

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOSPIRA, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-00805
Patent 7,371,379 B2

Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Hospira, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”), requesting institution of an *inter partes* review of claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of U.S. Patent No. 7,371,379 B2 (Ex. 1001, “the ’379 patent”). Genentech, Inc. (“Patent Owner”) timely filed a Preliminary Response (Paper 6, “Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We, thus, institute an *inter partes* review of claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of the ’379 patent.

A. *Related Proceedings*

As related matters, Petitioner and Patent Owner identify a concurrently-filed petition for *inter partes* review (IPR2017-00804) for a related patent, U.S. Patent 6,627,196 (“the ’196 patent”). *See* Pet. 2; Paper. 4, 4. Additionally, Petitioner identifies UK and European Patent Office (EPO) decisions concerning a European counterpart to the ’379 patent as related matters. Pet. 2. Patent Owner identifies other related issued patents and pending applications. Paper 4, 4.

B. *The ’379 Patent (Ex. 1001)*

The ’379 patent issued on May 13, 2008, with Sharon A. Baughman and Steven Shak as the listed co-inventors. Ex. 1001, (45), (75). The ’379

patent claims priority as the divisional of an application filed December 25, 2000, as well as to provisional applications filed June 23, 2000 and August 27, 1999. *Id.* at (22), (60).

The '379 patent relates generally to dosages for the treatment of anti-ErbB2 antibodies. *Id.* at (54). The overexpression of ErbB2 has been associated with cancer. *Id.* at 1:20–25. As noted in the '379 patent, a recombinant humanized anti-ErbB2 monoclonal antibody (alternatively referred to as “rhuMab HER2,” “trastuzumab,” or by its tradename “Herceptin”) had been clinically tested and approved for patients with ErbB2-overexpressing metastatic breast cancers who received prior anti-cancer therapy. *Id.* at 3:59–65. The recommended initial “loading dose” for Herceptin was 4 mg/kg administered as a 90-minute infusion, and the recommended weekly “maintenance dose” was 2 mg/kg, which could be administered as a 30-minute infusion if the initial loading dose was well-tolerated. *Id.* at 3:66–4:3.

The invention described in the '379 patent “concerns the discovery that an early attainment of an efficacious target trough serum concentration by providing an initial dose or doses of anti-ErbB2 antibodies followed by subsequent doses of equal or smaller amounts of antibody (greater front loading) is more efficacious than conventional treatments.” *Id.* at 4:26–31. The method of treatment, according to the invention described in the patent, “involves administration of an initial dose of anti-ErbB2 antibody of more than approximately 4 mg/kg, preferably more than approximately 5 mg/kg,” with the maximum dose not to exceed 50 mg/kg. *Id.* at 4:51–55. “[T]he initial dose or doses is/are followed by subsequent doses of equal or smaller amounts of antibody at intervals sufficiently close to maintain the trough

serum concentration of antibody at or above an efficacious target level.” Ex. 1001, 4:65–5:2. Preferably, “the amount of drug administered is sufficient to maintain the target trough serum concentration such that the interval between administration cycles is at least one week,” and “the trough serum concentration does not exceed 2500 µg/ml and does not fall below 0.01 µg/ml during treatment.” *Id.* at 5:4–9. The patent explains that “[t]he front loading drug treatment method of the invention has the advantage of increased efficacy by reaching a target serum drug concentration early in treatment.” *Id.* at 5:9–12. As a result, “[t]he efficacious target trough serum concentration is reached in 4 weeks or less . . . and most preferably 1 week or less, including 1 day or less.” *Id.* at 4:31–34. Additionally, the patent states that the method of therapy may involve “infrequent dosing” of the anti-ErbB2 antibody, wherein the first and second dose are separated by at least two weeks, and optionally at least about three weeks. *Id.* at 6:23–36.

The ’379 patent describes embodiments in which the initial dose of anti-ErbB2 is 6 mg/kg, 8 mg/kg, or 12 mg/kg, followed by subsequent maintenance doses of 6 mg/kg or 8 mg/kg administered once every 2 or 3 weeks, in a manner such that the trough serum concentration is maintained at approximately 10–20 µg/ml during the treatment period. *Id.* at 5:19–43, 45:19–45. The treatment regimen according to the invention may further comprise administration of a chemotherapeutic agent, such as a taxoid, along with the anti-ErbB2 antibody. *Id.* at 6:6–10, 7:26–32, 46:28–58.

