

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,  
v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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IPR2018-01679  
Patent 8,992,486 B2

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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 51–57 of U.S. Patent No. 8,992,486 B2. Paper 14. Subsequently, Patent Owner filed a Contingent Motion to Amend. Paper 25 (“Motion” or “Mot.”). Specifically, should we find in a final written decision that the challenged claims are unpatentable, Patent Owner proposes substitute claims 58–64, each of which corresponds to a respective one of challenged claims 51–57. *Id.* at 2. Petitioner filed its Opposition to the Motion. Paper 45 (“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. § 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

<b>Does Patent Owner propose a reasonable number of substitute claims? (35 U.S.C. § 316(d)(1)(B))</b>
Yes, Patent Owner proposes no more than one substitute claim for each challenged claim.

## 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 13–14 of the Motion. We have reviewed Petitioner’s arguments that Patent Owner has improperly shifted the claimed invention from a clutch to a pen-type drug-delivery device comprising a clutch (Opp. 2–3 (citing MPEP §§ 819, 821.03)), and we find those arguments do not persuasively address whether the amendments respond to a ground of unpatentability.

## 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. The proposed substitute claims retain all claim limitations of their corresponding challenged claims and include narrowing limitations. Mot. 5. Petitioner does not argue 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 5–13 of the Motion as well as in its declarant’s testimony (*see id.* (citing Ex. 2302 ¶¶ 24, 28–50, 52–53)).

Petitioner contends the following limitations lack support: (1) the “arc shaped body” in claim 58; (2) the arc shaped body “comprising inner and outer curved surfaces, one of the curved surfaces comprising a first thread that is engaged with a second thread” in claim 58; (3) “a first clicker feature” and a “second clicker feature spaced axially apart from the first clicker feature” in claims 59 and 63; and (4) “teeth formed in the interior of a flange” in claim 63. Opp. 4–12.

On this record, we find Patent Owner appears to have sufficiently identified written description support for these limitations in the proposed substitute claims. In particular, we find nut 40 and its “internal thread

matching the intermediate thread 36” in the application leading to the ’486 patent sufficiently describes (1) and (2). *See* Mot. 7; Ex. 2311, 7:9–10, Fig. 9. In addition, we find flexible arm 52 spaced apart from teeth 56 in that application provides sufficient support for (3). *See* Mot. 8, 12; Ex. 2311, Fig. 6, 3:19–31, 7:20–28, 10:5–8, 11:3–4. We find Petitioner’s argument as to (4) unpersuasive because the limitation was recited in original claim 56.

## 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 58–64 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 58–64 are unpatentable as obvious on the following grounds:

- (1) Steinfeldt-Jensen (Ex. 1014) and Atterbury (Ex. 1097) would have rendered obvious substitute claims 59 and 60;
- (2) Steinfeldt-Jensen, Burroughs (Ex. 1013), and Atterbury would have rendered obvious substitute claims 61 and 62;
- (3) Steinfeldt-Jensen, Klitgaard (Ex. 1017), and Strowe (Ex. 1105) would have rendered obvious substitute claim 58; and
- (4) Steinfeldt-Jensen, Atterbury, Klitgaard, and Strowe would have rendered obvious substitute claims 63 and 64. Opp. 16–21.

*For proposed substitute claims 59 and 60*, on this record, Petitioner sufficiently shows Steinfeldt-Jensen discloses the claimed invention including audible clicks, except that Steinfeldt-Jensen does not disclose the clicks occurring only during one of dialing down or dialing up.

Opp. 16–17 (citing Ex. 1014, 9:48–52, 11:20–67, 12:1–3; Ex. 1096 ¶ 68). 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 17 (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 18 (citing Ex. 1097, 11:3–18; Ex. 1096 ¶¶ 72–73). The record before us indicates a reason to combine teachings in the two cited references. *Id.* We find Petitioner’s contentions are sufficient to show a reasonable likelihood that proposed substitute claim 59 is unpatentable over Steinfeldt-Jensen and Atterbury. *See* Opp. 16–17. Our preliminary determination for proposed substitute claim 59 applies equally to proposed substitute claim 60.

*For proposed claims 61 and 62*, Petitioner merely relies on another section of its Opposition, as well as the arguments in the Petition, without sufficient explanation. Opp. 18 (citing Pet. 63–66; Ex. 1011 ¶¶ 497–506; Ex. 1096 ¶¶ 75–76). 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 the record before us indicates a reasonable likelihood that proposed substitute claims 61 and 62 are unpatentable. *See* Notice, 84 Fed. Reg. at 9,497.

