

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD.,
Petitioner,

v.

ATOSSA THERAPEUTICS, INC,
Patent Owner.

PGR2025-00043
Patent 12,071,391 B2

Before SHERIDAN K. SNEDDEN, CHRISTOPHER C. KENNEDY, and
JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

ORDER
Conduct of the Proceeding
Information and Guidance on Patent Owner's Proposed Motion to Amend
37 C.F.R. § 42.5

I. INTRODUCTION

A conference call was held on Tuesday, January 13, 2026, among Megan Raymond, counsel for Patent Owner; Alejandro Menchaca and Ben Mahon, counsel for Petitioner; and Administrative Patent Judges Snedden, Kennedy and Wisz. The purpose of the call was to discuss Patent Owner’s intention to file a motion to amend and, thus, meet its duty to confer as required by 37 C.F.R. § 42.221(a).

Our Scheduling Order sets forth guidance on motions to amend. We expand on that guidance below.

II. MOTION TO AMEND

As provided by Congress, patent owners are entitled to file a motion to amend in post-grant reviews. Specifically, 35 U.S.C. § 326(d) states:

(d) Amendment of the Patent.—

(1) IN GENERAL.—During a post-grant review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

(A) Cancel any challenged patent claim.

(B) For each challenged claim, propose a reasonable number of substitute claims.

* * * *

(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

Congress also authorized the Director to set forth “standards and procedures” for allowing a patent owner to move to amend, to cancel a challenged claim, or propose a reasonable number of substitute claims. 35 U.S.C. § 326(a)(9). A resulting regulation for filing motions to amend claims in a post-grant review is 37 C.F.R. § 42.221.

A. Contingent Motions to Amend

A motion to amend claims may cancel claims and/or propose substitute claims. 35 U.S.C. § 326(d)(1); 37 C.F.R. § 42.221(a)(3). A request to cancel claims will not be regarded as contingent. However, we shall treat a request to substitute claims as contingent. That means a proposed substitute claim will be considered only if a preponderance of the evidence establishes that the original patent claim it replaces is unpatentable. A patent owner should adopt a claim-by-claim approach to specifying the contingency of substitution, e.g., which claim for which claim and in what circumstance.

B. Burden of Persuasion

The Board must assess the patentability of proposed substitute claims “without placing the burden of persuasion on the patent owner.” *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017) (en banc); see also *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 3–4 (PTAB Feb. 25, 2019) (precedential). Subsequent to the issuance of *Aqua Products*, the Federal Circuit issued a decision in *Bosch Automotive Service Solutions, LLC v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017), as well as a follow-up Order amending that decision on rehearing. See *Bosch Auto. Serv. Sols., LLC v. Iancu*, No. 2015-1928 (Fed. Cir. Mar. 15, 2018) (Order on Petition for Panel Rehearing).

In accordance with *Aqua Products*, *Bosch*, and *Lectrosonics*, a patent owner does not bear the burden of persuasion to demonstrate the patentability of the substitute claims presented in the motion to amend. Rather, ordinarily, “the petitioner bears the burden of proving that the proposed amended claims are unpatentable by a preponderance of the

evidence.” *Bosch*, 878 F.3d at 1040 (as amended on rehearing); *see Lectrosonics*, Paper 15 at 3–4. In determining whether a petitioner has proven unpatentability of the substitute claims, the Board focuses on “arguments and theories raised by the petitioner in its petition or opposition to the motion to amend.” *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 51 (Fed. Cir. 2020). Accordingly, the Board will determine whether substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by the petitioner.

Before considering the patentability of any substitute claims, however, the Board first must determine whether the motion to amend meets the statutory and regulatory requirements set forth in 35 U.S.C. § 326(d) and 37 C.F.R. § 42.221. Those requirements and other guidance are discussed below.

