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Paper 29
Entered: January 19, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01582
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU, and KRISTINA M. KALAN, *Administrative Patent Judges.*

KALAN, *Administrative Patent Judge.*

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

I. INTRODUCTION

Wockhardt Bio AG ("Petitioner") filed a Petition (Paper 4, "Pet.") to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 8,822,438 B2 (Ex. 1001, "the '438 patent") pursuant to 35 U.S.C. §§ 311–319. Janssen Oncology, Inc. ("Patent Owner") filed a Preliminary Response (Paper 13, "Prelim. Resp."). Pursuant to Board authorization (Paper 17), Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 22, "Reply") and Patent Owner filed a Surreply to Petitioner's Reply (Paper 27, "Surreply"). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute an *inter partes* review as to claims 1–20 as discussed below.

Our findings of fact and conclusions of law, including those relating to the broadest reasonable construction of the patent claim terms, are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. Our final decision will be based on the full record developed during trial.

II. BACKGROUND

A. Related Matters

The parties indicate that the '438 patent is being asserted in a number of district court proceedings, some of which have been terminated. Pet. 66; Paper 8, 2–4. Of those, Patent Owner represents that the following proceedings have not been terminated: *BTG Int'l Ltd. v. Actavis Labs. FL, Inc.*, C.A. No. 2:15-cv-05909-KM-JBC (D. N.J.); *Janssen Biotech, Inc. v. Mylan Pharm. Inc.*, C.A. No. 1:15-cv-00130-IMK (N.D. W. Va.); *BTG Int'l Ltd. v. Amerigen Pharm., Inc.*, C.A. No. 2:16-cv-02449-KM-JBC (D. N.J.)

and *BTG Int'l Ltd. v. Glenmark Pharm. Inc.,* C.A. No. 2:16-cv-05909 (D. N.J.). Paper 8, 3–4. The '438 patent is the subject of *inter partes* review numbers IPR2016-00286 (instituted May 31, 2016), IPR2016-01337 (instituted and joined with IPR2016-00286 on September 19, 2016) and IPR2016-01332. *Id.* at 2–3. Patent Owner also states that the '438 patent "was the subject of *ex parte* reexamination request No. 90/020,096," but "will not be granted a filing date for failure to comply with the requirements of 37 C.F.R. § 1.501(a)." *Id.* at 2.

B. The '438 Patent

The '438 patent, titled "Methods and Compositions for Treating Cancer," describes methods that comprise "administering a 17α-hydroxylase/$C_{17, 20}$-lyase inhibitor, such as abiraterone acetate (i.e., 3β-acetoxy-17-(3-pyridyl)androsta-5,16-diene), in combination with at least one additional therapeutic agent such as an anti-cancer agent or a steroid." Ex. 1001, Title, Abstract. As described in the '438 patent, it is believed that testosterone and dihydrotestosterone promote the growth of prostate cancer. *Id.* at 1:49–51. Hormone therapy can be used to suppress the production or block the effects of hormones such as testosterone. *Id.* at 1:43–51.

The enzyme 17α-hydroxylase/$C_{17, 20}$-lyase ("CYP17") is involved in testosterone synthesis. *Id.* at 3:66–4:1. CYP17 inhibitors have been shown to be useful in the treatment of cancer, specifically, androgen-dependent disorders like prostate cancer. *Id.* at 5:23–27. Abiraterone acetate, a prodrug of abiraterone, is a CYP17 inhibitor. *Id.* at 2:10–12. The '438 patent describes administration of an effective amount of a CYP17 inhibitor, such as abiraterone acetate, with a steroid such as prednisone or dexamethasone. *Id.* at 2:9–3:20.

C. Claims

Claim 1 of the ’438 patent is reproduced below:

1. A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.

Ex. 1001, 16:16–20. Dependent claims 2–20 of the ’438 patent describe additional limitations of the method, including the amount of abiraterone acetate and the amount of prednisone administered, and the type of prostate cancer being treated. *Id.* at 16:21–17:14.