C. Illustrative Claim

Petitioner challenges claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of the ’379 Patent. Independent claim 1 is illustrative, and is reproduced below:

1. A method for the treatment of a human patient diagnosed with cancer characterized by overexpression of ErbB2 receptor, comprising administering an effective amount of an anti-ErbB2 antibody to the human patient, the method comprising:
administering to the patient an initial dose of at least approximately 5 mg/kg of the anti-ErbB2 antibody; and
administering to the patient a plurality of subsequent doses of the antibody in an amount that is approximately the same or less than the initial dose, wherein the subsequent doses are separated in time from each other by at least two weeks; and
further comprising administering an effective amount of a chemotherapeutic agent to the patient.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the claims of the '379 Patent based on the following ground:

References	Basis	Claims challenged
Herceptin Label, ¹ Baselga '96, ² Pegram '98, ³ and the Knowledge of a Person of Ordinary Skill in the Art	§ 103(a)	1–3, 5, 7, 9–11, 16–28, and 30–40

¹ Genentech, Inc, Herceptin® Trastuzumab, Sept. 1998 (hereinafter “Herceptin Label”) (Ex. 1008).

² Jose Baselga, *Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185^{HER2} Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer*, 14 JOURNAL OF CLINICAL ONCOLOGY 737–744 (1996) (hereinafter “Baselga '96”) (Ex. 1013).

³ Mark D. Pegram, *Phase II Study of Receptor-Enhanced Chemosensitivity Using Recombinant Humanized Anti-p185^{HER2/neu} Monoclonal Antibody Plus Cisplatin in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer Refractory to Chemotherapy Treatment*, 16 JOURNAL OF CLINICAL ONCOLOGY 2659–71 (1998) (hereinafter “Pegram '98”) (Ex. 1014).

Petitioner further relies upon the declarations of Allan Lipton, M.D. (Ex. 1002) and William Jusko, Ph.D. (Ex. 1003).

II. ANALYSIS

A. Claim Construction

We interpret claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are generally given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). “Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes a construction for “ErbB2 receptor.” *See* Pet. 24. Patent Owner proposes a construction for “effective amount.” *See* Prelim. Resp. 27–28. At this stage of the proceeding, we find that no explicit construction of any claim term is necessary to determine whether to institute a trial in this case. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

B. Level of Skill in the Art

Petitioner contends that a person of ordinary skill in the art for the '379 patent would be a "team" that includes both (1) a clinical or medical oncologist specializing in breast cancer with several years of experience in breast cancer research or clinical trials, and (2) a person with a Ph.D. in pharmaceutical sciences or a closely related field with an emphasis in pharmacokinetics with three years of relevant experience in protein based drug kinetics. Pet. 23–24 (citing Exs. 1002 ¶ 14; 1003 ¶ 15; 1006 ¶ 32). Patent Owner does not address the requisite level of skill in its Preliminary Response.

On this record, we adopt Petitioner's definition of the level of ordinary skill in the art as it undisputed at this time and consistent with the evidence of record. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Patentability Analysis

1. Content of the Prior Art

Petitioner relies upon the following prior art in its challenges.

a. Herceptin Label (Ex. 1008)

As recognized in the '379 patent, rhuMAb HER2 (trastuzumab) was already FDA-approved and commercially sold in the U.S. by 1998 under the tradename Herceptin. Ex. 1001, 3:59–4:3. The Herceptin Label teaches:

The pharmacokinetics of Trastuzumab were studied in breast cancer patients with metastatic disease. Short duration intravenous infusions of 10 to 500 mg once weekly demonstrated dose-dependent pharmacokinetics. Mean half-life increased and clearance decreased with increasing dose level. The half-life averaged 1.7 and 12 days at the 10 and 500 mg dose levels, respectively. Trastuzumab's volume of distribution was approximately that of serum volume (44 mL/kg). At the highest weekly dose studied (500 mg), mean peak serum concentrations were 377 microgram/mL.

Ex. 1008, 1.

