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**MAILED**

**JUN 17 2010**

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(For Third Party Requester)

**CENTRAL REEXAMINATION UNIT**

*In re Richard E. Fulton III et al.*  
*Ex Parte* Reexamination Proceeding  
Control No.: 90/008,995  
Filing Date: January 17, 2008  
For: U.S. Patent No. 6,699,205

:  
: **DECISION**  
: **DENYING**  
: **PETITION**  
:

This is a decision on the December 24, 2009 patent owner petition under 37 CFR 1.182 entitled "REQUEST FOR RECONSIDERATION OF THE DECISION ON RENEWED PETITION FOR CONTINUED EX-PARTE REEXAMINATION PROCEEDING," requesting reconsideration of the December 18, 2009 decision dismissing the November 4, 2009 patent owner renewed petition for continued reexamination of the above-captioned proceeding to provide for entry and consideration of a post final Office action proposed response and accompanying declarations.

Patent owner's petition for reconsideration is before the Office of Patent Legal Administration.

**SUMMARY**

Petitioner patent owner's request for reconsideration is granted to the extent that the prior decision has been reconsidered but is denied as to the underlying relief requested, for the reasons set forth below. Prosecution of the present *ex parte* reexamination proceeding is not being reopened by this decision, and the July 8, 2009 post final Office action submissions will not be entered.

35 U.S.C. § 305 mandates that "[a]ll reexamination proceedings under this section . . . will be conducted with **special dispatch** within the Office" [emphasis added]. The conscious choice by

patent owner not to seek evidence until after the examiner had responded to the patent owner's arguments in the final Office action (and did not accept the arguments) does not represent an effort that is consistent with conducting the present proceeding with special dispatch. The decision on a petition under 37 CFR 1.182 to continue reexamination, despite a patent owner's failure to comply with 37 CFR 1.116, is a decision based on equity. And, in this instance, the equities do not favor patent owner.

This decision is a final agency action within the meaning of 5 U.S.C. § 704.

### REVIEW OF FACTS

1. On March 2, 2004, the Office issued U.S. Patent No. 6,699,205 (the '205 patent) to Fulton, III et al.
2. On January 17, 2008, a request for *ex parte* reexamination of the '205 patent was filed by a third party requester. The resulting reexamination proceeding was assigned control number 90/008,995 (hereinafter '8995).
3. On February 12, 2008, the Office issued a notice of the filing of the '8995 *ex parte* reexamination with a filing date of January 17, 2008.
4. On March 7, 2008, the Office issued an order granting the '8995 *ex parte* reexamination request.
5. On June 12, 2008, a first Office action on the merits issued, rejecting claims 1-7, 9-17, 19-26, 28, and 29. Claims 8, 18, and 27 were not and are not subject to reexamination.
6. On August 12, 2008, patent owner filed a response retaining original claims 1-7, 9-17, 19-26, 28, and 29 as not amended and adding new claims 30 and 31.
7. On November 6, 2008, a second non-final Office action issued, withdrawing all the rejections in the first Office action and setting forth new grounds of rejections under 35 U.S.C. § 103 for claims 1-7, 9-17, 19-26, and 28-31.
8. On January 6, 2009, patent owner filed a response to the November 6, 2008 Office action in which no claim was amended.
9. On March 9, 2009, a final Office action was issued, maintaining the prior art rejections of claims 1-7, 9-17, 19-26, and 28-31 set forth in the previous Office action.
10. On April 23, 2009, patent owner filed a petition for a one-month extension of time to respond to the final Office action mailed March 9, 2009, and the April 27, 2009 Office decision granted the requested one-month extension.

