's determination that those three-drug combinations could properly claim priority to those earlier-filed applications was

<sup>&</sup>lt;sup>2</sup> The examiner's priority analysis referred both to the parent '649 application, filed December 10, 1998, and to the provisional '346 application, filed December

well-supported. For example, the provisional application states that "the present invention" is "the combined administration of an anti-ErbB2 antibody and a chemotherapeutic agent, other than an anthracycline derivative [*e.g.*, a taxoid]" and explains that further agents "such as antibodies which bind to the EGFR, ErbB3, ErbB2, or vascular endothelial factor (VEGF)," "one or more cytokines," or "a growth inhibitory agent" may be administered as part of that combination therapy. (Ex. 1120 at 37-38 (36:20-37:12).)

The pending claims at the time, however, were directed to *different* threedrug combinations that the examiner believed did "not appear to have been contemplated" by the parent application. (*Id.* at 42; *see, e.g., id.* at 21 (original claim 20: "a combination of an antibody that binds ErbB2, a taxoid and *a further chemotherapeutic agent*").) Based on her initial priority determination, the examiner rejected the pending claims as anticipated by Nabholtz (Ex. 1114), which is the same invalidity theory presented in Ground 1 here. (Paper 1 at 24-35.)

12, 1997. (*E.g.*, Ex. 1119-5 at 41 ("Parent application 09/208,649 ...."); Ex. 1119-6 at 245 ("parent application 60/069,346 (filed 12/12/1997)").) That the examiner referred to those applications interchangeably has no bearing on this petition. The applications are substantively identical, and both are before the publication of any of the references asserted in this petition.

Patent Owner then amended the pending claims to align with the three-drug combinations that the examiner acknowledged could properly claim priority to the parent application—*i.e.*, combinations with a "further growth inhibitory agent." (Ex. 1119-5 at 179.) As exemplary support for those amended claims, Patent Owner cited the parent application's discussion of combinations with growth inhibitory agents. (*Id.* ("This is supported in the '649 specification on at least page 37, lines 9-18, page 35, lines 6-14, and page 16, lines 11-24."); *see* Ex. 1121 at 20 (16:11-24), 39 (35:6-14), 41 (37:9-18).)

Patent Owner also continued to pursue claims relating to another three-drug combination (*i.e.*, original claim 32: "an antibody that binds ErbB2, a taxoid and carboplatin"). (Ex. 1119-5 at 179.) Patent Owner identified the following portions from the parent application as supporting that claim:

- Page 5, lines 4-5 referring to "chemotherapeutic regimens" (emphasis added);

- Page 5, lines 14-17 stating that "treatment with anti-ErbB2 antibodies markedly enhances the clinical benefit of the use of *chemotherapeutic agents in general*" (emphasis added);

- Page 37, line 2 which refers to "dosing schedules for such chemotherapeutic agents" (emphasis added),

"such chemotherapeutic agents" being other than an anthracycline derivative (page 36, lines 26-27) and including carboplatin and taxoids (page 16, lines 1-10)....

Support for the combination of anti-ErbB2 antibody, taxoid, and carboplatin, can be found elsewhere in the '649 disclosure. For example, the specification provides support for combining "*more than one active compound*," (page 35, line 6).

(Id. at 180.)

On September 11, 2007, the examiner issued a further office action in which she determined that the pending claims lacked priority because she believed that they still differed in scope from the disclosure of the parent applications. (*Id.* at 293 ("[T]hese claims are drawn to methods of treating human patients with breast cancer that *expresses* ErbB2 receptor, whereas the disclosures of the parent applications teach the treatment of breast cancer that *overexpresses* ErbB2 receptor." (emphasis added)).) The examiner also determined that claim 32 reciting a three-drug combination with carboplatin was not supported by those earlier applications. (*Id.*)

On February 8, 2008, Patent Owner submitted a response in which it amended the claims to refer to cancer that *overexpresses* ErbB2 and, without

acquiescing in the examiner's rejection, cancelled several pending claims, including claim 32 reciting the three-drug combination with carboplatin. (*Id.* at 306-07.) In that same response, Patent Owner amended pending claim 38 to refer to a "further therapeutic agent." As support for that limitation, Patent Owner cited:

> page 37, lines 7-29 of the application which provides support for the inclusion of a genus of further therapeutic agents in addition to the anti-ErbB2 antibody and a chemotherapeutic agent (*e.g.*, the taxoid), such as another ErbB2 antibody, EGFR antibody, ErbB3 antibody, ErbB4 antibody, vascular endothelial growth factor (VEGF) antibody, cytokine, or growth inhibitory agent.

