

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,
v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2018-01682
Patent 9,526,844 B2

Before HYUN J. JUNG, BART A. GERSTENBLITH, and
JAMES A. TARTAL, *Administrative Patent Judges*.

PER CURIAM.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

The Board instituted *inter partes* review of claims 21–30 of U.S. Patent No. 9,526,844 B2. Paper 19. Subsequently, Patent Owner filed a Contingent Motion to Amend. Paper 32 (“Motion” or “Mot.”). Specifically, should we find in a final written decision that the challenged claims are unpatentable, Patent Owner proposes substitute claims 31–35 and 38, each of which corresponds to a respective one of challenged claims 21, 23, 24, 26, 27, and 30, as well as substitute claims 36 and 37 corresponding to challenged claim 29. *Id.* at 2. Petitioner filed an Opposition to the Motion. Paper 52 (“Opposition” or “Opp.”).

In the Motion, Patent Owner requested that we provide preliminary guidance concerning the Motion in accordance with the Board’s pilot program concerning motion to amend practice and procedures. Mot. 3; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) (“Notice”). We have considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner (or the record) establishes a reasonable likelihood that the substitute claims are unpatentable. *See* 35 U.S.C.

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§ 316(d); 37 C.F.R. § 42.121; *Lectrosonics, Inc. v Zaxcom, Inc.*, IPR2018-01129, 01130, Paper 15 (PTAB Feb. 25, 2019) (precedential); *see also* Notice, 84 Fed. Reg. at 9,497 (“The preliminary guidance . . . provides preliminary, non-binding guidance from the Board to the parties about the [motion to amend].”).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties’ other substantive papers on the underlying merits of Petitioner’s challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

Does Patent Owner propose a reasonable number of substitute claims? (35 U.S.C. § 316(d)(1)(B))

Yes. Patent Owner proposes no more than one substitute claim for each challenged claim, other than challenged claim 29, for which Patent Owner proposes two substitute claims.

We have considered Petitioner’s contrary arguments (Opp. 2–3), but we find two substitute claims to be reasonable here because they differ from one another only in that they depend from different claims. Mot. 4.

2. Respond to Ground of Unpatentability

Does the Motion respond to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.121(a)(2)(i))

Yes. Patent Owner responds to the grounds of unpatentability at pages 17–18 of the Motion. Petitioner does not contend otherwise.

Regarding substitute claim 31, the Board notes that Patent Owner asserts the proposed amendment “eliminates Giambattista as a prior art reference.” Mot. 17. Giambattista is not relied upon by Petitioner as a prior art reference in this case to show the unpatentability of any challenged claim. Nevertheless, we recognize that Giambattista is relied upon by Petitioner in challenging the ’844 patent in IPR2018-01680 and that it is in the interests of the parties and the Board to have consistent amendments presented in both cases.

3. Scope of Amended Claims

Does the amendment seek to enlarge the scope of the claims? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))

No. *See* Mot. 5–7 (arguing that despite removing the phrase “either an internal or an external,” “the preexisting scope of original claim 21 is retained in substitute claim 31”). Petitioner does not contend otherwise.

4. New Matter

Does the amendment seek to add new subject matter? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii))

No. On this record, we find Patent Owner has set forth written description support for the proposed amendments at pages 8–17 of the Motion as well as in its declarant’s testimony (*see id.* (citing Ex. 2302 ¶¶ 23, 25–55)).

Petitioner contends that certain limitations lack written description support. Opp. 4–14.

On this record, the pin citations in Table 2 of the Motion, coupled with Patent Owner’s explanations, appear to sufficiently identify written description support for the proposed substitute claims. *See, e.g.*, Mot. 9; Ex. 1026, 6:7–14, Figs. 1, 2 (“a driving member comprising a third thread”); Mot. 9; Ex. 1026, 6:7–6:14, cls. 2, 6 (“a piston rod comprising a fourth thread that is engaged with the third thread”); Mot. 10, 12; Ex. 1026, 6:19–22, Fig. 9 (an “arc shaped body . . . comprising inner and outer curved surfaces, once of the curved surfaces comprising a fifth thread that is engaged with a sixth thread”); Mot. 10, 14–17; Ex. 1026, 10:30–11:7, Figs. 6, 7 (“a first clicker feature,” “a second clicker feature spaced axially apart from the first clicker feature,” and “a clicker . . . compris[ing]: a flexible arm . . . and one way teeth”).

