

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Lead Judge Michael Tierney

RE: Response to PTO Docket No. PTO-P-2011-0086 (Changes to implement
derivation proceedings)

Dear Judge Tierney,

Genentech, Inc. presents for consideration the following observations on the proposed rules to implement derivation proceedings pursuant to 35 U.S.C. §135(a), as revised by the Leahy-Smith America Invents Act (AIA).

Genentech believes that, while the framework of the proposed rules can serve as the basis for properly regulating derivation proceedings, several important changes are required to ensure that the proceeding stays true to its legislative purpose, and minimize unnecessary burdens on the Office and on patent applicants.

The derivation proceeding was included in the AIA to provide inventors whose inventions have been misappropriated by another patent applicant a remedy under the first-inventor-to-file system. Specifically, the law permits an inventor who has filed a patent application to commence a proceeding before the PTO to contest title to a patentable invention that another party has derived from the inventor and without authority claimed in an earlier-filed application. Implicit in the design of this proceeding is the recognition that a party who is not an inventor of an invention is not entitled to a patent on the derived invention. Thus, while the derivation proceedings are focused on ensuring that a later applicant who is the true inventor can secure a patent on the derived invention, the proceedings also ensure that the true inventor who has applied for a patent on the derived invention will be able to prevent the deriver from securing a patent on that invention.

The statutory authority for the derivation proceeding also recognizes that disputes over inventorship should mature into actual derivation proceedings only when necessary. As the drafters of the AIA were fully aware, many possible derivation disputes will not ripen into actual disputes because the invention defined by the first filed claims will prove not to be patentable to one or both parties to a possible dispute, or will require changes that differentiate the earlier filed claims in patentably significant ways from the invention claimed by the inventor in the later-filed application. Conversely, many possible derivation disputes could likely be resolved outside of the derivation proceedings by the parties by reaching an agreement on the correct inventorship of the invention. The parties also have a strong incentive to resolve inventorship disputes if possible, as resolution will result in a valid patent.

The Office has estimated that a party will incur approximately \$62,000 to prepare and file a derivation petition pursuant to the proposed rules. Yet, at the time a petition must be filed, many claims will not have been examined, much less examined to a point that makes clear that the applicant will receive a patent with those claims. Worse, the published claims that define the invention may prove to be unpatentable to either party, or may change in patentably significant ways between the time the petition is filed and the time a patent issues to the earlier-filer and the later filer. The proceeding as presently cast thus will impose tremendous costs on parties to preserve their interests at a point in time when the issuance of claims to the same or substantially the same invention as that which has been derived is highly speculative.

The proposed rules also compel the PTO to conduct derivation proceedings in situations where doing so is unnecessary, which will further burden both the Office and the parties especially in the case wherein claims have not been allowed. The Office has indicated that the Director is unlikely to declare a derivation proceeding until the petitioner's claims are allowable. Additionally, the Office has indicated that the Board may defer action on a derivation proceeding until up to three months after a patent has issued from the first filer. Unlike Inter Partes Review and Post Grant Review proceedings, the statutory date for conclusion of derivation proceedings has not been set. Despite these two probable scenarios above, under the currently proposed rules, a petitioner must present a fully actionable petition to the Office. Thus, the petitioner must commit substantial resources towards conducting the proceeding aggressively against published, but unexamined, partially examined or unpatentable claims. This may also have the unfortunate effect of deterring early settlement of derivation disputes, which, in turn, will consume more Office resources unnecessarily and impose substantial burdens on the parties.

Genentech submits the model reflected in the proposed rules does not achieve an appropriate balance between the initial burden placed on an applicant to take action to preserve its rights by petitioning for a derivation proceeding and the overall likelihood that such a proceeding will ultimately be initiated. The rules also hinder the possibility of settlement between the parties. Genentech proposes changes to the proposed rules to address these concerns.