(*Id.* at 306.) Those "further therapeutic agents" correspond to the therapeutic agents in the representative three-drug combinations that the examiner previously recognized could properly claim priority to the parent application. (*Id.* at 41.)

Following these amendments, the examiner determined that the amended claims "have priority to parent application 60/069,346 (filed 12/12/1997)." (Ex. 1119-6 at 245.) In view of that priority determination, the examiner withdrew the rejection over Nabholtz. (*Id.*)

#### **III. ARGUMENT**

## A. The Board Should Exercise Its Discretion To Deny Institution Under 35 U.S.C. § 325(d).

Under 35 U.S.C. § 325(d), the Board may deny institution if "the same or substantially the same prior art or arguments previously were presented to the Office." *See Apple Inc. v. Papst Licensing GmbH & Co. KG*, IPR2016-01841, Paper 10 at 20-22 (Apr. 17, 2017) (denying institution of petition that presented "substantially the same arguments regarding the unpatentability of the claimed subject matter over [the prior art]" that were considered during prosecution). That is precisely what the petition here seeks to do.

During prosecution, the Patent Office addressed the *same* priority issue with respect to the *same* Nabholtz reference (Ex. 1114) on which this petition rests. While Petitioner has identified two other references as well—Leyland-Jones (Ex. 1150) and Yardley (Ex. 1153)—these references are also not prior art under the examiner's priority determination. Leyland-Jones and Yardley were both published in December 2002 (Ex. 1150 at 1; Ex. 1153 at 1), long after the December 12, 1997 priority date for the challenged claims under the examiner's priority determination.

Petitioner has not identified any new issue or evidence that would warrant revisiting the examiner's priority determination. On the contrary, Petitioner's

priority challenge rests on a mischaracterization of the evidence and arguments that the examiner considered in making her priority determination.

For example, Petitioner suggests that Patent Owner defended the priority of the challenged claims based upon statements in the provisional application referring to "chemotherapeutic regimens," "agents," or "chemotherapeutic regimens *in general*." (Paper 1 at 12-14, 16-17 (emphasis in original).) That is incorrect. As described above (pp. 6-7), those portions of the prosecution history relate to the priority of then-pending claim 32, which recited a combination of an anti-ErbB2 antibody, a taxoid, and carboplatin. (Ex. 1119-5 at 179-81.) That claim was subsequently cancelled without acquiescing in the examiner's rejection. (*Id.* at 307.) Any priority issues with respect to claim 32 are irrelevant to the challenged claims—all of which recite a *different* three-drug combination.

For the claims reciting a three-drug combination with "a further growth inhibitory agent," Patent Owner did not rely on the portions of the parent applications on which Petitioner focuses. (*See* Paper 1 at 16-17.) Instead, Patent Owner established priority for those claims based upon the parent application's specific disclosure of using growth inhibitory agents as part of the present invention. (Ex. 1119-5 at 179 (citing Ex. 1121 at 20 (16:11-24), 39 (35:6-14), 41 (37:9-18).) Based upon that disclosure, the examiner agreed that the claims reciting a combination with "a further growth inhibitory agent" were supported by,

and thus entitled to priority to, the parent applications. (Ex. 1119-5 at 41; *id.* at 292-93; Ex. 1119-6 at 245.)<sup>3</sup>

Petitioner also asserts that Patent Owner supposedly advanced inconsistent positions on the issues of priority and obviousness. (Paper 1 at 17-18.) But that argument rests on another mischaracterization of what occurred during prosecution.

