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Paper 12
Entered: June 12, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

Case IPR2017-00323
Patent 6,943,166 B1

Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") to institute an *inter partes* review of claims 1–12 of U.S. Patent No. 6,943,166 B1 (Ex. 1001, "the '166 patent"). ICOS Corporation ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We review the Petition under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim, we institute an *inter partes* review of claims 1–12.

Related Proceedings

According to the parties, Patent Owner asserted the '166 patent against Petitioner in *Eli Lilly and Company et al. v. Mylan Pharmaceuticals Inc.*, No. 1:16-cv-01122 (E.D. Va.). Pet. 25; Paper 8, 2. Patent Owner also asserted the '166 patent against numerous other entities in the same district court. Pet. 25–26; Paper 8, 2–4.

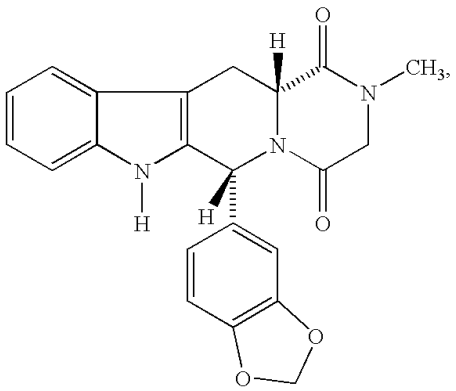
We previously denied a petition for *inter partes* review of the same challenged claims filed by IntelGenX Corp. *IntelGenX Corp. v. ICOS Corp.*, IPR2016-00678 (PTAB Sept. 1, 2016) (Paper 13). Thereafter, IntelGenX filed a request for rehearing, and we authorized Patent Owner to file a responsive brief. IPR2016-00678, Papers 14, 15. Before Patent Owner filed any responsive briefing, Petitioner withdrew its request. IPR2016-00678, Paper 16. We, thus, terminated that proceeding. IPR2016-00678, Paper 17.

The ’166 Patent

The ’166 patent relates to a highly selective phosphodiesterase (PDE) enzyme inhibitor, and its use in a pharmaceutical unit dosage form. Ex. 1001, Abstract, 1:14–16.

Type 5 cGMP-specific PDE (PDE5) is an attractive target in the treatment of sexual dysfunction. *Id.* at 1:34–39. The ’166 patent acknowledges a prior-art pharmaceutical product, which provides a PDE5 inhibitor, was available and marketed for treating male erectile dysfunction (“ED”) under the trademark VIAGRA®. *Id.* at 1:41–43. The active ingredient in VIAGRA® is sildenafil. *Id.* at 1:43–44. According to the ’166 patent, however, “[w]hile sildenafil has obtained significant commercial success, it has fallen short due to its significant adverse side effects.” *Id.* at 1:58–60.

The ’166 patent discloses a pharmaceutical unit dosage composition comprising about 1 to about 20 mg of compound tadalafil, which has the following structure:



Id. at 3:11–28. The ’166 patent discloses that the pharmaceutical unit dosage is suitable for oral administration, and is useful for treating sexual dysfunction. *Id.* at 3:29–31.

Illustrative Claim

Claim 1 is the sole independent claim challenged in the Petition. It reads:

> 1. A method of treating sexual dysfunction in a patient in need thereof comprising orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of a compound having the structure [of formula (I)].

Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–12 based on a single ground—obviousness over the combination of Daugan,[1] SNDA,[2] and the FDA Guideline.[3]

In support of its patentability challenges, Petitioner relies on the Declaration of Drs. George Grass (Ex. 1002) and Muta M. Issa (Ex. 1004).

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary

[1] Daugan, International Publication No. WO 97/03675, published Feb. 6, 1997 (Ex. 1007, "Daugan").
[2] Center for Drug Evaluation and Research, Approval Package for VIAGRA®, Approval Date March 27, 1998 (Ex. 1008, "SNDA").
[3] Dose-Response Information to Support Drug Registration, 59 Fed. Reg. 55972 (Nov. 9, 1994) (Ex. 1009, "the FDA Guideline").

skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, we see no need to construe any term expressly.