D. The Prior Art

Petitioner relies on the following prior art:

1. Gerber, G.S. & Chodak, G.W., *Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer*, 144 J. Urol. 1177–79 (1990) (“Gerber”) (Ex. 1004);
2. O’Donnell, A. et al., *Hormonal impact of the 17α-hydroxylase/$C_{17,20}$-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer*, 90 British Journal of Cancer 2317–2325 (2004) (“O’Donnell”) (Ex. 1005); and
3. Sartor, O. et al., *Effect of prednisone on prostate-specific antigen in patients with hormone-refractory prostate cancer*, 52 Urology 252–256 (1998) (“Sartor”) (Ex. 1006).

Petitioner also relies on the Declarations of Dr. Paul A. Godley (Ex. 1002, the “Godley Declaration”) and Dr. Robert Stoner (Ex. 1077, the “Stoner Declaration”) in support of its arguments.

E. The Asserted Ground

Petitioner challenges claims 1–20 of the '438 patent on the following ground:

References	Basis	Claims Challenged
Gerber, O'Donnell, and Sartor	§ 103(a)	1–20

III. ANALYSIS

We turn now to Petitioner's asserted ground of unpatentability, Patent Owner's arguments in the Preliminary Response, the Reply, the Surreply, and the supporting evidence to determine whether Petitioner has met the threshold standard of 35 U.S.C. § 314(a).

A. Claim Interpretation

The Board interprets claims in an unexpired patent 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 Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under the broadest reasonable interpretation standard, claim terms are generally given their ordinary and customary meaning in view of the specification, 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).

Petitioner proposes that we construe the claim terms "treat," "treating," "treatment," and "therapeutically effective amount of prednisone." Pet. 20–21. Petitioner notes that these claim terms have already been construed in IPR2016-00286, Paper 14, and states that it analyzes the claims under those constructions for the purpose of this proceeding. *Id*. Patent Owner does not

propose any claim constructions in its Preliminary Response. As proposed by Petitioner, we apply our claim constructions of "treat," "treating," "treatment," and "therapeutically effective amount of prednisone," as set forth in IPR2016-00286, to the present case. IPR2016-00286, Paper 14, 5–7.

The terms "treat," "treating," and "treatment" are discussed and defined explicitly in the specification of the '438 patent. Ex. 1001, 3:46–50. Accordingly, we construe those terms to "include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer."

Regarding the phrase "therapeutically effective amount of prednisone," the definition in the specification provides: "As used herein, and unless otherwise defined, the phrase 'therapeutically effective amount' when used in connection with a 17α- hydroxylase/$C_{17, 20}$-lyase inhibitor or therapeutic agent means an amount of the 17α-hydroxylase/$C_{17, 20}$-lyase inhibitor or therapeutic agent effective for treating a disease or disorder disclosed herein, such as cancer." Ex. 1001, 4:17–22. The specification's definition of "therapeutically effective amount," applies to a therapeutic agent. *Id.* The specification provides examples of a "therapeutic agent" such as "an anti-cancer agent or a steroid, e.g., a corticosteroid or, more specifically, a glucocorticoid." *Id.* at 1:14–16. Thus, the definition of "therapeutically effective amount" in the specification would apply to prednisone, a glucocorticoid. *Id.* at 3:10–11. Furthermore, claim 1 is directed to "A method for the treatment of a prostate cancer in a human." *Id.* at 16:16–17. Based on the definition and discussion the specification, and the manner in which the term is used in the claims, we construe "therapeutically effective

amount of prednisone" as "an amount of prednisone effective for treating prostate cancer."

B. Ground Asserted by Petitioner

Petitioner challenges claims 1–20 as obvious under 35 U.S.C. § 103(a) over Gerber, O'Donnell, and Sartor. Pet. 23–46.

