



Comments on USPTO's Proposed Rule Making

April 9, 2012

VIA E-MAIL: patent_trial_rules@uspto.gov
inter_partes_review@uspto.gov
post_grant_review@uspto.gov

U.S. Patent and Trademark Office
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Lead Judge Michael Tierney:
Patent Trial Proposed Rules;
Inter Partes Review Proposed Rules;
Post-Grant Review Proposed Rules

RE: Comments by Novo Nordisk Inc. in Response to the PTO's Request for Comments in Implementation of Trial Proceedings described in the America Invents Act

Dear Judge Tierney:

Novo Nordisk A/S and Novo Nordisk Inc. ("Novo Nordisk") respectfully request that the United States Patent and Trademark Office ("PTO") consider the following comments in response to its request for comment on:

- Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions.¹
- Changes to Implement Inter Partes Review ("IPRe") Proceedings.²
- Changes to Implement Post-Grant Review ("PGR") Proceedings.³

¹ 77 Fed. Reg. 6879-6914 (Feb. 9, 2012).

² 77 Fed. Reg. 7041-7060 (Feb. 10, 2012).

³ 77 Fed. Reg. 7060-7080 (Feb. 10, 2012).



Novo Nordisk also submits, at the conclusion of this letter, amendments to the proposed rules which would resolve the issues that are raised by the comments herewith.

Novo Nordisk appreciates the PTO's decision to solicit comments on the provision's implementation in advance of rulemaking, and wishes to assist the PTO in developing its rules and guidance regarding its implementation of the Leahy-Smith America Invents Act ("AIA"). Novo Nordisk's specific comments and proposed changes to the rules at this time are as follows:

Novo Nordisk's Background

Novo Nordisk is a pioneer in biotechnology and a world leader in diabetes care with more than 31,000 employees, with offices in the United States, Denmark and many other areas of the world, including Japan, China, India, Africa, and Brazil. For nearly 90 years Novo Nordisk has combined drug discovery with technology to turn science into solutions for people with diabetes. Novo Nordisk also provides treatments for people with hemophilia and growth hormone deficiency, and for women experiencing symptoms of menopause. Novo Nordisk manufactures and markets pharmaceutical products, including medical devices, that make a significant difference to our patients' lives, the medical profession, and society.

Novo Nordisk has been involved in at least one inter partes proceeding, lasting over four years, and welcomes the tighter timelines⁴ to aid in bringing more timely certainty to the patents in inter partes proceedings. Novo Nordisk also welcomes the concrete lengths for PGR proceedings,⁵ as Novo Nordisk is involved in multiple European Opposition proceedings, many lasting two to three years or more, and European Oppositions provide insight as to how U.S. PGR's may proceed.

General Comments Favoring the Proposed Rules

The PTO is to be commended on its efforts to devise a workable system for managing the inter partes review proceedings and post-grant review proceedings, as created by the AIA. In Novo Nordisk's view, the rules proposed as Part 42, Subparts A, B, and C, with a few exceptions, consistent with the AIA and with the history of that legislation leading up to its enactment in 2011.

⁴ See AIA Section 6, § 316(a)(11) (allowing 12 to 18 months for *inter partes* review after a review is instituted).

⁵ See AIA Section 6, § 326(a)(11) (allowing 12 to 18 months for post-grant review after a review is instituted).



In Novo Nordisk's view, with a few exceptions as detailed below, the proposed rules represent a reasonable and workable way to conduct post-grant proceedings (including inter partes review and post-grant review) in a timely and just manner at a reasonable cost, given the contested nature of such proceedings.

The exceptions relate to patent owner responses, proposed Rules 42.51(b)(3) governing noncumulative and inconsistent information, and 42.73(d)(3) pertaining to estoppel of the patent applicant or owner.

Difficulties With the Proposed Rules

(1) The Time Periods for Submitting Patent Owner Responses are Too Short

For both PGR and IPRe, the AIA leaves to the Director's discretion, the subject of this proposed rule making, to set the time periods for the preliminary patent owner response ("PPOR"),⁶ and patent owner response ("POR").⁷ In contrast with the POR (after institution of the inter partes review), the time period of the PPOR (before institution) **does not** impact the overall statutory requirement that the IPRe or PGR to complete within 12 months after institution, or 18 months for good cause shown.⁸

However, these tighter timelines must be balanced with practical business considerations, such as those required by a multinational corporation such as Novo Nordisk. Therefore, Novo Nordisk suggests that certain timelines, such as those pertaining to the patent owner responses, be extended to comport with practical business considerations.