B. Patentability

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Petitioner (or the record) has shown a reasonable likelihood that proposed substitute claims 31–38 are unpatentable.

Does the record establish a reasonable likelihood that the proposed substitute claims are unpatentable?

1. Obviousness

Yes. On this record, it appears that Petitioner (or the record) has shown a reasonable likelihood proposed substitute claims 31–38 are unpatentable as obvious on the following grounds:

- (1) Giambattista (Ex. 1016) anticipates and Steinfeldt-Jensen (Ex. 1014) would have rendered obvious substitute claim 31;
- (2) Steinfeldt-Jensen and Atterbury (Ex. 1097) would have rendered obvious substitute claims 33 and 35;
- (3) Steinfeldt-Jensen, Klitgaard (Ex. 1017), and Atterbury would have rendered obvious substitute claim 38; and
- (4) Steinfeldt-Jensen, Klitgaard, Atterbury, and Strowe (Ex. 1105) would have rendered obvious substitute claims 32, 34, 36, and 37. Opp. 19–24.

For proposed substitute claim 31, Patent Owner’s amendment removes the phrase “either an internal or an external” before the term “fourth thread” of challenged claim 21 in a purported attempt to obtain priority to the GB Application, and thereby predate Giambattista. Mot. 5–8. Patent Owner concedes that “despite removal of this phrase, the preexisting scope of original claim 21 is retained in substitute claim 31.” *Id.* at 5. Patent Owner, however, provides little explanation in the Motion of how it contends the amendments it proposes in substitute claim 31 preclude Giambattista from being asserted as prior art to the ’844 patent. *Id.* at 17, 19.

On this record, it appears that the recitation in substitute claim 31 of “threads,” even without the phrase “either an internal or an external,” may still encompass internal threads, and that substitute claim 31 is, therefore, potentially broader than what the GB Application supports. Opp. 6 (citing Ex. 1096 ¶¶ 25–27). Patent Owner has not proposed an amendment that would unambiguously narrow the scope of original claim 21. Thus, at this stage, we determine that there is a reasonable likelihood that Giambattista is prior art to, and anticipates, proposed substitute claim 31. *See Mylan*

Pharm. v. Sanofi-Aventis Deutschland, IPR2018-01680, Paper 22 at 23–27 (PTAB Apr. 3, 2019) (Institution Decision).

Patent Owner also argues, without further explanation, that substitute claim 31 “is patentable over Steinfeldt-Jensen for the reasons of record in the concurrently filed Patent Owner responses.” Mot. 19 (citing Paper 30, 21–39, 42–54). Patent Owner’s attempt to incorporate arguments from another paper is improper. *See* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”).

Petitioner similarly asserts in its Opposition that, because Patent Owner asserts the scope of substitute claim 31 is the same as the scope of claim 21, the analysis provided by Petitioner in the Petition to show that Steinfeldt-Jensen would have rendered claim 21 obvious “applies equally to claim 31.” Opp. 19. That incorporation of an argument by reference is also improper for the same reason as above.

To the extent the parties seek to avoid replicating arguments presented in other papers in this proceeding, the necessary course of action is to request a conference with the Board to pursue an appropriate procedural mechanism. As the record currently stands, we view the arguments of the parties as a concession that our ultimate determination of whether Steinfeldt-Jensen renders claim 21 obvious will dictate the same result when applying Steinfeldt-Jensen to substitute claim 31 in the present case.

For proposed substitute claims 33 and 35, on this record, Petitioner sufficiently shows Steinfeldt-Jensen discloses the claimed invention of claim 33 including audible clicks, except that Steinfeldt-Jensen does not disclose the added “clicker” limitations, i.e., clicks occurring only during one of dialing down or dialing up. Opp. 19–20 (citing Ex. 1096 ¶¶ 65–74).

The record before us also indicates that Atterbury teaches that clicks may be tuned to only occur on dialing down or dialing up. *Id.* at 19–21 (citing Ex. 1097, 46:4–16, 11:3–18; Ex. 1096 ¶¶ 69–73). In addition, the record before us indicates that modifying Steinfeldt-Jensen with Atterbury’s “tuning capability would provide for different clicking sounds, making it particularly advantageous for visually-impaired users in distinguishing between dialing-up and dialing-down” and that the tuning could be routinely implemented “without significantly impacting pen size.” *Id.* at

20–21 (citing Ex. 1097, 11:3–18; Ex. 1096 ¶¶ 72–73). The record before us indicates a reason to combine teachings in the cited references. *Id.*

We find Petitioner’s contentions are sufficient to show a reasonable likelihood that proposed substitute claim 33 is unpatentable over Steinfeldt-Jensen and Atterbury. *See* Opp. 19–21. Our preliminary determination for proposed substitute claim 33 applies equally to proposed substitute claim 35.