11. On June 3, 2009, patent owner filed a petition for a second one-month extension of time to respond to the final Office action mailed March 9, 2009, and the June 5, 2009 Office decision granted the requested second one-month extension.
12. On July 8, 2009, patent owner filed a submission as a proposed response to the final Office action, the proposed response being accompanied by a declaration under 37 CFR 1.132 by William A. Bernie and a declaration under 37 CFR 1.132 by Trevor Speeg.
13. On July 17, 2009, the Office issued an advisory Office action stating that the July 8, 2009 declarations under 37 CFR 1.132 would not be entered because they were not timely, and patent owner did not present any reasons why the declarations were not presented earlier (e.g., after the first time the same rejections were applied to the claims).
14. On July 30, 2009, patent owner filed a petition entitled "PETITION UNDER 37 C.F.R. § 1.182 FOR CONTINUED REEXAMINATION AND IN THE ALTERNATIVE UNDER § 1.181 AND/OR § 1.183 FOR ENTRY OF THE PATENT OWNER'S RESPONSE FILED JULY 8, 2009" to request continued reexamination of the subject patent and entry of the response after final and accompanying declarations filed on July 8, 2009.
15. On September 8, 2009, patent owner filed a Notice of Appeal.
16. On October 27, 2009, the Office mailed a decision dismissing the July 30, 2009 patent owner petition.
17. On October 30, 2009, patent owner filed a request for a one-month extension of time pursuant to 37 CFR 1.550(c) for filing an appeal brief.
18. On November 4, 2009, patent owner filed a petition entitled "RENEWED PETITION UNDER 37 C.F.R § 1.182 FOR CONTINUED REEXAMINATION."
19. On November 6, 2009, the Office mailed a decision granting a one-month extension of time to file an appeal brief.
20. On December 2, 2009, patent owner filed a request for an additional one-month extension of time pursuant to 37 CFR 1.550(c) for filing an appeal brief, and the December 7, 2009 Office decision granted the requested additional one-month extension. The due date of the appeal brief was extended to January 8, 2010.
21. On December 18, 2009, the Office mailed a decision dismissing the November 4, 2009 renewed patent owner petition.
22. On December 24, 2009, patent owner filed the present petition for reconsideration of the December 18, 2009 decision dismissing the renewed petition for continued *ex parte* reexamination.
23. On January 8, 2010, patent owner timely filed an appeal brief.

24. On January 27, 2010, the Office mailed a Notification of Non-Compliant Appeal Brief (37 CFR 41.37) in *Ex Parte* Reexamination.
25. On February 11, 2010, patent owner filed a corrected appeal brief.

## RELEVANT REGULATIONS

### 37 CFR 1.181 provides, in pertinent part:

(a) Petition may be taken to the Director:

(1) From any action or requirement of any examiner in the *ex parte* prosecution of an application, or in *ex parte* or *inter partes* prosecution of a reexamination proceeding which is not subject to appeal to the Board of Patent Appeals and Interferences or to the court.

### 37 CFR 1.182 provides:

All situations not specifically provided for in the regulations of this part will be decided in accordance with the merits of each situation by or under the authority of the Director, subject to such other requirements as may be imposed, and such decision will be communicated to the interested parties in writing. Any petition seeking a decision under this section must be accompanied by the petition fee set forth in § 1.17(f).

## DECISION

The present petition requests reconsideration of the Office's December 18, 2009 decision dismissing patent owner's November 4, 2009 renewed petition for continued reexamination of the instant proceeding. In order to give the full context of the present petition, this decision is organized as follows: Section I provides the background for the present petition and discusses (1) the relevant Office actions and patent owner responses, (2) the patent owner's July 30, 2009 petition under 37 CFR 1.182 for continued reexamination, (3) the October 27, 2009 dismissal of patent owner's July 30, 2009 petition, (4) the patent owner's November 4, 2009 renewed petition under 37 CFR 1.182 for continued reexamination, and (5) the December 18, 2009 dismissal of the November 4, 2009 patent owner petition. Section II discusses the present patent owner petition for reconsideration of the December 18, 2009 dismissal. Finally, Section III discusses the analysis and findings on the present petition for reconsideration.