Gerber

Gerber, which is titled "Prostate Specific Antigen for Assessing Response to Ketoconazole and Prednisone in Patients with Hormone Refractory Metastatic Prostate Cancer," discloses use of ketoconazole, a known CYP17 inhibitor and inhibitor of gonadal and adrenocortical steroid synthesis, with prednisone to treat patients with progressive prostate cancer. Ex. 1004, 1177. Gerber provides that patients exhibiting progressively increasing prostate specific antigen ("PSA") levels, when treated with ketoconazole and prednisone, experienced a decrease in PSA levels. *Id.* at 1178–79.

O'Donnell

O'Donnell, which is titled "Hormonal impact of the 17α-hydroxylase/$C_{17, 20}$-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer," discloses that treatment of prostate cancer with abiraterone acetate, at a dose of 500–800 mg, can successfully suppress testosterone levels. Ex. 1005, Abstract. O'Donnell also discloses that ketoconazole, another CYP17 inhibitor, has been evaluated as a possible agent with which to achieve decreased production of adrenal steroids, but that abiraterone acetate was developed as a more selective inhibitor. *Id.* at 2318. O'Donnell further discloses that adrenocortical suppression may require administration of replacement glucocorticoid. *Id.* at Abstract, 2323.

O'Donnell states that "[s]ome impact on adrenal reserve was predictable from the steroid synthesis pathway." *Id.* at 2323. Regarding administration of ketoconazole, O'Donnell states that "it is common practice to administer supplementary hydrocortisone" and that this may prove necessary with abiraterone acetate. *Id.* On the basis of the clinical evidence, O'Donnell reports that the need for concomitant therapy of abiraterone acetate with a glucocorticoid needs to be further investigated. *Id.*

Sartor

Sartor, which is titled "Effect of Prednisone on Prostate-Specific Antigen in Patients with Hormone-Refractory Prostate Cancer," discloses a trial in which patients with hormone-refractory progressive prostate cancer, who were not receiving concomitant anticancer therapies, were treated with 10 mg of prednisone orally two times a day. Ex. 1006, Abstract. Sartor discloses that administration of prednisone alone, as shown by its results, led to an average decline of 33% in PSA responses after initiating prednisone; a majority of patients had PSA progression-free survival for a matter of months following treatment. *Id.* at 254, Table III. Sartor concludes that prednisone "can decrease PSA by more than 50% in approximately one third of patients" and hypothesizes "a dose-responsive relationship between glucocorticoid dose and PSA decline." *Id.* at Abstract.

Arguments

Petitioner argues that Gerber teaches co-administering the CYP17 inhibitor ketoconazole with prednisone to treat prostate cancer. Pet. 28–29 (citing Ex. 1004, 1177–1179). Petitioner further argues that abiraterone acetate "was known to be a potent and more specific inhibitor of CYP17 than ketoconazole and it effectively reduced testosterone levels" (citing Ex. 1002

¶ 72) and that O'Donnell discloses administering abiraterone acetate to castrate and non-castrate males (citing Ex. 1005, 2320–2321, 2324). *Id.* at 29–30. Finally, Petitioner argues that "prednisone was known to treat prostate cancer, as well as to offset the side effects from administering a CYP17 inhibitor, such as abiraterone acetate and ketoconazole" (citing Ex. 1002 ¶¶ 75–84), and that Sartor "teaches administering 20 mg/day prednisone as a monotherapy in patients with mCRPC" (citing Ex. 1006, 252–254). *Id.* at 31. Petitioner presents a claim chart for claim 1, citing prior art disclosure that Petitioner alleges teaches each element of claim 1. *Id.* at 25–28.

