

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOSPIRA, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-00731
Patent 7,846,441 B1

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

YANG, Administrative Patent Judge.

DECISION
Patent Owner's Request for Rehearing
37 C.F.R. § 42.71(d)

BACKGROUND

Petitioner challenges claims 1–14 of the '441 patent as obvious over (1) Baselga '94 and Baselga '97, and (2) Baselga '94 and Baselga '96.

Paper 1. We initially instituted on Ground 2, based on Baselga '94 and Baselga '96, but denied institution of Ground 1, based on Baselga '94 and Baselga '97. Paper 29. On December 22, 2017, Patent Owner filed its Response and a Motion to Amend. Papers 48, 50.

On May 9, 2018, after the Supreme Court's decision in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), and in view of the Office Guidance on the Impact of SAS on AIA Trial Proceedings,¹ we modified our institution decision to include Ground 1 and set August 2, 2018 as the date for a supplemental hearing on that issue. Paper 87.

On May 18, 2018, we held an oral hearing on Ground 2 and Patent Owner's Motion to Amend.² See Paper 104.

On June 7, 2018, at Patent Owner's request, we held a conference with the parties to discuss whether Patent Owner may file another motion to

¹ <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>.

² On May 18, we also heard arguments in IPR2017-01121, in which Celltrion, Inc., a different petitioner, challenged the same claims of the '441 patent. IPR2017-02063, filed by the same Petitioner in the current proceeding, had been joined to the Celltrion IPR. Patent Owner filed a motion to amend in IPR2017-01121, which is identical to the one filed in this case. Further, on May 18, we heard arguments in IPR2017-00737 (and a case joined thereto, IPR2017-01960), and IPR2017-01122, filed by Petitioner in the current proceeding and Celltrion, respectively, challenging a patent in the same family as the '441 patent. None of IPR2017-00737, -01121, -01122, -01960, and -2063 has any SAS related issues.

amend in view of the newly instituted Ground 1. Ex. 2150. Based on 35 U.S.C. § 316(d)(1) and 37 C.F.R. § 121(a), we informed the parties that the panel will consider a single motion to amend. Paper 101, 3. In view of 35 U.S.C. § 316(d)(2) and 37 C.F.R. § 42.121(c), however, we authorized Patent Owner to file a second motion to amend with respect to Ground 1, but required that for any such motion to be considered, Patent Owner “must establish the ‘good cause showing’ as required in 37 C.F.R. 121(c).” *Id.*

On June 18, 2018, at Petitioner’s request, we held another conference with the parties to discuss Petitioner’s proposal to withdraw Ground 1 from further consideration in this proceeding. Ex. 2155. Patent Owner opposed Petitioner’s proposal. *Id.* at 17:1–18:5. During the conference, Patent Owner also argued that it has, “as a matter of right,” an opportunity to file the second motion to amend, contrary to our earlier instruction. *Id.* at 24:4–6.

In view of Patent Owner’s argument that “the good cause standard should not be applicable in this particular situation” (*id.* at 13:6–7), we modified our June 8 order (Paper 101) and required that Patent Owner must first file a motion to show good cause. Paper 103 (“Order”), 3. We explained that if Patent Owner is able to establish the “good cause showing” required by 37 C.F.R. § 42.121(c), the panel will issue an order authorizing Patent Owner to file a second motion to amend. *Id.* We authorized Petitioner to file a response (*id.*) and Patent Owner to file a reply (Paper 108). The parties has completed briefing. Papers 105, 107, 112. Concurrently with this Decision, we issue a decision on Patent Owner’s Motion Regarding Good Cause. Paper 115. Patent Owner now files a Request for Rehearing of our Order requiring Patent Owner to brief the issue

of good cause before we authorize any additional motion to amend.
Paper 113.

For the following reasons, we deny Patent Owner's Request.

STANDARD OF REVIEW

A party dissatisfied with a decision may file a request for rehearing. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply. 37 C.F.R. § 42.71(d).

DISCUSSION

Patent Owner argues that to the extent our Order "definitively resolved that PO must show 'good cause' in these circumstances, that decision would be an abuse of discretion because it takes away PO's statutory right to amend under 35 U.S.C. § 316(d)(1) and does not comply with the Administrative Procedure Act ('APA')." Reh'g. Req. 2.

In our Order, we stated that "[t]o the extent that Patent Owner suggests we should not impose any good-cause requirement on Patent Owner in view of the Supreme Court's decision in *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018), we disagree." Order 2. Patent Owner alleges that we "disagreed without providing any reasoned basis for its conclusion." Reh'g. Req. 8. Patent Owner mischaracterizes our Order. Immediately after the sentence "we disagree," we explained:

As previously explained, under the statute, generally, during an *inter partes* review, "the patent owner may file 1 motion to amend." 35 U.S.C. § 316(d)(1); *see also* 37 C.F.R. § 42.121(a).

“Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.” 35 U.S.C. § 316(d)(2). The Regulation provides that “[a]n additional motion to amend *may be authorized when there is a good cause showing* or a joint request of the petitioner and the patent owner to materially advance a settlement.” 37 C.F.R. § 42.121(c) (emphasis added).

Because we clearly explained that the Rule, which states that we may not authorize an additional motion to amend without a good cause showing, we did not misapprehend or overlook any matter, or abuse our discretion, in requiring Patent Owner to first file a motion to show good cause.

Patent Owner argues that “[r]equiring ‘good cause’ under these circumstances would deprive PO of its statutory right to amend ‘[d]uring an inter partes review instituted under this chapter.’ 35 U.S.C. § 316(d)(1).” Reh’g. Req. 9. Patent Owner fails to mention that it has already filed a Motion to Amend (Paper 48) and defended that Motion (Paper 71), as authorized by 35 U.S.C. § 316(d)(1). As explained below, that Motion must be assessed based on the “entire record,” including Baselga ’97. Thus, we did not deprive Patent Owner its statutory right.

Patent Owner further argues that imposing a good cause requirement in this case would violate the notice requirement under the APA because “both the law and facts have changed over the course of this proceeding.” Reh’g. Req. 11. According to Patent Owner, “this is PO’s first opportunity to amend in response to Ground 1 [because t]hat ground had not been instituted at the time of PO’s original MTA and only came into the proceeding in the wake of the Board’s post-SAS guidance.” *Id.* at 14. We disagree.

As a general matter, “[d]uring an inter partes review . . . the patent owner may file 1 motion to amend the patent.” 35 U.S.C. § 316(d)(1). The statute, thus, permits a patent owner to file a single motion to amend regardless of how many claims or grounds are in a proceeding. The mere addition of another ground to the proceeding, in and of itself, does not afford a patent owner an opportunity to a second motion to amend as a matter of right. That is especially so in this case. First, the originally instituted review based on Ground 2 covers all challenged claims.³ Second, the disclosures of Baselga ’97, although not identical, are similar, to those of prior art already asserted in Ground 2. Indeed, as Patent Owner acknowledges, Baselga ’97 discloses the design of an ongoing phase III clinical trial, whereas Baselga ’96 similarly discloses “the clinical development of rhuMAb HER2 in combination with chemotherapy—*i.e.*, that ‘clinical trials of such combination therapy are currently in progress.’” Paper 105 (citing Ex. 1004, 15; Ex. 1006, 10).

Importantly, Patent Owner has received adequate notice with regard to Baselga ’97 as it applies to the motion to amend in this *inter partes* review. Baselga ’97 was asserted in the Petition (Paper 1, 25–42) and discussed in Patent Owner’s Preliminary Response (Paper 9, 34–48). Initially, we exercised our discretion under 35 U.S.C. § 325(d) and declined to institute

³ Patent Owner argues that it has been the Board’s practice to “allow[] MTAs post-institution where new grounds involving new references have come into an IPR as a result of SAS.” Paper 105, 8–9 (citing *Coastal Indus., Inc. v. Shower Enclosures Am., Inc.*, IPR2017-00573, Paper 49; *Masabi Ltd. v. Bytemark, Inc.*, IPR2017-01449, Paper 21). But in *Coastal Industries* and *Masabi*, the newly instituted grounds challenged additional claims. Here, Ground 1 does not add any claim into the proceeding.

an *inter partes* review of Ground 1 because, during prosecution, the applicant successfully antedated Baselga '97. Paper 19, 7–8. Although we, therefore, dismissed Baselga '97 in our analysis of the original claims, it is part of the record in determining the patentability of any amended claim. That is because priority, and thus, evidence for antedating purposes, must be analyzed on a claim-by-claim basis. Accordingly, as part of the record in this proceeding, Baselga '97 must be considered in analyzing any proposed amended claim. *See Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1296, 1325 (Fed. Cir. 2017) (en banc) (instructing that the entirety of the record must be considered when assessing the patentability of amended claims under § 318(a)).

Patent Owner recognizes those points. When Petitioner again asserted Baselga '97 in opposition to Patent Owner's first Motion to Amend (Paper 63, 21–23), Patent Owner again attempted to antedate the reference (Paper 71, 11–12). Perhaps more clearly demonstrating the point is Patent Owner's current pursuit of “an amended claim that does not antedate Baselga '97” in an additional motion to amend. Reply 2. Simply put, when it filed the first Motion to Amend, Patent Owner recognized Baselga '97 as part of the record that we must consider in assessing the patentability of the amended claim. Patent Owner also knew it could either antedate the reference, as it did in its first Motion to Amend, or amend the claim differently so that the amended claim does not antedate Baselga '97, as it now attempts to do in an additional motion. Patent Owner *chose* its course in that regard; it may not acquire a second chance as a matter of right based upon an unsubstantiated lack of notice.