The current proposed rules make it very difficult for a multinational corporation such as Novo Nordisk to adhere to the 2-month response timelines. (By contrast, a 3rd party challenging a patent using PGR has up to nine months to prepare their petition. Moreover, a 3rd party

⁶ See AIA Section 6, § 313 (patent owner's preliminary response must "set[] forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter"); *id.* Section 6, § 323 (patent owner's preliminary response must "set[] forth reasons why no post-grant review should be instituted based upon the failure of the petition to meet any requirement of this chapter").

⁷ See AIA Section 6, §§ 316(a)(8) (providing for the filing by the patent owner of a response to the petition), 326(a)(8) (providing for the filing by the patent owner of a response to the petition).

⁸ See AIA Section 6, §§ 316(a)(11) (allowing 12 to 18 months for *inter partes* review after a review is instituted), 326(a)(11) (allowing 12 to 18 months for post-grant review after a review is instituted).



challenging a patent using IPRe will likely have more than two months, and sometimes many years to prepare their petition.)

Preparing a defense in either the PPOR and/or POR is not trivial, and requires the patentee to “get their house in order” by coordinating many events. In addition to substantive activities after receipt of a PGR/IPRe petition, the patentee must: secure counsel, secure funding, line up internal and/or external experts, and many more practical realities to support preparation of the actual PPOR and/or POR.

A PPOR is not like an answer in a district court litigation, where the answer simply confirms or denies each individual allegation in the complaint. By contrast, the PPOR must be a much more detailed document that sets forth reasons (supported by evidence) why no PGR/IPRe should be instituted.⁹

Simply put, a two month response time for the PPOR is too short. Novo Nordisk respectfully submits that the PPOR time period for responding to the petition should be four months to account for the realities of different patentees’ situations. Extending the time period for the PPOR would not impact in any way the statutory mandate to complete the PGR/IPRe within one year.¹⁰

Regarding the POR, a two month response time is also too short. If, as proposed, a PPOR cannot include any new testimonial evidence,¹¹ the patentee must be given sufficient time to present a full defense. In the subsequent POR, a full defense, which could include cross examining the 3rd parties’ expert(s), finding and preparing an expert for testimonial evidence, and developing (if necessary) amended claims is likely take more than two months.

In the alternative, the PTO could allow extensions of time upon agreement of the parties for a reasonable amount of time, if good cause is shown.¹²

⁹ See AIA Section 6, § 313 (patent owner’s preliminary response must “set[] forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter”); *id.* Section 6, § 323 (patent owner’s preliminary response must “set[] forth reasons why no post-grant review should be instituted based upon the failure of the petition to meet any requirement of this chapter”).

¹⁰ See AIA Section 6, §§ 316(a)(11) (allowing 12 to 18 months for *inter partes* review after a review is instituted), 326(a)(11) (allowing 12 to 18 months for post-grant review after a review is instituted).

¹¹ See Proposed 42 C.F.R. §§ 107(c), 207(c) (The preliminary response shall not present new testimony evidence beyond that already of record).

¹² See, e.g. Fed. R. Civ. P. 6(b), for an analog to extensions in district court litigation.



(2) The PTO Should Not Adopt 37 C.F.R § 42.51(b)(3) OR §42.73(d)(3)

Proposed § 42.51(b)(3) provides in relevant part that as “routine discovery,” the parties are entitled to discover:

Unless previously served, noncumulative information that is inconsistent with a position advanced by the patent owner or petitioner during the proceeding. The information is to be filed as soon as practicable in a motion identifying supplemental information or as part of a petition, motion, opposition, reply, preliminary patent owner response to petition, or patent owner response to petition. The party submitting the information must specify the relevance of the information, including where the information is presented in a document and, where applicable, how the information is pertinent to the claims.

The underlined language appears to impose an additional duty of disclosure beyond that imposed in 37 CFR § 1.56. Having a separate duty appears unwise. Having an analog to 37 CFR § 1.56 (albeit somewhat different), obfuscated into the discovery rule confuses the issues. Therefore it is proposed to delete this provision in its entirety.