Petitioner argues that one of ordinary skill in the art "would have had a reason to modify Gerber's method of administering ketoconazole to use abiraterone acetate, as taught in O'Donnell" because "abiraterone acetate is a potent and more selective inhibitor of CYP17 than ketoconazole and that abiraterone acetate effectively suppressed testosterone levels in both castrate and non-castrate males." Pet. 24 (citing Ex. 1002 ¶ 67). Additionally, Petitioner argues, one of ordinary skill in the art "would have had a reason to maintain coadministration of prednisone, as taught in Gerber, because prednisone was known to treat prostate cancer on its own, as demonstrated by Sartor." *Id.* (citing Ex. 1002 ¶ 68). Petitioner summarizes that one of ordinary skill in the art, reading Gerber, O'Donnell, and Sartor "would have had a reason to co-administer a therapeutically effective amount of prednisone with abiraterone acetate because (1) prednisone was known to treat prostate cancer and (2) prednisone would reduce the side effects of mineralocorticoid excess that could result from abiraterone acetate treatment." *Id.* at 33–34 (citing Ex. 1002 ¶¶ 83–84). Patent Owner does not specifically address Petitioner's arguments directed to how the prior art

allegedly teaches claim 1. *See generally* Prelim. Resp. Regarding dependent claims 2–20, Petitioner argues that the additional limitations found in the dependent claims also are obvious over Gerber, O'Donnell, and Sartor. *Id.* at 36–46. Patent Owner does not specifically address Petitioner's arguments directed to the dependent claims.

On this record, we are persuaded by Petitioner's arguments and presentation of the evidence. Gerber discloses co-administration of a glucocorticoid, prednisone, with ketoconazole for the safe and effective treatment of prostate cancer. Ex. 1004, 1179. O'Donnell suggests that co-administration of a glucocorticoid, of which prednisone is one, may be needed in connection with administration of abiraterone acetate in the treatment of prostate cancer. Ex. 1005, 2323. Ketoconazole and abiraterone acetate are both characterized as CYP17 inhibitors. *Id.* at 2318; Ex. 1002 ¶¶ 36, 38. Sartor discloses that, even without a concomitant anticancer therapy such as a CYP17 inhibitor, prednisone as a monotherapy results in a PSA decline in patients with hormone-refractory prostate cancer. Ex. 1006, 253–254. We are persuaded, on this record, that that a person of ordinary skill in the art "would have reasonably expected each of abiraterone acetate and prednisone to treat prostate cancer when co-administered" (Pet. 25) and that, therefore, Petitioner has demonstrated a reasonable likelihood of prevailing on its obviousness challenge to claim 1.

Claims 2–20 each depend directly or indirectly from claim 1. Petitioner contends these claims are also unpatentable under 35 U.S.C. § 103(a) based on Gerber, O'Donnell, and Sartor. Pet. 36–46. Concerning these claims, we determine that the supporting evidence demonstrates a

reasonable likelihood that Petitioner would prevail in its showing, the substance of which has not been addressed specifically by Patent Owner.

In view of the arguments and the evidence before us, therefore, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1–20 are obvious over Gerber, O'Donnell, and Sartor.

1. Objective Indicia of Non-Obviousness

Petitioner contends that the Patent Owner may try to rely on secondary considerations of non-obviousness. Pet. 46–65. Specifically, Petitioner pre-emptively raises arguments and evidence relating to unexpected results, commercial success, long-felt need and failure of others, and copying. Pet. 48–59. Patent Owner does not present any arguments directed to objective indicia of non-obviousness.

The issue of secondary considerations is highly fact-specific. At this stage of the proceeding, the record regarding such secondary considerations is incomplete. Based on the record before us, and Patent Owner's lack of argument on this issue, Petitioner's preemptive evidence regarding lack of objective indicia anticipates arguments not yet made by Patent Owner. Thus, we have an inadequate framework to determine whether evidence of secondary considerations is insufficient to preclude trial. Evidence of secondary considerations should be more fully evaluated in the context of a trial when the ultimate determination of obviousness is made. We conclude that the information presented in the Petition on the matter of obviousness establishes a reasonable likelihood that the Petitioner will prevail in challenges to claims 1–20 of the '438 patent, but we do not make any

determination as to objective indicia of non-obviousness on the record before us at present.