Disclosures of Asserted Prior Art

Daugan

Daugan identifies (6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylene-dioxyphenyl)pyrazino[2',1':6.1] pyrido[3,4-b]indole-1,4-dione, also known as compound (A), as a compound of the invention. Ex. 1007, 3:24–25. Compound (A) is the same as the compound of the formula in the '166 patent set forth above, i.e., tadalafil.

Daugan teaches that tadalafil is useful for treating male or female sexual dysfunction. *Id.* at 4:25–28. According to Daugan, tadalafil may be administered orally to treat ED. *Id.* at 3:30–32. It also teaches that "for a typical adult patient, individual tablets or capsules contain from 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day," and that generally, the dosage is "in the range of from 0.5-800mg daily." *Id.* at 5:1–7. Further, Daugan teaches preparing tablets with 50 mg active compound. *Id.* at 12:15–14:16.

SNDA

SNDA teaches sildenafil is a potent PDE5 inhibitor and is useful for treating ED. Ex. 1008, 35. Sildenafil is therapeutically effective for treating ED at doses of 25, 50, and 100 mg. *Id.* at 127–28, 215, 217–19. According to SNDA, in some patients, doses as low as 5 and 10 mg are therapeutically effective over placebo. *Id.* SNDA states that the "maximum recommended dosing frequency is once per day." *Id.* at 50.

The FDA Guideline

The FDA guideline "describes why dose-response information is useful and how it should be obtained in the course of drug development. This information can help identify an appropriate starting dose as well as how to adjust dosage to the needs of a particular patient. It can also identify the maximum dosage beyond which any added benefits to the patient would be unlikely or would produce unacceptable side effects." Ex. 1009, 55972.

Level of Ordinary Skill

Petitioner argues that an ordinary artisan at the time of the '166 patent invention would have "some combination of (a) experience with the research or development of pharmaceuticals; (b) the ability to gather and interpret pharmacokinetic and pharmacodynamics data including dose-response curves; and (c) the ability to understand results and findings presented or published by others in the field, including the references discussed in this Petition." Pet. 15 (citing Ex. 1002 ¶¶ 38–39; Ex. 1004 ¶¶ 24–25). According to Petitioner, an ordinary artisan "would have, or would be a member of a team with individuals having, a Pharm.D. or Ph.D. with experience in clinical pharmacology, medicinal chemistry, or in a related field." *Id.* at 16. In addition, Petitioner contends, an ordinary artisan "may

also have, or have access as part of a team to a person having, an M.D. with experience in the field of urology, with specific experience in sexual dysfunction." *Id.*

Patent Owner contends that Petitioner's proposed definition of the skill level "does not require any expertise in the claimed subject matter" because Petitioner states that an ordinary artisan *may* have an M.D. with experience in urology.[4] Prelim. Resp. 21. According to Patent Owner, an ordinary artisan "would have been a team including, or an individual having the collective experience of, at least: (1) a scientist having a Ph.D. in pharmacy, or an equivalent discipline, with approximately seven years of experience in preclinical and clinical pharmacokinetics and pharmacodynamics; and (2) a board certified M.D. with a specialty in the medical management of sexual dysfunction, including approximately seven years of experience in its research, diagnosis, and/or treatment." *Id.* at 19–20.

We agree with Patent Owner that an ordinary artisan would have, or have access to, an M.D. with a specialty in the medical management of sexual dysfunction. Indeed, Dr. Grass, the declarant for Petitioner, testifies that "as pharmaceutical development is an inherently collaborative process, the skilled artisan would have access to, or be part of a team including, other skilled individuals such as an M.D. with experience in the field of urology,

[4] Patent Owner represents that Petitioner's definition is "without reference to the sexual dysfunction subject matter." Prelim. Resp. 21. We disagree. The Petition specifically states that an ordinary artisan may have an M.D. with experience in urology, "with specific experience in sexual dysfunction." Pet. 16.

with specific experience in sexual dysfunction." Ex. 1002 ¶ 38.