## I. BACKGROUND FOR PETITION REQUESTING CONTINUED REEXAMINATION

### 1. Relevant Office Actions and Patent Owner Responses

On November 6, 2008, a second non-final Office action was issued in the '8995 proceeding. The action withdrew all prior art rejections made in the first non-final Office action and set forth new

grounds of rejections for claims 1-7, 9-17, 19-26, and 28-31. The claims were rejected under 35 U.S.C. § 103 over Foerster in view of Nabai et al (a newly cited reference by the examiner) and Anderson et al.

On January 6, 2009, patent owner filed a response to the November 6, 2008 second non-final Office action *in which no claim was amended and no evidence was provided*. The response provided arguments alleging patentability of the rejected claims over the applied prior art of record.

On March 9, 2009, a final Office action was issued, maintaining the prior art rejections for claims 1-7, 9-17, 19-26, and 28-31 initially set forth in the November 6, 2008 second non-final Office action. No new ground of rejection was made in the final Office action.

On July 8, 2009, after being granted two “one-month extensions of time” to respond to the final Office action, patent owner filed a response that was accompanied by a declaration under 37 CFR 1.132 by William A. Bernie and a declaration under 37 CFR 1.132 by Trevor Speeg.

On July 17, 2009, the Office issued an advisory Office action stating that the July 8, 2009 declarations under 37 CFR 1.132 would not be entered because they were not timely, and patent owner did not present any reasons why the declarations were not presented earlier (*e.g.*, after the first time the same rejections were applied to the claims).

## **2. Patent Owner’s July 30, 2009 Petition to Request Continued Reexamination**

In its July 30, 2009 petition to request continued reexamination and entry and consideration of the response after final and accompanying declarations filed on July 8, 2009, patent owner asserted that it was only after the examiner had responded to the patent owner’s arguments in the March 9, 2009 final Office action did the patent owner consider the submission of additional data and testimony to be warranted.<sup>1</sup> Accordingly, patent owner filed the Bernie and Speeg declarations with the post-final response on July 8, 2009.<sup>2</sup> Patent owner stated that Speeg’s declaration attested to the fact that GELFOAM absorbable gelatine sponge, the hemostat used in the Nabai reference in the performance of a skin biopsy, was not swellable.<sup>3</sup> Patent owner asserted that the Bernie declaration gave numerous reasons why the Nabai and Anderson references were not likely to lead a person of ordinary skill in the art to modify Foerster’s biopsy marker to arrive at a method for marking a breast biopsy site that employed a swellable bioresorbable body having a radiopaque marker carried by the bioresorbable body.<sup>4</sup> Patent owner argued, as a basis for granting its petition, that patent owner could not know with certainty (when response was made to the second non-final Office action) whether arguments would be successful when considered on their own merits, or whether the patent owner would need to buttress those arguments with additional data and/or testimony.<sup>5</sup>

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<sup>1</sup> July 30, 2009 petition at page 4.

<sup>2</sup> July 30, 2009 petition at page 4.

<sup>3</sup> July 30, 2009 petition at page 4.

<sup>4</sup> July 30, 2009 petition at pages 4-5.

<sup>5</sup> July 30, 2009 petition at page 3.

Patent owner also argued that given the time and expense involved in retaining an expert and/or a laboratory, the patent owner could not reasonably be expected to incur these costs in response to an Office action, since it was reasonable for the patent owner to believe that the merits and logic of the arguments themselves would be sufficient. The basis for this belief was stated to be that, in the prosecution of the present reexamination proceeding, the patent owner was able to overcome the prior art rejections in the June 12, 2008 first non-final Office action without submitting additional evidence under § 1.132.<sup>6</sup> Finally, patent owner explained that the *costs and substantial efforts* that went into preparing these declarations impeded the patent owner's ability to submit such declarations at an earlier date.<sup>7</sup>

### 3. Dismissal of the July 30, 2009 Petition to Request Continued Reexamination

In its October 27, 2009 dismissal of patent owner's July 30, 2009 petition for continued reexamination, the Office stated that the petition included two separate requests:<sup>8</sup> (1) The request under 37 CFR 1.182 for continued reexamination of the present proceeding; and (2) The assertion under 37 CFR 1.181 that the July 8, 2009 post-final submissions should have been entered under 37 CFR 1.116. The decision dismissed the combined petition, pursuant to 37 CFR 1.4(c), which requires different matters raised in a given proceeding be raised in separate papers. The first request was subject to decision by the Office of Patent Legal Administration, and the second, by the Central Reexamination Unit. In advisory comments, the decision addressed the aspect of the petition directed to the request under 37 CFR 1.182 for continued reexamination.