The Herceptin Label also teaches that “[i]n studies using a loading dose of 4 mg/kg followed by a weekly maintenance dose of 2 mg/kg, a mean half-life of 5.8 days . . . was observed,” and “[b]etween week 16 and 32, Trastuzumab serum concentration reached a steady state with a mean trough and peak concentrations of approximately 79 [mg]/mL and 123 [mg]/mL, respectively. *Id.* The Label further describes clinical studies in which metastatic breast cancer patients with certain levels of HER2 overexpression were administered either chemotherapy alone or in combination with Herceptin given intravenously as a 4 mg/kg loading dose followed by weekly doses at 2 mg/kg. *Id.* The chemotherapy in these clinical studies (e.g., paclitaxel) was administered every 3 weeks (21 days). *Id.*

b. Baselga '96 (Ex. 1013)

Baselga '96 reports the results of a phase II clinical trial in which patients with ErbB2-overexpressing metastatic breast cancer were treated with rhuMAb HER2. Ex. 1013, 737. The pharmacokinetic goal of the trial “was to achieve rhuMAb HER2 trough serum concentrations greater than 10 µg/mL, a level associated with optimal inhibition of cell growth in the preclinical model.” *Id.* at 738. Further, the “[s]erum levels of rhuMAb

HER2 as a function of time were analyzed for each patient using a one-compartment model.” *Id.*

According to the results reported in Basegla '96, “[m]ore than 90% of the examined population (41 patients) had rhuMAb HER2 trough levels above the targeted 10 µg/mL level. *Id.* at 739. Moreover, the treatment “was remarkably well tolerated.” *Id.* “Toxicity [from rhuMAb HER2] was minimal,” and no immune response against the antibody was detected. *Id.* at 737. Out of the 768 times rhuMAb HER2 was administered, “only 11 events occurred that were considered to be related to the use of the antibody.” *Id.* at 739. Baselga '96 also teaches that in preclinical studies (both in vitro and in xenografts), rhuMAb HER2 “markedly potentiated the antitumor effects of several chemotherapeutic agents, including cisplatin, doxorubicin, and paclitaxel, without increasing their toxicity.” *Id.* at 743.

c. Pegram '98 (Ex. 1014)

Pegram '98 reports the results of a phase II clinical trial using a combination of rhuMAb HER2 plus cisplatin. Ex. 1014, 2659. Pegram '98 states that “[t]hese studies showed that the pharmacokinetics of rhuMAb HER2 were predictable, and that the doses delivered achieved a target trough serum concentration of 10 to 20 µg/mL, which is associated with antitumor activity in preclinical models.” *Id.* at 2660. Pegram '98 also reports a toxicity profile of the combination that paralleled the toxicity of cisplatin alone, which led to the conclusion that rhuMAb HER2 did not increase toxicity. *Id.* at 2668.

2. *Obviousness Based on the Herceptin Label, Baselga '96, Pegram '98, and the Knowledge of a Person of Ordinary Skill in the Art of the Prior Art*

Petitioner has provided a claim-by-claim explanation for the basis of its contention that claims 1–3, 5, 7, 9–11, 16–28, and 30–40 are obvious over the Herceptin Label in view of Baselga '96, Pegram '98, and the Knowledge of a Person of Ordinary Skill in the Art. Pet. 29–54.

We focus our analysis primarily on the method of treatment recited in independent claim 1. The challenged claims are directed to a dosing regimen for the treatment of cancer in which an anti-ErbB2 antibody is administered at an initial dose, followed by administration of the antibody at subsequent doses that are the same or less than the initial dose and separated in time by at least about two weeks. Independent claim 1 specifies an initial dose of approximately 5 mg/kg, while certain dependent claims specify higher initial doses of 6 mg/kg, 8 mg/kg, or 12 mg/kg (e.g., cls. 2, 3, 9), whereas other dependent claims specify that the subsequent doses are separated in time by at least three weeks (e.g., cl. 10). The claims further require administering an effective amount of chemotherapy to the patient.

Petitioner relies upon the teaching in the Herceptin Label that rhuMAB HER2 doses of up to 500 mg had been successfully administered to patients. Pet. 31 (citing Ex. 1008, 1). Based on a patient weight range of 55–85 kg, Petitioner calculates that the weight-based dose for the 500 mg absolute dose taught by the Herceptin Label ranges from 5.88–9.09 mg/kg. *Id.* (citing Ex. 1002 ¶¶ 55–57; Ex. 1003 ¶ 45; Ex. 1026, 3; Ex. 1027, 334 (Table 7-2)). Petitioner further relies upon the Herceptin Label's teaching that rhuMAB HER2 doses should be front-loaded. *Id.* at 33. Additionally, Petitioner relies upon the teaching in Herceptin Label describing the

administration of rhuMAb HER2 in combination with chemotherapeutic agents, and that these chemotherapeutic agents are administered once every three weeks to patients. *Id.* at 35–36, 43–44. Petitioner further relies upon Baselga '96 and Pegram '98 insofar as they confirm that the weekly dosing regimen encompassed by the Herceptin Label was successfully administered to patients in phase II clinical trials, and that the skilled artisan would have been aware of a target trough serum concentration of 10–20 µg/mL for rhuMAb HER2. Pet. 33, 37.