Because Patent Owner had adequate notice that its proposed amendment must be analyzed based on the entirety of the record, including Baselga '97, Patent Owner has not adequately supported its assertion that imposing a good cause requirement would violate the notice requirement under the APA. Accordingly, we reject Patent Owner's contention that it is entitled to file a second motion to amend as a matter of right, i.e., without showing good cause.

Patent Owner asserts that

The Board's guidance on amendment practice has changed drastically since PO filed its original MTA. At that time, the Board's then-informative decision in *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012-00027, Paper 26 (June 11, 2013) suggested a restrictive approach requiring each portion of an amendment on its own to be responsive to the instituted grounds. The Board's recent informative guidance on amendment practice, however, has disavowed any such restrictions. *Western Digital Corp. v. SPEX Techs., Inc.*, IPR2018-00082, -00084, Paper 13 at 6 (Apr. 25, 2018)

Reh'g. Req. 12. We are not persuaded by this argument, either.

First, Patent Owner states that its second proposed motion to amend would change the limitation from without increase in "severe adverse events" to without increase in "Grade 3/4 myocardial dysfunction, as compared to a combined treatment of doxorubicin or epirubicin [anthracyclines]; cyclophosphamide; and rhuMAb HER2." Paper 105, 1–2. Patent Owner does not point to, and we do not discern, any evidence that this amendment is specifically responsive to Baselga '97. Compare *id.* at 8 (contending that the claim it intends to propose in the second motion to amend "specifically recites the unexpected clinical outcomes disclosed in the '441 patent"), with Paper 48, 4 (arguing a proposed claim limitation in the

first Motion to Amend “directly corresponds to the specific clinical results reported in the ’441 patent’s specification”) (citing Ex. 1001 at 29:9–30:25).

Second, according to Patent Owner, the designation of *Western Digital* as informative on June 1, 2018, and the simultaneous de-designation of *Idle Free* as informative, amount to a drastic change in the Board’s guidance on amendment practice. Reh’g. Req. 12. Patent Owner filed both its first Motion to Amend and the reply in support thereof months before the alleged change. Yet, in its first Motion to Amend, Patent Owner did include amendments that were not responsive to the instituted ground. And Patent Owner admitted so. Indeed, in the first Motion to Amend, citing *Veeam Software Corp. v. Veritas Techs., LLC*, IPR2014-00090, Paper 48 at 28-29 (PTAB July 17, 2017), Patent Owner argued that “[i]t is not required that **every** amended limitation be solely for the purpose of overcoming an instituted ground.” Paper 48, 8 n.3; *see also* Paper 71, 2 (arguing in the reply that when assessing responsiveness, “[t]he amendments are to be read **together**” and as long as some amendments are responsive, other amendments “do not make the Substitute Claim any **less** responsive to the institution”) (citing *Apple v. Realtime Data LLC*, IPR2016-01737, Paper 57 at 45 (Mar. 13, 2018)).

In sum, *Western Digital* may be newly-designated as informative; but the legal position it stands for, which Patent Owner fully embraced when filing its first Motion to Amend, is not new. As a result, the designation of *Western Digital* does not justify that Patent Owner can file, as a matter of right, an additional motion to amend in this case.

In sum, Patent Owner has not shown that we abused our discretion in requiring Patent Owner to brief the issue of good cause before we authorize

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any additional motion to amend. We, therefore, deny Patent Owner's Request for Rehearing.

ORDER

Accordingly, it is

ORDERED that Patent Owner's Request for Rehearing is denied.

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PETITIONER:

Amanda Hollis
amanda.hollis@kirkland.com
Stefan Miller
Stefan.Miller@kirkland.com
Mark McLennan
mark.mclennan@kirkland.com
Benjamin Lasky
blasky@kirkland.com
Christopher Citro
christopher.citro@kirkland.com

PATENT OWNER:

David Cavanaugh
david.cavanaugh@wilmerhale.com
Lauren Blakely
lauren.blakely@wilmerhale.com
Robert J. Gunther, Jr.
Robert.Gunther@wilmerhale.com
Lisa J. Pirozzolo
Lisa.Pirozzolo@wilmerhale.com
Andrew J. Danford
Andrew.Danford@wilmerhale.com
Kevin S. Prussia
Kevin.Prussia@wilmerhale.com

Adam Brausa
abrausa@durietangri.com
Daralyn J. Durie
ddurie@durietangri.com