Proposed § 42.73(d)(3) provides in relevant part that the patent applicant or owner is to be subject to certain estoppels:

Patent applicant or owner. A patent applicant or owner whose claim is canceled is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent:

- (i) A claim to substantially the same invention as the finally refused or cancelled claim;
- (ii) A claim that could have been filed in response to any properly raised ground of unpatentability for a finally refused or cancelled claim; or
- (iii) An amendment of a specification or of a drawing that was denied during the trial proceeding.

However, although the AIA sets forth estoppel provisions that apply against an unsuccessful petitioner in inter partes review and post-grant review,¹³ it does not include provisions that impose “estoppel” against an unsuccessful patent owner. Thus, these provisions appear to not be warranted by the existing statute.

¹³ See AIA Section 6, §§ 315(e) (inter partes review), 325(e) (post grant review).



Suggested Changes to the Proposed Guidance and Rules for Implementation

We respectfully requests that the proposed regulations be changed in the following ways consistent with the above comments. We present below both the proposed revisions (showing markup) and a clean version incorporating those revisions. We take no position with respect to other aspects of the rules that do not relate to the comments raised above.

Markup Showing Requested Changes

Selected Trial Rules Provisions

§ 42.51 Discovery.

- (a) **Limited discovery.** A party is not entitled to discovery except as authorized in this subpart. The parties may agree to discovery between themselves at any time.
- (b) **Routine discovery.** Except as the Board may otherwise order:
 - (1) Unless previously served, any exhibit cited in a paper or in testimony must be served with the citing paper or testimony.
 - (2) Cross examination of affidavit testimony is authorized within such time period as the Board may set.
 - ~~(3) Unless previously served, noncumulative information that is inconsistent with a position advanced by the patent owner or petitioner during the proceeding. The information is to be filed as soon as practicable in a motion identifying supplemental information or as part of a petition, motion, opposition, reply, preliminary patent owner response to petition, or patent owner response to petition. The party submitting the information must specify the relevance of the information, including where the information is presented in a document and, where applicable, how the information is pertinent to the claims.~~
- (c) **Additional discovery.**
 - (1) A party may move for additional discovery. Except in post-grant reviews, the moving party must show that such additional discovery is in the interests of justice. The Board may specify conditions for such additional discovery.
 - (2) When appropriate, a party may obtain production of documents and things during cross examination of an opponent's witness or during authorized compelled testimony under § 42.52.



§ 42.73 Judgment.

- (a) A judgment disposes of all issues that were, or by motion could have properly been, raised and decided.
- (b) **Request for adverse judgment.** A party may request judgment against itself at any time during a proceeding. Actions construed to be a request for adverse judgment include:
 - (1) Disclaimer of the involved application or patent;
 - (2) Cancellation or disclaimer of a claim such that the party has no remaining claim in the trial;
 - (3) Concession of unpatentability or derivation of the contested subject matter; and
 - (4) Abandonment of the contest.
- (c) **Recommendation.** The judgment may include a recommendation for further action by an examiner or by the Director.
- (d) **Estoppel.**
 - (1) Petitioner other than in derivation proceeding. A petitioner, or the real party in interest or privy of the petitioner, is estopped in the Office from taking an action that is inconsistent with a judgment as to any ground that the petitioner raised or reasonably could have raised during the trial, except that estoppel shall not apply to a petitioner, or to the real party in interest or privy of the petitioner who has settled under 35 U.S.C. 317 or 327.
 - (2) In a derivation, the losing party who could have properly moved for relief on an issue, but did not so move, may not take action in the Office after the judgment that is inconsistent with that party's failure to move, except that a losing party shall not be estopped with respect to any contested subject matter for which that party was awarded a favorable judgment.
 - ~~(3) **Patent applicant or owner.** A patent applicant or owner whose claim is canceled is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent:
 - ~~(i) A claim to substantially the same invention as the finally refused or cancelled claim;~~
 - ~~(ii) A claim that could have been filed in response to any properly raised ground of unpatentability for a finally refused or cancelled claim; or~~
 - ~~(iii) An amendment of a specification or of a drawing that was denied during the trial proceeding.~~~~



Selected Inter Partes Review Provisions

§ 42.107 Preliminary response to petition.