For example, contrary to Petitioner's suggestion (*id.* at 18), Patent Owner did not argue that it was necessary for the prior art to disclose clinical results for the claimed three-drug combination to render the challenged claims obvious. Rather, the quoted passage from the file history explained that the cited Perez reference "<u>supports</u> the patentability of the present invention" because it explains that the data from its ongoing clinical trial would "answer the question of the potential role" of the combination of paclitaxel and carboplatin under evaluation in

<sup>&</sup>lt;sup>3</sup> Patent Owner similarly supported the priority of the claims reciting a combination with a "further therapeutic agent" by citing the listing of further therapeutic agents provided in the provisional application. (Ex. 1119-5 at 306.) That listing corresponds with the representative three-drug combinations that the examiner determined could properly claim priority to the parent applications. (Ex. 1119-5 at 41; *id.* at 292-93.)

the study. (Ex. 1119-5 at 308.) Petitioner's quotation out of context does not accurately reflect Patent Owner's position during prosecution, which was simply that the cited Perez reference supported the patentability of the pending claims, not that the results of clinical trials were necessary to render obvious the claimed threedrug combination.

In fact, the same office action response that Petitioner alleges reflects an inconsistent approach between priority and obviousness addressed *both* issues. (*Id.* at 307-08 (priority), 308-13 (obviousness).) If there was any inconsistency in Patent Owner's position (which there was not), it would have been apparent to the examiner who considered the issues of priority and obviousness at the same time.

Because the Patent Office already addressed the same question of priority on which this petition rests, it would waste party and administrative resources to revisit that same issue here. *See, e.g., Neil Ziegman, N.P.Z., Inc. v. Stephens,* IPR2015-01860, Paper 11 at 13-14 (Feb. 24, 2016) (denying institution under § 325(d) because it was not "an efficient use of Board resources" to address "an issue already and unambiguously presented previously to and considered by the Office" during prosecution). In fact, the Board has previously denied institution under § 325(d) in precisely these circumstances. *See Prism Pharma Co. v. Choongwae Pharma Corp.*, IPR2014-00315, Paper 14 at 12-13 (July 8, 2014) (denying institution under § 325(d) where examiner during prosecution considered

the same priority issue with respect to the same reference); *see also Hulu Inc. v. Intertainer, Inc.*, IPR2014-01456, Paper 8 at 7-8 (Mar. 6, 2015) (denying institution where the Patent Office had already determined during prosecution that the same asserted reference was not prior art).

Indeed, the reasons for denying institution under § 325(d) are especially strong here. Petitioner has filed a separate petition (IPR2017-00737) challenging the same claims of the '549 patent on different grounds. Denying this petition thus would not deprive Petitioner of the opportunity to challenge the '549 patent, which weighs further in favor of denying institution under § 325(d). *See, e.g., Medtronic, Inc. v, Nuvasive, Inc.*, IPR2014-00487, Paper 8 at 7 (Sept. 11, 2014) (denying institution under § 325(d) because Petitioner had previously filed a petition for *inter partes* review challenging the same claims).

Accordingly, the Board in its discretion should deny institution pursuant to 35 U.S.C. § 325(d).

#### B. Petitioner Has Not Demonstrated A Reasonable Likelihood Of Success Because It Did Not Present Evidence Under The Correct Legal Standard For Determining Priority.

If the Board does not exercise its discretion to deny institution under § 325(d), then it should deny institution because the petition on its face fails to demonstrate that the challenged claims lack priority to the provisional application. Where, as here, the issue of priority was previously considered by the Patent Office, Petitioner bears the burden to demonstrate that the earlier priority determination was incorrect. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (explaining the patent challenger has the burden of showing that the claims lack priority where the Patent Office previously found priority established); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1573-74 (Fed. Cir. 1985) (same); *Microsoft Corp. v. Raniere*, IPR2016-00663, Paper 10 at 6 n.3 (Nov. 10, 2016) (acknowledging that "the burden of proving insufficient disclosure in the parent application [is] on the patent challenger" where priority has been previously addressed by the Patent Office).

To demonstrate a lack of priority, Petitioner must show that the provisional application for the '549 patent does not contain sufficient enablement or written description support for the challenged claims. *See* 35 U.S.C. § 119(e). As explained below, the petition fails on its face to meet that burden because it fails to provide sufficient evidence to demonstrate that the provisional application lacks enablement and written description support for the challenged claims under the correct legal standard.