Aside from the medical expertise in managing sexual dysfunction, we do not discern other appreciable differences in the parties' respective definitions of the level of ordinary skill in the art. Both parties contend that a person of ordinary skill in the art would have experience with and knowledge of pharmaceutical development, including preclinical and clinical pharmacokinetics and phamacodynamics. Pet. 15; Prelim. Resp. 20. Both parties acknowledge that an ordinary artisan would have access to, or be part of a multidisciplinary team of specialists. Prelim. Resp. 20; Ex. 1002 ¶ 38. Thus, on this record, we determine it is unnecessary to resolve any other perceived differences in the parties' definitions of the level of ordinary skill in the art, as any distinction does not impact our Decision.

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)).

Obviousness over Daugan, SNDA, and the FDA Guideline

Petitioner contends that claims 1–12 would have been obvious over the combined teachings of Daugan, SNDA, and the FDA Guideline. Pet. 20–46. Based on the current record, we determine Petitioner has established a reasonable likelihood that it would prevail in this assertion.

Petitioner argues that SNDA qualifies as prior art under 35 U.S.C. § 102(b). Pet. 11–14. Patent Owner disagrees. Prelim. Resp. 8–19. At this

stage of the proceeding, having reviewed the parties' arguments and supporting evidence, we determine that Petitioner has presented sufficient evidence regarding the prior-art status of SNDA.

To qualify as a printed publication, a reference "must have been sufficiently accessible to the public interested in the art" before the critical date. *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989). Whether a reference is publicly accessible is determined on a case-by-case basis based on the "facts and circumstances surrounding the reference's disclosure to members of the public." *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009). A reference is considered publicly accessible if it was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it. *Id.*

Petitioner points out that the "FDA approved sildenafil (VIAGRA®) on March 27, 1998." Pet. 13 (citing Exs. 1008, 1032). Petitioner refers to a printout of an FDA webpage showing the table of contents of SNDA, and emphasizes the statement on the printout: "Date created: March 27, 1998." *Id.* at 13; Ex. 1031. Patent Owner challenges that Petitioner has not shown the "Date created" language in Exhibit 1031 relates to the underlying documents (i.e., SNDA), and not merely the webpage with the table of contents of SNDA. Prelim. Resp. 12–13. In addition, Patent Owner contends that even if SNDA was created on the "Date created," as shown in Exhibit 1031, "this does not alone establish" the public availability of SNDA on that date. *Id.* at 12–13.

We agree with Patent Owner that Exhibit 1031, by itself, does not show that SNDA was publicly available on March 27, 1998. This exhibit,

however, is not the only evidence Petitioner relies on.[5]

Under 21 C.F.R. § 314.430(e), after FDA sends an approval letter to the applicant of a new drug, certain data and information in the application are "immediately available for public disclosure." These data and information include "a summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the application," including "a Summary Basis of Approval (SBA) document that contains a summary of the safety and effectiveness data and information evaluated by FDA during the drug approval process." 21 C.F.R. § 314.430(e)(2)(ii).

Petitioner asserts that an ordinary artisan would have been aware of the approval of sildenafil on March 27, 1998 because it "was publicized broadly that same day." Pet. 13–14 (citing Exs. 1033–34). According to Petitioner, after FDA sent the approval letter to the applicant on March 27, 1998, SNDA became "immediately available for public disclosure" under 21 C.F.R. § 314.430(e). *Id.* at 12–13. Thus, Petitioner argues that an ordinary artisan, upon the approval of sildenafil on March 27, 1998, "could have requested and obtained the documents containing the safety and effectiveness information contained within" the SNDA. *Id.* at 14.