Claims 61 and 62 are proposed as substitutes for original claims 54 and 55. At this stage, Patent Owner has not contested substantively Petitioner’s obviousness challenge of claims 54 and 55 based on Steinfeldt-Jensen and Burroughs. *See, e.g.*, Paper 43, 2. In particular, Patent Owner has not argued that Steinfeldt-Jensen and Burroughs fail to teach the limitations of claims 54 and 55. And, as discussed above, the record before us indicates that Atterbury teaches that clicks may be tuned, via routine implementation, to only occur on dialing down or dialing up, for example, to allow users to better distinguish between dialing down and up. *See* Opp. 17–18 (citing Ex. 1097, 46:4–16, 11:3–18; Ex. 1096 ¶¶ 69–73). The record at this stage, thus, indicates sufficiently that Steinfeldt-Jensen, Burroughs, and Atterbury teach all the limitations of proposed

substitute claims 61 and 62. The record before us also indicates a reason to combine the teachings in the cited references. *Id.* Our above discussion of the newly added limitations in claim 61 applies equally to claim 62.

For proposed substitute claim 58, Petitioner refers to arguments made in IPR2018-01682, which Petitioner asserts “appl[y] equally to substitute claim 58.” Opp. 19 (citing *Mylan Pharm. v. Sanofi-Aventis Deutschland*, IPR2018-01682, Paper 2 at 70–71 (PTAB Sept. 10, 2018) (Petition); Ex. 1011 ¶¶ 685–93; Ex. 1096 ¶ 80). Arguments cannot be incorporated by reference, 37 C.F.R. § 42.6(a)(3), and we do not consider arguments that have not been made in this proceeding. Again, however, in an effort to provide useful information at this stage, we note the following.

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. 19 (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 19–20 (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.* at 20 (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 20–21 (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 21).

For proposed substitute claims 63 and 64, our above discussions of claims 58, 59, and 61 also apply to claims 63 and 64. The record before us also indicates a reason to combine teachings in the cited references.

Opp. 18, 21. Thus, at this stage, the record shows a reasonable likelihood that proposed substitute claims 63 and 64 are unpatentable over Steinfeldt-Jensen, Atterbury, Klitgaard, and Strowe.

*For the above obviousness challenges*, we acknowledge that Patent Owner has not yet had the opportunity to address Atterbury, Strowe, 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 claim 58 is indefinite. 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. 2311, 7:9–10, Fig. 9. We also reject Petitioner's argument that the term “the body” is indefinite because when read in the context of proposed substitute claim 58, that term would be understood to refer to “an arc shaped body.”

Although Petitioner does not show a reasonable likelihood that the term “the body” of proposed substitute claim 58 is indefinite, if Patent Owner decides to file a revised motion to amend, Patent Owner may wish to consider modifying “the body” to refer clearly to the “arc shaped body.”

IPR2018-01679  
Patent 8,992,486 B2

PETITIONER:

Richard Torczon  
Douglas Carsten  
Wesley Derryberry  
Tasha Thomas  
Lorelei Westin  
Nicole Stafford  
Jeffrey Guise  
Yahn-Lin Chu  
Elham Steiner

[rtorczon@wsgr.com](mailto:rtorczon@wsgr.com)

[dcarsten@wsgr.com](mailto:dcarsten@wsgr.com)

[wderryberry@wsgr.com](mailto:wderryberry@wsgr.com)

[tthomas@wsgr.com](mailto:tthomas@wsgr.com)

[lwestin@wsgr.com](mailto:lwestin@wsgr.com)

[nstafford@wsgr.com](mailto:nstafford@wsgr.com)

[jguise@wsgr.com](mailto:jguise@wsgr.com)

[ychu@wsgr.com](mailto:ychu@wsgr.com)

[esteiner@wsgr.com](mailto:esteiner@wsgr.com)

IPR2018-01679  
Patent 8,992,486 B2

PATENT OWNER:

Elizabeth Stotland Weiswasser  
W. Karl Renner  
William Ansley  
Adrian C. Percer  
Brian C. Chang  
Sudip Kundu  
Kathryn Kantha  
Matthew Sieger  
Sudip Kundu  
Anish Desai  
John S. Goetz  
Joshua A. Griswold  
Kenneth W. Darby  
Matthew S. Colvin  
[elizabeth.weiswasser@weil.com](mailto:elizabeth.weiswasser@weil.com)  
[axf-ptab@fr.com](mailto:axf-ptab@fr.com)  
[sutton.ansley@weil.com](mailto:sutton.ansley@weil.com)  
[adrian.percer@weil.com](mailto:adrian.percer@weil.com)  
[brian.chang@weil.com](mailto:brian.chang@weil.com)  
[sudip.kundu@weil.com](mailto:sudip.kundu@weil.com)  
[kathryn.kantha@weil.com](mailto:kathryn.kantha@weil.com)  
[matthew.sieger@weil.com](mailto:matthew.sieger@weil.com)  
[sudip.kundu@weil.com](mailto:sudip.kundu@weil.com)  
[anish.desai@weil.com](mailto:anish.desai@weil.com)  
[goetz@fr.com](mailto:goetz@fr.com)  
[griswold@fr.com](mailto:griswold@fr.com)  
[kdarby@fr.com](mailto:kdarby@fr.com)  
[colvin@fr.com](mailto:colvin@fr.com)

IPR2018-01679  
Patent 8,992,486 B2