#### 1. Enablement

The enablement requirement is satisfied if a person of ordinary skill could practice the claimed invention "without undue experimentation" based upon the

disclosure in the application. *Daiichi Sankyo Co. v. Alethia Biotherapuetics, Inc.*, IPR2015-00291, Paper 75 at 7 (June 14, 2016). In *In re Wands*, the Federal Circuit identified several relevant factors for evaluating whether undue experimentation would be required, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." 858 F.2d 731, 737 (Fed. Cir. 1988). The Board has applied the *Wands* factors when evaluating priority challenges in *inter partes* review proceedings. *See Daiichi*, IPR2015-00291, Paper 75 at 7-15.

Here, Petitioner acknowledges that enablement is measured against the "undue experimentation" standard. (Paper 1 at 16.) Yet Petitioner's priority analysis does not cite or discuss the *Wands* factors, or otherwise analyze whether the disclosure of the provisional application would have required undue experimentation by a person of ordinary skill trying to make and use the invention. (Paper 1 at 16-19; Ex. 1111, Lipton Decl. ¶¶ 53-55.)

The only enablement analysis that Petitioner and its expert appear to provide rests on the fact that the provisional application does not include clinical results for the claimed three-drug combination. (Paper 1 at 18-19; Ex. 1111, Lipton Decl. ¶ 51 ("[T]he '549 patent contains no data demonstrating efficacy of the claimed

three-drug combination—none in humans, mice, or using cells.").) But that is not sufficient proof that the claims lack enablement support. An invention may be enabled even without an example disclosing experimental results if a person of ordinary skill still could practice the invention without undue experimentation. *See, e.g., Allergan, Inc. v. Sandoz, Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) ("[A] patentee is not required to provide actual working examples ...."); *In re Borkowski*, 422 F.2d 904, 908 (C.C.P.A. 1970) ("[A] specification need not contain a working example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation."). Petitioner has provided no evidence suggesting that practicing the challenged claims would require undue experimentation in the absence of experimental results for the claimed three-drug combination.

Petitioner cites *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1324 (Fed. Cir. 2005), for the proposition that an "inventor must 'provide experimental proof that his invention could be effective in treating cancer."" (Paper 1 at 18-19.) But *Rasmusson* was addressing a different legal issue: *i.e.*, the requirements for demonstrating *utility* of a compound that had not previously been demonstrated to be effective at treating cancer. *See Rasmusson*, 413 F.3d at 1324. Here, by contrast, Petitioner is not contesting the utility of the claimed invention, and has not argued that a person of ordinary skill would have been unable to use the '549 invention without undue experimentation. In fact, Petitioner's own expert has opined that "determining an effective amount of a three drug combination is a matter of routine experimentation within the general knowledge and skill set of a POSITA." (Ex. 1111, Lipton Decl. ¶ 52.) *Rasmusson* therefore has no application to this case given Petitioner's position that only "routine experimentation" would have been necessary to determine efficacy.

In sum, the petition fails to provide the proof necessary to show that a person of ordinary skill could not make and use the '549 invention without undue experimentation. By itself, the absence of experimental results in the provisional application is legally insufficient to carry Petitioner's burden.

#### 2. Written Description

Petitioner's proof with respect to written description is similarly deficient. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that a person of ordinary skill can reasonably conclude that the inventor was in possession of what is claimed. *See Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Importantly, "the written description requirement *does not demand either examples* or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." *Id.* at 1352 (emphasis added).

The petition does not present sufficient evidence to demonstrate a lack of written description support under the correct legal standard. Instead, Petitioner's priority analysis rests solely on the fact that the provisional application contains no working example of the claimed three-drug combination. (Paper 1 at 16 ("There is no disclosure of any method of treatment in which the claimed three-drug combination is administered.").) But the mere absence of experimental examples is not legally sufficient proof of insufficient written description support. See, e.g., Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1285 (Fed. Cir. 2012) (finding sufficient written description support in the absence of experimental examples); Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (same). Petitioner has not addressed whether the disclosure of the provisional application as a whole—regardless of whether it discloses any working example would have demonstrated to a person of ordinary skill that the inventors were in possession of their invention, which is the relevant analysis.