2. Patent Owner's Arguments

Patent Owner makes several arguments in its Preliminary Response, namely: (A) Petitioner fails to identify Amerigen as a real party-in-interest; and (B) the Petition should be denied under 35 U.S.C. § 325(d). We address these arguments in turn.

(A) Real party-in-interest

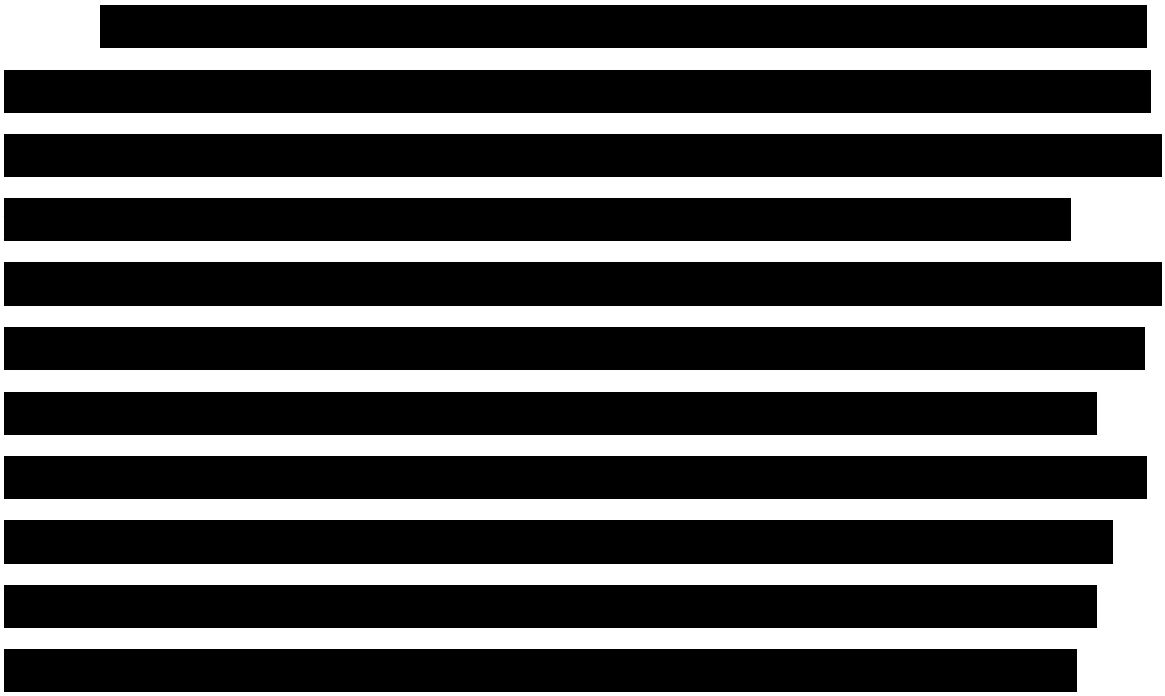
The Petition identifies as real parties-in-interest "Wockhardt Bio AG, Wockhardt Limited, Wockhardt USA LLC, Morton Grove Pharmaceuticals, Inc., and MGP Inc." Pet. 66. According to Patent Owner, however, because the Petition "fails to identify Amerigen as a RPI," it is "defective on its face and should be denied pursuant to 35 U.S.C. § 312(a)(2)." Prelim. Resp. 8.

A petition for *inter partes* review under 35 U.S.C. § 311 may be considered only if, among other things, the petition identifies all real parties-in-interest. 35 U.S.C. § 312(a)(2). The Office Patent Trial Practice Guide explains that, in the context of an *inter partes* review and at a general level, the real party-in-interest "is the party that desires review of the patent." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012). The real party-in-interest "may be the petitioner itself, and/or it may be the party or parties at whose behest the petition has been filed." *Id.*

Whether a non-identified party is a real party-in-interest to a proceeding is "a highly fact-dependent question" that is assessed "on a case-by-case basis taking into consideration how courts have viewed the term[] 'real party-in-interest.'" *Id.* (citing *Taylor v. Sturgell*, 553 U.S. 880 (2008)). "A common consideration is whether the non-party exercised or could have

exercised control over a party's participation in a proceeding." *Id.* (citing *Taylor*, 553 U.S. at 893–95). Relevant factors may include the non-party's relationship with the petitioner; the non-party's relationship to the petition itself, including the nature and/or degree of involvement in the filing; and the nature of the petitioner. *Id.* at 48,760.