A. Permit Petitions in the Form of Notice-Style Petitions and Defer Commencement of Derivation Proceedings Until Disputes are Ripe

Genentech submits that the Office should permit parties to file simplified, notice-style petitions that identify the basis of the petitioner's contentions of derivation along with the evidence that supports those specific contentions. The requirement to present more detailed information and further evidence, and to commence the proceeding, could then be deferred until the derivation dispute is later determined to be ripe for resolution. Restructuring the process in this manner will avoid wasting limited Office resources and imposing unnecessary burdens on patent applicants.

The rules should provide that § 135(a) will be satisfied by a petition which identifies the essential factual basis of the contentions of the petitioner that, if later proven, would establish that an earlier filer had derived the disputed invention and, without authority, made it the subject

of claims in the earlier-filed application. Specifically, proposed rule 42.405 should be revised to require a derivation petition to:

- (i) identify at least one claim of the petitioner's applications or patents that is the same or substantially the same (Section C below) as a claimed invention of the alleged deriver;
- (ii) provides a statement that identifies basic facts that will, if proven, establish that an inventor named in an application or patent of the alleged deriver derived the claimed invention from the petitioner and without authority presented claims to the allegedly derived invention in the earlier filed application;
- (iii) provide substantial evidence in support of the facts that are alleged;
- (iv) be submitted under oath; and
- (v) provide the fee for the derivation proceeding specified by the Office.

Additional requirements, such as the requirement to provide a proposed claim construction or additional analyses or evidence should be eliminated or deferred.

Proposed § 42.407 then should be revised to provide that a petition will be considered "complete" if it complies with the revised form of § 42.405, it has been served as required by § 42.406 and is accompanied by the fee required by § 42.15(c).

B. Derivation Proceedings Should Not Be Initiated Until a Dispute Is Ripe and Appropriate for Resolution

Proposed § 42.408 should be revised to expressly provide that the Office will not take action on a petition filed under § 42.405 (other than to confirm compliance with formalities) until at least (i) the date that at least one of the claims each party that is identified in the petition as defining an invention has been found allowable by the Office¹ (but for the earlier-filed claim), or (ii) the date on which either party requests that the Office commence a proceeding to determine the issue of derivation and provides good cause to proceed, or (iii) the date that both parties mutually request commencement of the proceeding. Examples of good cause may include actual or threatened litigation by the holder of the patent or an explanation that intervening prior art may preclude the finding of the petitioner's claims allowable, which would establish futility in meeting the requirement of holding allowable claims.

Additionally, just prior to the date the Office considers a petition requesting initiation of a trial to determine derivation, the petitioner should be required to update the status of the claims previously identified in the petition. The Office has explained that it will defer action on a petition in the typical case until at least three months after the issuance of a patent to the earlier

¹ In the case of the petitioner's application, at least one claim to a patentably indistinct invention has been allowable but for the prior art effect of the earlier-filer's application(s) or patent(s).

file or until the termination of the examination of the application of the later filer. Consequently, many months may pass between the filing of the petition and its consideration by the Office. During this period one or both of the parties may have amended their respective claims, which may materially change the circumstances existing at the time the petition was filed. Consequently, the rules should require a petitioner to again specifically identify the claims of each party that define the same or substantially the same invention which are pending on the date the Office considers the petition. The Office could clarify in the rules that this requirement for updating the status of the claims be done after the petitioner is given notice that the Office intends to consider the petition.

Finally, the rules should also include the option for the petitioner to withdraw the petition prior to the commencement of a derivation proceeding or withdraw from the derivation proceeding.

The changes proposed above relating to commencement and conduct of derivation proceedings will conserve limited Office resources by deferring derivation proceedings until a point in time when the derivation dispute is ripe for adjudication. In addition, this model will satisfy the important notice function of § 135(a); namely, it will communicate to the alleged deriver the basis of the petitioner's contentions that a derivation has occurred along with the key evidence alleged to support those contentions. This model will also encourage communications between the parties to resolve many of the disputes without a derivation proceeding.