Petitioner discusses certain portions of the provisional application that it contends Patent Owner supposedly relied upon as written description support for the claimed three-drug combinations. (Paper 1 at 16-17.) But as discussed above (pp. 6-7), those portions of the provisional application were the support that Genentech cited for original claim 32—directed to a *different* three-drug combination from the claims at issue here. Petitioner ignores that Genentech cited

different support for the claims reciting a three-drug combination that included "a further growth inhibitory agent" or "a further therapeutic agent," which are the claims challenged here. (Ex. 1119-5 at 179 (citing Ex. 1121 at 20 (16:11-24), 39 (35:6-14), 41 (37:9-18)); *id.* at 306 (citing Ex. 1121 at 41 (37:7-29)).)

Petitioner also argues that the discussion of administering growth inhibitory agents on page 37, lines 9-18 of the parent application "does not disclose administration of a combination of an anti-ErbB2 antibody, a taxoid, and a growth inhibitory agent." (Paper 1 at 17 (citing Ex. 1121 at 41 (37:9-18)).) But that argument fails to assess that portion of the parent application in the context of the application as a whole. The preceding paragraph provides two of the three drugs in the claimed combination, describing "the present invention" as "the combined administration of an anti-ErbB2 antibody and a chemotherapeutic agent, other than an anthracycline derivative [e.g., a taxoid]." (Ex. 1121 at 40 (36:26-27).) The passage that Petitioner cites describes a "preferred embodiment" in which a third drug—a "growth inhibitory agent"—is "co-administered" as part of that invention. (Id. at 41 (37:13-14).) Taken together, those two paragraphs thus clearly describe the three-drug combination of an anti-ErbB2 antibody, a taxoid, and a further

growth inhibitory agent required by the challenged claims.<sup>4</sup> Petitioner's priority argument erroneously fails to evaluate the written description support in view of the specification as a whole. *See Purdue Pharma LP v. Faulding, Inc.*, 230 F.3d 1320, 1328 (Fed. Cir. 2000); *In re Long*, 368 F.2d 892, 838 (C.C.P.A. 1966) ("We emphasize that the specification as a whole must be considered in determining its sufficiency [of section 112, first paragraph].").

#### \*\*\*

Petitioner has failed to provide evidence that the provisional application lacks enablement and written description support for the challenged claims under the correct legal standard. Petitioner therefore cannot carry its burden to demonstrate that the examiner's previous priority determination was incorrect. Because each proposed ground in this petition depends on Petitioner's challenge to

<sup>&</sup>lt;sup>4</sup> As Patent Owner explained during prosecution, the same two paragraphs of the specification provide written description support for the claims reciting a threedrug combination with a "further therapeutic agent." (*See supra* p. 8.) The first paragraph describes the combination of an anti-ErbB2 antibody and a taxoid. (Ex. 1121 at 40 (36:26-27).) And the second paragraph identifies representative "further therapeutic agents" that may be administered with that combination. (*Id.* at 41 (37:9-18).)

the examiner's priority determination, Petitioner has not demonstrated a reasonable

likelihood of success for any of its proposed grounds.

## **IV. CONCLUSION**

The Board should deny institution of all grounds.

Respectfully submitted,

Date: May 3, 2017

/David L. Cavanaugh/ David L. Cavanaugh Registration No. 36,476

Robert J. Gunther, Jr. *Pro Hac Vice* Motion To Be Filed

Counsel for Patent Owner

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## **CERTIFICATE OF COMPLIANCE**

I hereby certify that the foregoing Patent Owner's Preliminary Response contains 4,219 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. § 42.24(d).

Respectfully submitted,

Dated: May 3, 2017

<u>/David L. Cavanaugh/</u> David L. Cavanaugh Registration No. 36,476

## **CERTIFICATE OF SERVICE**

I hereby certify that, on May 3, 2017, I caused a true and correct copy of the

following materials:

• Patent Owner's Preliminary Response

to be served electronically via File Transfer Protocol (FTP), as previously agreed

by the parties, on the following attorneys of record:

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