The Board generally accepts a petitioner's real party-in-interest identification at the time of filing the petition. 77 Fed. Reg. 48,680, 48,695 (Aug. 14, 2012) (Changes to Implement *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, Response to Comment 9) ("The Office generally will accept the petitioner's 'real party-in-interest' identification at the time of filing the petition."). A "patent owner may provide objective evidence to challenge the identification in a preliminary response, which the Board will consider in determining whether to grant the petition." *Id.*



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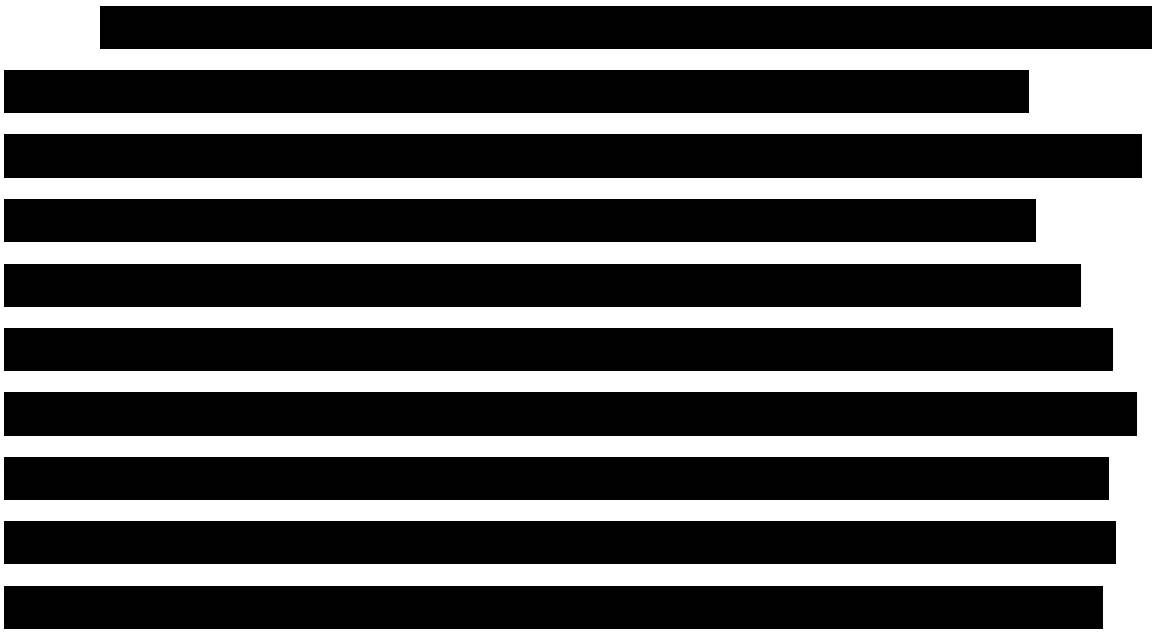
Petitioner responds that Amerigen is not a real party-in-interest, because "Amerigen has never funded, controlled, or in any other way been involved in this proceeding." Reply 1. Relying on the Declaration of corporate representative Mr. Gopal Venkatesan (Ex. 1081), Petitioner asserts that Patent Owner has not demonstrated "that Amerigen funded or had any ability to control this proceeding;" that Petitioner and Amerigen "are entirely separate and unrelated corporations;" that Petitioner has "no corporate relationship with Amerigen, has never entered into a contract of any sort with Amerigen, has never had a financial dealings with Amerigen, and did not coordinate or otherwise collaborate with Amerigen with respect to this IPR." *Id.* Rather, Petitioner and Amerigen "are nothing more than codefendants in a joint defense group with respect to the underlying district court litigation" and "deliberately chose not to be involved in each other's IPR filings." *Id.* at 1–2. Petitioner characterizes the settlement negotiations embodied in Exhibit 2002 as inadmissible under Fed. R. Evid. 408 as compromise offers and negotiations, but nevertheless argues that these communications do not establish funding or control by Amerigen, nor that Petitioner has authority to settle a dispute on Amerigen's behalf. *Id.* at 6–7.