Petitioner acknowledges that the Herceptin Label, along with Baselga '96 and Pegram '98, teach only a *weekly* dosing regimen, but asserts that a skilled artisan would nonetheless have been motivated to decrease the frequency of rhuMAb HER2 injections to once every three weeks for several reasons. *Id.* at 34–42. First, Petitioner contends that “a skilled artisan would decrease the frequency of injections to improve efficiency, to provide a more convenient dosing regimen—particularly for terminally ill patients—, and to improve patient compliance and quality of life.” *Id.* at 34. Second, Petitioner contends that the skilled artisan would have been motivated to apply a tri-weekly regimen for the antibody in order to align with the dosing schedules of the chemotherapy so that patient would have to only make one trip to the clinic to receive both doses. *Id.* at 36.

Finally, Petitioner contends that the skilled artisan would decrease the frequency of injections and use a tri-weekly dosing regimen in view of rhuMAb HER2's known pharmacokinetic properties. *Id.* at 36. In this regard, Petitioner relies upon Dr. Jusko's Declaration to assert that it would have been a matter of routine calculation for a skilled artisan to determine that a tri-weekly 500 mg rhuMAb HER2 dosing regimen would have

resulted in a serum concentration well above the target minimum trough concentration of 10–20 µg/ml. *Id.* at 37–39 (citing Ex. 1003 ¶¶ 46–47, 49–51, 56–58, 62). Petitioner also relies upon Dr. Jusko’s calculation of an initial loading dose of approximately 712 mg for a dosing regimen where the dose interval is three weeks and the maintenance dose is 500 mg. *Id.* at 40–41 (citing Ex. 1003 ¶¶ 59, 61–62).

We are persuaded by Petitioner’s arguments as set forth in the Petition at this stage of the proceeding. We address Patent Owner’s preliminary arguments below. Patent Owner in its Preliminary Response does not argue the claims separately.

Patent Owner first argues that we should deny institution pursuant to 35 U.S.C. § 325(d) because the Examiner, during prosecution of the ’379 patent’s parent and the ’379 patent, considered the teachings of “Goldenberg ’99,”⁴ a reference that includes the same information as set forth in the Herceptin Label. Prelim. Resp. 20–24, 28–33. We recognize that Goldenberg ’99 contains substantially the same teachings as the Herceptin Label with regard to the dosing regimen, but we decline to deny consideration of Petitioner’s patentability challenge on that basis.

Under § 325(d), we have discretion to deny a petition that raises substantially the same prior art or arguments previously presented to the Office. Here, especially when taking the Lipton and Jusko Declarations that were not before the Examiner into account, Petitioner’s testimonial evidence

⁴ Marvin M. Goldenberg, *Trastuzumab, A Recombinant DNA-Derived Humanized Monoclonal Antibody, a Novel for the Treatment of Metastatic Breast Cancer*, 21 CLINICAL THERAPEUTICS (1999) (hereinafter “Goldenberg ’99”) (Ex. 2001).

presents the prior art in a new light. For example, there is no basis to suggest that the Examiner considered the calculations set forth by Dr. Jusko showing that a tri-weekly dosing regimen would have resulted in an acceptable trough serum concentration above 10–20 µg/ml. *See* Ex. 1003 ¶¶ 61–62. Based upon these differences in the current record, we exercise our discretion not to deny the Petition as containing “the same or substantially the same prior art or arguments previously were presented to the Office.” *See* 35 U.S.C. § 325(d).