C. Reasonable Number of Substitute Claims

By statute, in a motion to amend, a patent owner may cancel challenged claims or propose a reasonable number of substitute claims for each challenged claim. 35 U.S.C. § 326(d)(1)(B). There is a rebuttable presumption that a reasonable number of substitute claims per challenged claim is one (1) substitute claim. 37 C.F.R. § 42.221(a)(3). A patent owner may rebut this presumption upon demonstration of a need to present more than one substitute claim per challenged claim. *Id.* (“A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims. The presumption is that only one substitute claim would be needed to replace each challenged claim, and it may be rebutted by a demonstration of need.”). Thus, to the extent a patent owner seeks to propose more than one substitute claim for each cancelled claim, the patent owner shall explain

in the motion to amend the need for the additional claims and why the number of proposed substitute claims is reasonable.

The determination of whether the number of proposed substitute claims is reasonable is made on a claim-by-claim basis, consistent with the statutory language that refers to a reasonable number of substitute claims for “each” challenged claim. 35 U.S.C. § 326(d)(1)(B); 37 C.F.R.

§ 42.221(a)(3). To help the Board determine whether a motion to amend meets the requirement, the motion should, for each proposed substitute claim, specifically identify the challenged claim that it is intended to replace. All proposed claims should be traceable to an original challenged claim as a proposed substitute claim for that challenged claim.

D. Respond to a Ground of Unpatentability Involved in the Trial

37 C.F.R. § 42.221(a)(2)(i) states that “[a] motion to amend may be denied where . . . [t]he amendment does not respond to a ground of unpatentability involved in the trial.” Thus, in considering the motion, we review the entirety of the record to determine whether a patent owner’s amendments respond to a ground of unpatentability involved in the trial. The rule does not require, however, that every word added to or removed from a claim in a motion to amend be solely for the purpose of overcoming an instituted ground. Additional modifications that address potential 35 U.S.C. § 101 or § 112 issues, for example, are not precluded by rule or statute. Thus, once a proposed claim includes amendments to address a prior art ground in the trial, a patent owner also may include additional limitations to address potential § 101 or § 112 issues, if necessary. Allowing an amendment to address such issues, when a given claim is being amended already in view of a 35 U.S.C. § 102 or § 103 ground, serves the public

interest by helping to ensure the patentability of amended claims. *See Veeam Software Corp. v. Veritas Techs., LLC*, Case IPR2014-00090, slip op. at 26–29 (PTAB July 17, 2017) (Paper 48). In addition, allowing such amendments helps ensure a “just” resolution of the proceeding and fairness to all parties. 37 C.F.R. § 42.1(b).

E. Scope of the Claims

A motion to amend may not present substitute claims that enlarge the scope of the claims of the challenged patent or introduce new subject matter. *See* 35 U.S.C. § 316(d)(3) (“An amendment . . . may not enlarge the scope of the claims of the patent or introduce new matter.”); *see also* 37 C.F.R. § 42.221(a)(2)(ii) (“A motion to amend may be denied where . . . [t]he amendment seeks to enlarge the scope of the claims of the patent or introduce new subject matter.”).

1. No enlargement

A patent owner may not seek to broaden a challenged claim in any respect that enlarges the scope of the claims of the patent, for example, in the name of responding to an alleged ground of unpatentability. Likewise, a proposed substitute claim may not remove a feature of the claim in a manner that broadens the scope of the claims of the challenged patent. A substitute claim will meet the requirements of § 42.221(a)(2)(i) and (ii) if it narrows the scope of at least one claim of the patent, for example, the challenged claim it replaces, in a way that is responsive to a ground of unpatentability involved in the trial. In addition, a proposed substitute claim adding a novel and nonobvious feature or combination to avoid the prior art in an instituted ground of unpatentability will not enlarge the scope of the claims of the patent.

2. *No new matter*

New matter is any addition to the claims without support in the original disclosure. *See TurboCare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“When [an] applicant adds a claim . . . the new claim[] . . . must find support in the original specification.”). Normally, a claim element without support in the original disclosure (i.e., the application as originally filed) merits a rejection under 35 U.S.C. § 112 for lack of written description support. *See, e.g., In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981) (“The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is § 112, first paragraph . . .”).