Patent Owner replies that the undisputed evidence demonstrates that Wockhardt and Amerigen are more than just codefendants in a patent lawsuit. Surreply 2. Patent Owner criticizes Mr. Venkatesan's declaration for failing

to refer to the communication between Petitioner's counsel and Patent Owner's counsel, and as not credible on the issue of control. *Id.* at 3–4.

Although we may consider the relationship between the parties, the focus of our real party-in-interest inquiry is the relationship between a party and a proceeding. *Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, Case IPR2014–01288, slip op. at 11 (PTAB Feb. 20, 2015) (Paper 13). Patent Owner may provide objective evidence to challenge Petitioner's identification of real parties-in-interest in a preliminary response; here, Patent Owner provided an exhibit containing an email exchange between counsel for Petitioner and counsel for Patent Owner as the initial basis for its allegation, supported by a Declaration by Patent Owner's counsel. We are not persuaded at this juncture that FRE 408 applies to the email exchange, as the evidence is being offered for a purpose other than to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction. We have reviewed this email exchange and the Declaration and do not find them supportive of Patent Owner's allegations.



[redacted] Patent Owner provides no other evidence regarding its allegations.

In view of the arguments and testimony presented by the parties at this juncture regarding whether Amerigen is a real party-in-interest to this proceeding, we are not persuaded that Petitioner "fails to identify Amerigen" as a real party-in-interest.

(B) 35 U.S.C. § 325(d)

Patent Owner requests that the Board exercise its discretion under 35 U.S.C. § 325(d) and decline to initiate *inter partes* review of the '438 patent because the Petition presents the same prior art and substantially the same arguments as those presented in co-pending IPRs. Prelim. Resp. 15–21.

In the Petition, Petitioner preemptively makes arguments directed to Patent Owner's anticipated § 325(d) arguments: (1) the Petition relies on a different combination of prior art than the 286 IPR, including Sartor; (2) the Petition addresses the Board's construction of "therapeutically effective amount of prednisone;" (3) Petitioner's ground relies on the Godley Declaration and the Stoner Declaration, which have not been previously considered by the Board; (4) Petitioner has not previously challenged the '438 Patent and is not a party to the 286 IPR; and (5) the 286 IPR is still in the beginning stages. Pet. 22.

Patent Owner argues, first, that the petition in the Argentum IPR and the present petition "rely on the same prior art and the same or substantially the same arguments raised in the Amerigen IPR." Prelim. Resp. 16. Patent Owner discounts Sartor as "adding nothing of substance to the prior art and arguments already presented in the Amerigen IPR." *Id.* at 18. Patent Owner further argues that Petitioner is involved in the Amerigen IPR, as argued in

connection with its real party-in-interest arguments; that Petitioner's addressing the Board's claim construction is insufficient to justify institution of this petition; and that the Amerigen IPR is no longer in its beginning stages. *Id.* at 19–20.