Importantly, circumstances will arise where a derivation proceeding should be conducted even though the petitioner may not be able to establish it is entitled to a patent on its application even if it were to prevail in the proceeding. Specifically, if intervening prior art renders the claims of the later filed application unpatentable but is not prior art to the earlier filed application or patent, a patent could issue on the first but not the second application. This situation would represent an example of "good cause" for conducting the proceeding, because if the petitioner were able to establish derivation, a remedy would be warranted. Of course, only a petitioner that had filed an application would have standing to participate in a derivation proceeding in these circumstances.

C. The "Two Way" Patentability Test Should be Used to Determine if the Parties have Claimed the "Same or Substantially the Same" Invention

The proposed rules, particularly proposed §§ 42.403 and 42.405(a)(2) address the statutory requirement that the claims of the petitioner recite the "same or substantially the same" invention as the allegedly derived invention. Genentech submits that the rules should expressly define – in proposed 42.401 – the essential terms needed to frame this question.

Proposed rule 42.401 should include a definition of the test that will determine if an invention is the "same or substantially the same" as the allegedly derived invention. This definition should provide that a claim recites the same or substantially same invention as an allegedly derived invention if (i) the claim recites an invention that would be anticipated by or obvious over the allegedly derived invention, and (ii) the allegedly derived invention would be anticipated by or obvious over the invention defined by that claim.

Genentech submits the proposed definitions and recast rule 42.405(a) improves the clarity of the requirements of a derivation petition and are consistent with statutory requirements of a petition under 35 U.S.C. § 135(a).

D. Definition of First Publication of a Claim

Genentech believes that a definition of when a patent claim is “first published” should be added to the definitions in § 42.401.

As the Office is aware, patent applicants frequently amend claims or present new claims in an application after it has been published under 35 U.S.C. § 122(b). The revised claims may be patentably distinct from the claims that were published. For example, the claims as published may define a genus of compounds, while a later amendment may present a new claim to only one species within that genus. If the new claim to the species is patentably distinct over the published claims, then the date of first publication of the species claim should be the date of its first publication in an application under 35 USC § 122(b) or issuance in a patent, not the date of publication of the genus claim.

To avoid this confusion and further confusion, and to give applicants and the Office clarity in applying the “first published” standard, a definition should be added to proposed rule 42.401 that specifies that a claim presented in an application or issued in a patent which defines an invention that is patentably distinct from a claim that was earlier published in the corresponding application or patent is the date of the first publication of that patentably distinct claim. Importantly, the rules should also confirm that public availability of a claim through the PTO PAIR system does not constitute a “first publication” of the claim, as mere presentation of the claim during prosecution is not sufficient to constitute “first publication” within the meaning of the statute.

E. The Board Should Identify in the Rules the Forms of Relief that May Be Granted if Derivation is Established

Pursuant to § 135(a), if the petitioner establishes that a derivation has occurred that is addressed by the statute, “the Patent Trial and Appeal Board may correct the naming of the inventor in any application or patent at issue.” The Board may thus grant limited forms of relief that will remedy the harm caused by the derivation and unauthorized filing by the party that has derived the invention from the true inventor.

The limited forms of relief that the Board may grant should be set forth expressly in the rules. Specifically, the rules should specify that the relief that may be requested and granted by the Board may include:

- (i) that the inventive entity of the earlier filed application or patent may be amended to add the name of an inventor of the later filed application of the petitioner;
- (ii) that the inventive entity of the earlier filed application or patent may be amended to change or remove the name of one or more of the named inventors on that earlier filed patent or application and who is established to have derived the invention; and

- (iii) if the inventive entity of the earlier filed application or patent and the inventive entity of the petitioner's application thereby are made to be identical, by removing the name of one or more inventors, the petitioner may amend its application to claim the benefit under 35 U.S.C. § 120 to the earlier filed application.

Genentech submits that specifying the relief that will be available in a derivation proceeding by rule will add clarity and certainty to the proceedings.

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Genentech appreciates the opportunity to provide these comments on the proposed rules to govern derivation proceedings.

Sincerely,



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Head of Patents, Senior Director
Genentech, Inc.