Patent Owner challenges that Petitioner has not submitted any expert declaration to support its assertion. Prelim. Resp. 15. Patent Owner also questions whether SNDA corresponds to the "safety and effectiveness data"

[5] To the extent Patent Owner challenges the admissibility of Exhibit 1031 (*see* Prelim. Resp. 12–13), the proper avenue is through a motion to exclude. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012).

under 21 C.F.R § 314.430(e), pointing out that SNDA contains sections that "on their face appear to *not* be 'safety and effectiveness data.'" *Id.* at 16. In addition, relying on a 2003 report by the Office of the Inspector General (Ex. 2005) and the 2014 CDER Manual of Policies and Procedures titled "Communicating Drug Approval Information" (Ex. 2006), Patent Owner contends that "immediately available" does not mean documents are available to the public on the very day a drug is approved. *Id.* at 16–17. We are not persuaded by Patent Owner's arguments.

First, the documents Patent Owner relies on, i.e., the report by the Office of the Inspector General and the CDER Manual of Policies and Procedures, are from 2003 and 2014, respectively. *Id.* at 16–17; Exs. 2005, 2006. Sildenafil, however, was approved in 1998. Ex. 1032. Thus, at this stage of the proceeding, although we consider Exhibits 2005 and 2006, we accord them limited weight. Second, the majority of SNDA is directed to "Joint Clinical Reviews," "Pharmacology Reviews," "Statistical Review and Evaluation" including "Carcinogenicity Review," and "Carcinogenicity Assessment Committee Report and FDA-CDER Rodent Carcinogenicity Database Factsheet." Ex. 1008, 2–257, 264–496. Patent Owner does not dispute that these sections are directed to the "safety and effectiveness" of sildenafil. Thus, we are not persuaded that the mere inclusion of other sections would disqualify SNDA as the "safety and effectiveness data" under 21 C.F.R § 314.430(e). Third, we do not find the lack of expert testimony here fatal to the Petition. To be sure, direct evidence, such as a declaration, would have been more persuasive in establishing the public availability of SNDA. Nevertheless, for purposes of deciding whether to institute an *inter partes* review in this case, we find Petitioner presented has

sufficient indirect evidence, including the broadly publicized approval of sildenafil and the FDA regulation, regarding the prior-art status of SNDA.

Substantively, Petitioner points to Daugan for teaching tadalafil as a "potent and selective" inhibitor of PDE5, and thus, is useful in treating sexual dysfunction. Pet. 31–32 (citing Ex. 1007, 1, 3–4, 6). Petitioner also relies on Daugan for teaching administering tadalafil orally to avoid "the disadvantages associated with i.c. administration." Ex. 1007, 3–4; Pet. 32–33. Petitioner refers to Daugan for teaching tadalafil formulations comprising individual tablets or capsules containing "from 0.2-400mg of active compound, . . . for administration in single or multiple doses, once or several times per day." Pet. 32 (citing Ex. 1007, 5).

According to Petitioner, "[i]t was a routine matter for a person of ordinary skill in the art to identify a safe and effective dose range of tadalafil for the treatment of sexual dysfunction." Pet. 33 (citing Ex. 1002 ¶ 71). In support, Petitioner refers to the FDA Guideline for teaching the development of dose-responsive information. *Id.* at 33–34.

Petitioner contends that an ordinary artisan would have had a reason to look to SNDA to inform the dose-ranging studies for tadalafil because tadalafil and sildenafil "were known to have utility for the same indication, as well as share a common enzymatic target, PDE5, and the adverse events associated with PDE5 inhibition." *Id.* at 34–35. In addition, according to Petitioner, tadalafil is a more potent inhibitor of PDE5 than sildenafil. *Id.* at 35 (citing Ex. 1002 ¶ 75); *compare* Ex. 1007, 17 (showing IC_{50} for tadalafil is 2 nM) *with* Ex. 1008, 37 (showing IC_{50} for sildenafil is 3.5 nM).