For proposed substitute claim 38, Petitioner merely relies on another section of its Opposition, as well as the arguments made in the Petition, without sufficient explanation. Opp. 21 (also citing Ex. 1096 ¶ 77–79). Our rules do not allow arguments to be incorporated by reference from one document into another document. 37 C.F.R. § 42.6(a)(3). Nevertheless, in an effort to provide useful information at this stage, we note that it appears that claim 38 recites “clicker” limitations similar to those added in claims 33 and 35 and thus would be subject to similar analysis. Opp. 21.

For proposed substitute claims 32, 34, 36, and 37, Petitioner refers to arguments made in the Petition, asserting its analysis in that case “applies equally” to substitute claim 32. Opp. 22 (also citing Ex. 1011 ¶¶ 685–693; Ex. 1096 ¶ 86). Again, arguments cannot be incorporated by reference. 37 C.F.R. § 42.6(a)(3). However, in an effort to provide useful information at this stage, we note the following.

Regarding substitute claim 32, the record before us now indicates that “Klitgaard describes a nut member 32 (a body) that follows a helical track for dose-tracking and prevents a user from dialing a dose larger than what remains in the cartridge” and that one of ordinary skill in the art “would have found it beneficial to incorporate a similar mechanism in the device of Steinfeldt-Jensen.” Opp. 22 (citing Ex. 1096 ¶ 80). At this stage, we also find Petitioner has sufficiently shown it would have been obvious (1) to configure a dial member to rotate relative to the body (*id.* at 22–23 (citing Ex. 1054, 387:7–23; Ex. 1096 ¶ 81)); (2) to “switch” the position of the helical track to arrive at an arc shaped body rotatable relative to the dose indicator and movable axially relative to the housing without rotating relative to the housing (*id.* (citing Ex. 1054, 387:7–23; Ex. 1096 ¶ 81)); (3) to modify threaded nut member 32 to be an “arc shaped body” in view of Strowe’s half nut 12, as partial nuts were commonplace, would not

impact dose-tracking operation, and would aid in device assembly (*id.* at 23 (citing Ex. 1105, 4:60–5:15, Figs. 4a, 4b; Ex. 1096 ¶¶ 82–84)); and (4) to provide a radial stop separate from the combination’s helical track (the asserted second thread), because those of ordinary skill in the art “were very familiar with such stops and would not have had any difficulty adding a tooth or similar type of stop in the context of a dose-tracking half nut” (*id.* at 23–24). The record before us also indicates a reason to combine teachings in the cited references. *Id.* at 23–24.

Substitute claim 32 adds the same the same “clicker” limitation discussed above with respect to claim 33. Substitute claims 34, 36, and 37 add the same “arc shaped body” limitation discussed above with respect to claim 32. Substitute claims 36 and 37 also add the “clicker” limitation discussed above with respect to substitute claim 38. Our analysis discussed above also applies to these claims. Thus, we find Petitioner’s contentions are sufficient to show a reasonable likelihood that proposed substitute claims 32, 34, 36, and 37 are unpatentable over Steinfeldt-Jensen, Klitgaard, Atterbury, and Stowe. *See* Opp. 21–24.

For the above obviousness challenges, we acknowledge that Patent Owner has not yet had the opportunity to address Atterbury, Stowe, or the Declaration of Karl Leinsing in support of Petitioner’s Opposition (Ex. 1096), which were all filed with and relied on in Petitioner’s Opposition. Opp. 5–21. Patent Owner will have the opportunity to do so in further briefing on its motion (or a revised motion) in this proceeding.

2. Indefiniteness

No. On this record, it appears that Petitioner has not shown a reasonable likelihood of establishing that proposed substitute claims 32, 34, 36, and 37 are indefinite based on the term “arc shaped body.” On this record, we are not presently persuaded that those skilled in the art would fail to understand what is meant by the term “arc shaped body” when read in light of Patent Owner’s Specification, in particular, the disclosure of half nut 40. *See, e.g.*, Ex. 2304 ¶ 43.

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