- (a) The patent owner may file a preliminary response to the petition. The response is limited to setting forth the reasons why no inter partes review should be instituted under 35 U.S.C. 314. The response can include evidence except as provided in paragraph (c) of this section. The preliminary response is an opposition for purposes of determining page limits under § 42.24.
- (b) **Due date.** The preliminary response must be filed no later than ~~two~~four months after the date of a notice indicating that the request to institute an inter partes review has been granted a filing date. A patent owner may expedite the proceeding by filing an election to waive the preliminary patent owner response.
- (c) **No new testimonial evidence.** The preliminary response shall not present new testimony evidence beyond that already of record.
- (d) **No amendment.** The preliminary response shall not include any amendment.
- (e) **Disclaim Patent Claims.** The patent owner may file a statutory disclaimer under 35 U.S.C. 253(a) in compliance with § 1.321(a), disclaiming one or more claims in the patent. No inter partes review will be instituted based on disclaimed claims.

§ 42.120 Patent owner response.

- (a) **Scope.** A patent owner may file a response to the petition addressing any ground for unpatentability not already denied. A patent owner response is filed as an opposition and is subject to the page limits provided in § 42.24.
- (b) **Due date for response.** If no time for filing a patent owner response to a petition is provided in a Board order, the default date for filing a patent owner response is ~~two~~three months from the date the inter partes review was instituted.



Selected Post-Grant Review Provisions

§ 42.207 Preliminary response to petition.

- (a) The patent owner may file a preliminary response to the petition. The response is limited to setting forth the reasons why no post-grant review should be instituted under 35 U.S.C. 324. The response can include evidence except as provided in paragraph (c) of this section. The preliminary response is an opposition for purposes of determining page limits under § 42.24.
- (b) **Due date.** The preliminary response must be filed no later than ~~two~~four months after the date of a notice indicating that the request to institute a post-grant review has been granted a filing date. A patent owner may expedite the proceeding by filing an election to waive the preliminary patent owner response.
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§ 42.220 Patent owner response.

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- (b) **Due date for response.** If no date for filing a patent owner response to a petition is provided in a Board order, the default date for filing a patent owner response is ~~two~~three months from the date the post-grant review is instituted.



Proposed Regulation Incorporating Requested Changes
Selected Trial Rules Provisions

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- (b) **Routine discovery.** Except as the Board may otherwise order:
 - (1) Unless previously served, any exhibit cited in a paper or in testimony must be served with the citing paper or testimony.
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- (a) A judgment disposes of all issues that were, or by motion could have properly been, raised and decided.
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- (b) **Due date.** The preliminary response must be filed no later than four months after the date of a notice indicating that the request to institute an inter partes review has been granted a filing date. A patent owner may expedite the proceeding by filing an election to waive the preliminary patent owner response.
- (c) **No new testimonial evidence.** The preliminary response shall not present new testimony evidence beyond that already of record.
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- (e) **Disclaim Patent Claims.** The patent owner may file a statutory disclaimer under 35 U.S.C. 253(a) in compliance with § 1.321(a), disclaiming one or more claims in the patent. No inter partes review will be instituted based on disclaimed claims.

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- (a) **Scope.** A patent owner may file a response to the petition addressing any ground for unpatentability not already denied. A patent owner response is filed as an opposition and is subject to the page limits provided in § 42.24.
- (b) **Due date for response.** If no time for filing a patent owner response to a petition is provided in a Board order, the default date for filing a patent owner response is three months from the date the inter partes review was instituted.



Selected Post-Grant Review Provisions

§ 42.207 Preliminary response to petition.

- (a) The patent owner may file a preliminary response to the petition. The response is limited to setting forth the reasons why no post-grant review should be instituted under 35 U.S.C. 324. The response can include evidence except as provided in paragraph (c) of this section. The preliminary response is an opposition for purposes of determining page limits under § 42.24.
- (b) **Due date.** The preliminary response must be filed no later than four months after the date of a notice indicating that the request to institute a post-grant review has been granted a filing date. A patent owner may expedite the proceeding by filing an election to waive the preliminary patent owner response.
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- (b) **Due date for response.** If no date for filing a patent owner response to a petition is provided in a Board order, the default date for filing a patent owner response is three months from the date the post-grant review is instituted.

Respectfully Submitted,

A handwritten signature in blue ink, appearing to read "Reza Green".

Reza Green, J.D., Ph.D.
Chief Intellectual Property Counsel
Novo Nordisk Inc.