Petitioner argues that an ordinary artisan "would expect that lower doses of tadalafil would achieve similar efficacy as higher doses of sildenafil

in the treatment of sexual dysfunction." Pet. 35 (citing Ex. 1002 ¶¶ 77–78). Petitioner further contends that an ordinary artisan would have appreciated the lower doses of tadalafil would result in lower frequencies of adverse events because they were known to be "clearly dose-related." *Id.* at 35–36. As a result, Petitioner asserts, an ordinary artisan would have been motivated to look to the doses of sildenafil, as taught in SNDA, to identify the doses of tadalafil that are efficacious while retaining favorable adverse event profiles. *Id.*

Petitioner points to SNDA for teaching that sildenafil is therapeutically effective in treating ED at doses as low as 5 mg and as high as 100 mg. *Id.* at 36 (citing Ex. 1008, 126–28). Citing the testimony of Dr. Grass, Petitioner argues that "these doses, adjusted for the increased potency of tadalafil, are expected to be approximately equivalent to tadalafil doses of 2.8 mg and 57 mg, respectively." *Id.* (citing Ex. 1002 ¶ 79); *see also* Ex. 1002 ¶ 77 (calculating the predicted doses of tadalafil based on the doses of sildenafil and the ratio of IC_{50} values).

Petitioner emphasizes the teaching of SNDA that a dose of 25 mg sildenafil "is already fairly high on the dose-response curve." Pet. 37 (citing Ex. 1008, 70). According to Petitioner, 25 mg of sildenafil is approximately equivalent to 15 mg of tadalafil. *Id.* (citing Ex. 1002 ¶¶ 77–78). Relying on the testimony of Dr. Grass, Petitioner contends that an ordinary artisan "would have reasonably expected a 15 mg dose of tadalafil to be near the top of the tadalafil dose-response curve based on the PDE5 inhibition results disclosed" in the SNDA. *Id.* (citing Ex. 1002 ¶ 78).

Petitioner also refers to SNDA for repeatedly teaching that sildenafil is to be administered "not more than once per day," and for conducting the

dose-ranging studies using once-daily dosing of sildenafil. *Id.* at 35 (citing Ex. 1008, 126, 132, 139, 146, 155, 217, 223, 238, 245, 251). In view of this teaching, Petitioner asserts that administering tadalafil in a unit dose of 15 mg once daily meets the limitations of the challenged claim 1, i.e., "the unit dose must be between 1 to 20 mg and the total daily dose of tadalafil be no larger than 20 mg." *Id.* at 38 (citing Ex. 1002 ¶ 82).

At this stage of the proceeding, we find that Petitioner has offered sufficient evidence to institute trial. Although Patent Owner's arguments are not unreasonable, they do not persuade us that we should decline to go forward with a trial.

For example, Patent Owner challenges the assertion by Petitioner that the doses of tadalafil can be predicted based on the doses of sildenafil and the ratio of the IC_{50} values. Prelim. Resp. 24. Patent Owner contends that Dr. Grass, the declarant for Petitioner, cites no support for his testimony that "Potencies, as expressed in terms of IC_{50} and EC_{50} of known pharmaceuticals having a common target, can be compared to yield estimates of appropriate dosing." *Id.* (quoting Ex. 1002 ¶ 55). We note that Dr. Grass cites Exhibits 1015 and 1025 to support the two sentences immediately preceding the quoted statement. See Ex. 1002 ¶ 55 (citing Ex. 1015, 50; Ex. 1025, 27). Considering this paragraph of Dr. Grass's testimony as a whole, we are not persuaded that the challenged testimony is, as Patent Owner contends, entirely unsupported.

In addition, according to Patent Owner, Petitioner has neither addressed the structural difference between tadalafil and sildenafil, nor explained the propriety of extrapolating *in vitro* data, such as IC_{50}, to predict *in vivo* effects in patients. *Id.* at 24–25. Based on the current record, in

which Petitioner's declarant has drawn plausible comparisons as to the relative potency of tadalafil to sildenafil, these are merely attorney argument as to how such structural or *in vitro* versus *in vivo* differences would affect the obviousness inquiry. We would be better equipped to resolve these factual disputes after the record is fully develop during trial.