As to the merits of Petitioner’s patentability challenge, Patent Owner argues that (1) the prior art upon which Petitioner relies only describe weekly dosing of the antibody (Prelim. Resp. 3, 35–36), (2) that the reported half-life of trastuzumab would have discouraged skilled persons from applying a tri-weekly dosing regimen (*id.* at 3, 42–44), (3) that the prior art does not articulate or suggest the alleged desire for convenience in the dosing regimen, which would have been secondary to efficacy (*id.* at 3–4, 37–41), and (4) that Petitioner’s arguments concerning “routine calculation and optimization” is based on hindsight, and contradicts historical reality and the prior art (*id.* at 4–5, 32, 49). With regard to the last point, Patent Owner contends that trastuzumab was known to have “dose-dependent” (i.e., non-linear) kinetics, which would have made any prediction concerning drug concentration in the body difficult because the elimination rate changes over time. *Id.* at 10–14, 36, 38, 46. Because Dr. Jusko assumes linear kinetics in making his calculations (Ex. 1003 ¶¶ 60, 71), Patent Owner contends that Petitioner has failed to establish a “reasonable expectation of success.” Prelim. Resp. 47–51.

In view of the current record, we are unpersuaded by Patent Owner’s preliminary arguments on the merits, which mostly focus on whether it would have been obvious to utilize the extended dosing interval required by the claimed methods. We recognize that the prior art only explicitly described weekly dosing intervals for administration of the rhuMAb HER2 antibody, but we do not find that the current record supports a conclusion that the skilled artisan would have been discouraged from extending the dosing interval to once every three weeks. We do not find any basis in the current record to conclude that the skilled artisan would have limited the dosing interval in view of the disclosed half-life of the antibody; rather, the record suggests that half-life may be one factor to consider among others in determining the dosing frequency. *See* Ex. 2007, 152 (disclosing that “dosage interval can *generally* be extended in relation to half-life,” but further identifying “therapeutic index,” “body clearance,” and “side effects” as other factors to consider) (emphasis added). Furthermore, contrary to Patent Owner’s arguments, the prior art need not have expressly articulated or suggested patient convenience as a motivation to extend the dosing interval. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“[T]he [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”); *Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1329 (Fed. Cir. 2014) (“A relatively infrequent dosing schedule has long been viewed as a potential solution to the problem of patient compliance.”).

We nonetheless recognize that the desire for patient convenience must be balanced with the desire for efficacy in determining the appropriate

dosing interval, but note that “[c]onclusive proof of efficacy is not necessary to show obviousness.” *Hoffmann-La Roche Inc.*, 748 F.3d at 1331. In this regard, we take into account Patent Owner’s contention that Petitioner failed to establish a “reasonable expectation of success” because Dr. Jusko’s calculations are erroneously based on linear (dose-independent) kinetics rather than the non-linear (dose-dependent) kinetics taught in the prior art for trastuzumab. Prelim. Resp. 47–51. At this stage of the proceeding, and without the benefit of expert testimony from Patent Owner, we decline to give Petitioner’s arguments based on expert testimony less weight in comparison to Patent Owner’s attorney arguments. As such, we determine that Petitioner has shown a reasonable expectation of success based, *inter alia*, on the calculations set forth in Dr. Jusko’s Declaration.

Accordingly, based on the foregoing analysis, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its obviousness challenge based on the combined prior art teachings of Herceptin Label, Baselga ’96, and Pegram ’98, in combination with the knowledge of the skilled artisan as set in the declarations of Dr. Lipton and Dr. Jusko.

III. CONCLUSION

We conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of the ’379 patent are unpatentable as obvious.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or the construction of any claim term. Thus, our view with regard to any

conclusion reached in the foregoing could change upon consideration of Patent Owner's merits response and upon completion of the current record.

IV. ORDER

Accordingly, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–3, 5, 7, 9–11, 16–28, and 30–40 of U.S. Patent No. 7,371,379 B2 based on the following ground of unpatentability:

- A. Claims 1–3, 5, 7, 9–11, 16–28, and 30–40 under 35 U.S.C. § 103(a) as obvious over the Herceptin Label in view of Baselga '96, Pegram '98, and the Knowledge of a Person of Ordinary Skill in the Art;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '379 Patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is limited to the single ground of unpatentability listed above, and no other grounds of unpatentability are authorized for *inter partes* review.

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Patent 7,371,379 B2

PETITIONER:

Amanda Hollis
Stefan Miller
Karen Younkins
KIRKLAND & ELLIS LLP
Amanda.hollis@kirkland.com
dichromik@gmail.com
Karen.younkins@kirkland.com

PATENT OWNER:

David Cavanaugh
Owen Allen
WILMER CUTLER PICKERING HALE AND DORR LLP
David.cavanaugh@wilmerhale.com
Owen.allen@wilmerhale.com

Adam Brausa
DURIE TANGRI LLP
abrausa@durietangri.com