We have discretion under 35 U.S.C. § 325(d) to reject a petition when the same or substantially the same prior art or arguments were presented previously to Office. The relevant portions of that statute are reproduced below:

> In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

35 U.S.C. § 325(d). In exercising our discretion under § 325(d), we take into account numerous factors, including the facts of each case, and the burden on the parties and the Board. *See Conopco, Inc. v. Proctor & Gamble Co.*, Case IPR2014-00506, slip op. at 4, 6 (PTAB Dec. 10, 2014) (Paper 25) (Informative), slip op. at 6 (PTAB July 7, 2014) (Paper 17), *cited in NVIDIA Corp. v. Samsung Elec. Co.*, Case IPR2016-00134, slip op. at 6–7 (PTAB May 4, 2016) (Paper 9); *see also* Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 77 Fed. Reg. 18750, 18759 (Apr. 1, 2016) ("[T]he current rules provide sufficient flexibility to address the unique factual scenarios presented to handle efficiently and fairly related proceedings before the Office on a case-by-case basis, and that the Office will continue to take into account the interests of justice and fairness to both petitioners and patent owners where multiple proceedings involving the same patent claims are before the Office.").

Although we have discretion to reject a petition when the same or substantially the same prior art or arguments previously were presented to the Office, we decline to exercise that discretion here. We agree that the present Petition and the Amerigen IPR petition rely on some of the same prior art. The present Petition, however, relies on Sartor, which was not a reference in the Amerigen IPR. The present Petition also does not rely on Barrie, a reference relied upon in the Amerigen IPR petition. Petitioner relies on different declarants than those relied upon in the Amerigen IPR. The depositions of those declarants, as well as the additional evidence and reference presented by Petitioner, may affect the course of this trial relative to the course of the trial in the Amerigen IPR.

Moreover, it appears that this case will involve arguments concerning objective indicia of non-obviousness, which involves a fact-specific analysis that often turns on evidence presented during trial. Pet. 46–65. A patent owner generally presents arguments based on objective indicia in response to a petitioner's allegations of obviousness. Here, Petitioner preemptively presented arguments directed to objective indicia. *Id.* Patent Owner presented arguments directed to objective indicia in its Preliminary Response in the Amerigen IPR (IPR2016-00286, Paper 12, 46–52), but has not presented the same arguments in the Preliminary Response in this case. As such, the objective indicia arguments possibly differ between the Amerigen IPR and the present case. Because evidence directed to objective indicia typically develops during trial, we cannot assume, at this stage, that the arguments to be made during the course of the trial are the same or similar to those made in IPR2016-00286.

Other than these differences, however, both the instant Petition and the petition in the Amerigen IPR assert similar challenges to patentability. We are mindful of the burden on Patent Owner and the Office to rehear the same or substantially the same prior art or arguments that were considered previously by the Office. However, given the similar challenges in these two proceedings, we do not perceive that either Patent Owner or the Board will be overwhelmed with an unreasonable number of challenges to patentability.

Unlike other cases in which we have exercised our discretion under § 325(d) to deny institution of a follow-on petition, based on the particular facts of this case, we are not presented with a second bite at the apple by an identical petitioner. In addition, in view of our grant, rather than denial, of institution in the Amerigen IPR, we do not perceive Petitioner as seeking to cure any problems of the petition in the Amerigen IPR with the filing of the present Petition. Also, we have not decided the outcome in IPR2016-00286.

In view of the challenges in the Petition, and having considered Patent Owner's Preliminary Response, we do not exercise our discretion to decline an *inter partes* review of the '438 patent under 35 U.S.C. § 325(d).

C. Conclusion

We conclude that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to its challenge of claims 1–20 of the '438 patent. We have not made, however, a final determination under 35 U.S.C. § 318(a) with respect to the patentability of the challenged claims. In view of the timeline of the Amerigen IPR, and in view of the number of common issues between the cases, we implement a condensed schedule in the present case to allow for resolution of these two cases involving the '438 patent in relative proximity to each other.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* review is instituted on the following ground of unpatentability asserted in the Petition:

Claims 1–20 as obvious under 35 U.S.C. § 103(a) over Gerber, O'Donnell, and Sartor; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '438 patent is hereby instituted commencing on the entry date of this decision, 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; and

FURTHER ORDERED that the trial is limited to the ground identified above and no other grounds are authorized.

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