Thus, the Board requires that a motion to amend set forth written description support in the originally filed disclosure of the subject patent for each proposed substitute claim, and also set forth support in an earlier filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought. *See* 37 C.F.R. §§ 42.221(b)(1), 42.221(b)(2). If a petitioner, in an opposition to a motion to amend, raises an issue of priority of a proposed substitute claim, for example, based on art identified in the opposition, the patent owner may respond in a reply to the opposition.

Importantly, to meet this requirement, citation should be made to the original disclosure of the application, as filed, rather than to the patent as issued. The written description support must be set forth in the motion to amend itself, not the claim listing (discussed below). *See MLB Advanced Media, L.P. v. Front Row Techs., LLC*, Case IPR2017-01127, slip op. at 2–4 (PTAB Jan. 16, 2018) (Paper 24). In addition, the motion must set forth written description support for each proposed substitute claim as a whole,

and not just the features added by the amendment. This applies equally to independent claims and dependent claims, even if the only amendment to a dependent claim is in the identification of the claim from which it depends.

3. Claim Listing

A motion to amend must include a claim listing reproducing each proposed substitute claim. *See* 37 C.F.R. § 42.221(b). Any claim with a changed scope subsequent to the amendment should be included in the claim listing as a proposed substitute claim, and should have a new claim number. This includes any dependent claim that a patent owner intends to be depending from a proposed substitute independent claim. For each proposed substitute claim, the motion must show clearly the changes in the proposed substitute claim with respect to the original patent claim that it is intended to replace. No particular form is required, but use of brackets to indicate deleted text and underlining to indicate inserted text is strongly suggested. The claim listing may be filed as an appendix to the motion to amend, and shall not count toward the page limit for the motion. The appendix, however, shall not contain any substantive briefing. All arguments and evidence in support of the motion to amend shall be in the motion itself.

F. Default Page Limits

The page limits set forth in the rules apply. A motion to amend, as well as any opposition to the motion, are limited to twenty-five pages. *See* 37 C.F.R. §§ 42.24(a)(1)(vi), (b)(3). A patent owner's reply is limited to twelve pages. *See* 37 C.F.R. § 42.24(c)(3). A petitioner's sur-reply is limited to twelve pages. *See* Consolidated Trial Practice Guide ("Consolidated Practice Guide"), Appendix A-1, available at

www.uspto.gov/patents/ptab/trial-practice-guide. The parties may contact the Board to request additional pages or briefing.

A petitioner may submit additional testimony and evidence with an opposition to the motion to amend, and a patent owner may do likewise with a reply. Generally, a reply or sur-reply may only respond to arguments raised in the preceding brief. Consolidated Practice Guide, Sec. II.I. A petitioner's sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness. *Id.* at 14. A petitioner's sur-reply should only respond to arguments made in a reply, comment on reply declaration testimony, or point to cross-examination testimony. *Id.* Deadlines to submit any motion to amend, opposition, reply, sur-reply, or additional briefing may be stipulated by the parties, to the extent permitted by the instructions set forth in the Scheduling Order.

G. Duty of Candor

Under 37 C.F.R. § 42.11, all parties have a duty of candor, which includes a patent owner's duty to disclose to the Board information that the patent owner is aware of that is material to the patentability of substitute claims, if such information is not already of record in the case. When considering the duty of candor in connection with a proposed amendment, a patent owner should consider each added limitation. Information about an added limitation can still be material even if it does not include the rest of the claim limitations.

Likewise, a petitioner should keep in mind that it has a duty of candor in relation to relevant information that is inconsistent with a position advanced by the petitioner during the proceeding. *Cf.* 37 C.F.R.

§ 42.51(b)(iii). For example, such information could include objective evidence of non-obviousness of proposed substitute claims, if a petitioner is aware of such evidence and it is not already of record in the case.

H. Other General Information

Additional information concerning motions to amend is published in the Consolidated Practice Guide, Sections II.G., II.H., and II.I.

III. ORDER

In consideration of the foregoing, it is:

ORDERED that Patent Owner has satisfied the requirement of conferring with us prior to filing a motion to amend under 37 C.F.R. § 42.221(a).

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