Patent Owner asserts that even if the doses of tadalafil can be predicted based on the doses of sildenafil and the ratio of IC_{50} values, it would have led to a maximum of at least 57 mg tadalafil, which corresponds to the maximum dose of 100 mg sildenafil. Prelim. Resp. 27. Thus, according to Patent Owner, an ordinary artisan "would not have been motivated to limit the dose of tadalafil to a maximum of 20 mg per day, as claimed." *Id.* Based on the current record, we are not persuaded by this argument.

> As Petitioner points out, the FDA Guideline teaches that
>
> > Historically, drugs have often been initially marketed at what were later recognized as excessive doses (i.e., doses well onto the plateau of the dose-response curve for the desired effect), sometimes with adverse consequences. . . . What is most helpful in choosing the starting dose of a drug is knowing the shape and location of the population (group) average dose-response curve for both desirable and undesirable effects. Selection of dose is best based on that information, together with a judgment about the relative importance of desirable and undesirable effects.

Pet. 33 (quoting Ex. 1009, 55973).

Although SNDA teaches the maximum dose of 100 mg sildenafil, it also teaches that sildenafil is therapeutically effective in treating ED at doses as low as 5 mg. Ex. 1008, 126–28. In addition, SNDA teaches that a dose of 25 mg sildenafil "is already fairly high on the dose-response curve" (*id.* at 70), and that the frequencies of adverse events are "clearly dose-related" (*id.*

at 95). Thus, an ordinary artisan would have taken these teachings into consideration in identifying the optimal maximum dose of tadalafil.

Patent Owner further argues that "Petitioner's obviousness analysis tries to merge 'a maximum total dose of 20 mg per day' and 'one or more unit dose containing about 1 to about 20 mg' together." Prelim. Resp. 27. We are not persuaded. As we understand the Petition, Petitioner relies on the unit doses of sildenafil and the ratio of IC_{50} values to account for the unit doses of tadalafil. *See* Pet. 39–40 (citing Ex. 1002 ¶¶ 76–79). Petitioner then relies on the teaching in SNDA that sildenafil is administered "not more than once per day" to account for the maximum total dose per day. *Id.* at 35 (citing Ex. 1008, 126, 132, 139, 146, 155, 217, 223, 238, 245, 251).

Patent Owner argues that Petitioner improperly relies on the disclosure of the challenged '166 patent (i.e., tadalafil in a 10 mg dosage form) to support the limitation of maximum daily dose. Prelim. Resp. 28 (citing Pet. 28). We are not persuaded by this argument, either. Petitioner proposes that we construe claim 1 to require "the unit dose is in the range of 1 to 20 mg ***and*** that the total daily dose does not exceed 20 mg" (Pet. 28), which Patent Owner does not dispute (Prelim. Resp. 22). Again, as we understand the Petition, in support of its proposed construction, Petitioner merely states that the most preferred dose disclosed in the '166 patent satisfies the limitations of claim 1 because (1) a 10 mg dosage form meets the requirement of a "unit dose containing about 1 to about 20 mg;" and (2) when administered once per day, meets the requirement of "up to a maximum total dose of 20 mg per day." *See* Pet. 28.

In sum, based on the current record, we conclude that Petitioner has established a reasonable likelihood of prevailing on its assertion that claim 1

would have been obvious over the combined teachings of Daugan, SNDA, and the FDA Guideline.

CONCLUSION

For the foregoing reasons, we find that Petitioner has offered sufficient evidence to institute an *inter partes* review. The information presented in the Petition and accompanying evidence establishes a reasonable likelihood that Petitioner would prevail in showing the unpatentability of claim 1of the ’166 patent.

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

ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted to determine whether claims 1–12 of the ’166 patent would have been obvious over the combination of Daugan, SNDA, and the FDA Guideline.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the ’166 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.

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