The October 27, 2009 decision stated that granting the equitable relief sought would be contrary to Office policy as it would undermine the policy intent of the relevant Office rule, *e.g.* 37 CFR 1.116(e).<sup>9</sup> 37 CFR 1.116(e) permits the submission of an "affidavit or other evidence" after a final Office action in an *ex parte* reexamination if (1) the evidence is submitted before or on the same date of filing an appeal, and (2) it is accompanied by a showing of good and sufficient reasons why the evidence is necessary and was not earlier presented. In this instance, the examiner's final Office action neither changed nor added a basis or grounds of rejection in terms of prior art rejections (*i.e.*, neither shifted from the obviousness grounds of rejection nor added new references into the grounds of rejection). When patent owner responded to the action preceding the final rejection, it was reasonably foreseeable (by patent owner) that the examiner would not be persuaded by attorney argument and would maintain the rejection; it is not uncommon for an examiner to find attorney arguments not persuasive. Patent owner's decision to see how things "turned out," rather than timely filing evidence in response to the second non-final Office action, was its own choice, and did not support the unequivocal requirement for the Office to carry out an *ex parte* reexamination proceeding with special dispatch.

The decision indicated, on page 6, that given the Office's statutory mandate of 35 U.S.C. § 305 for special dispatch in reexamination, patent owner could have, and should have, submitted declaratory evidence regarding this finding of fact to support the argument made (and further special dispatch by placing everything before the examiner in the response) after the second

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<sup>6</sup> July 30, 2009 petition at page 3.

<sup>7</sup> July 30, 2009 petition at page 5.

<sup>8</sup> October 27, 2009 decision at page 4.

<sup>9</sup> October 27, 2009 decision at pages 5-6.

action non-final, but patent owner chose not to do so. The actions taken by the examiner (i.e., responding to the patent owner's arguments in the final Office action and maintaining all of the previous prior art rejections) were not unforeseeable, and patent owner's argument that it was only after the examiner had responded to patent owner's arguments did the patent owner consider the submission of additional data and testimony to be warranted was found unpersuasive.

In response to patent owner's explanation that the costs and substantial efforts that went into preparing the § 1.132 declarations impeded the patent owner's ability to submit such declarations at an earlier date, the decision pointed out that it appeared that patent owner did not make any efforts to submit additional evidence until after the final Office action was mailed.<sup>10</sup> The patent owner to date has not taken issue with the Office's determination regarding patent owner's lack of effort to seek evidence prior to the final Office action. The decision also pointed out that such an argument went to the § 1.181 aspect of the petition, as to why the evidence could not have been submitted sooner, and specifics of the delay would be required to support such a showing.<sup>11</sup>

#### **4. Patent Owner's Renewed Petition of November 4, 2009 for Continued Reexamination**

In its November 4, 2009 renewed petition for continued reexamination, patent owner stated that additional arguments were provided in support of the petition for continued reexamination, namely, additional explanation regarding why patent owner's two declarations (i.e., declarations of William A. Bernie and Trevor Speeg) could not have been earlier presented and why they would advance the prosecution of the present reexamination proceeding.<sup>12</sup>

Patent owner explained in the renewed petition that, *in response to the final Office action*, patent owner obtained a sample of the GELFOAM material to see if there was anything about that material that might *reinforce* the patent owner's argument (made in the January 6, 2009 response to the second non-final Office action) that the Nabai reference would not lead a person of ordinary skill in the art to modify Foerster.<sup>13</sup> Patent owner stated in the renewed petition that it was not until after receiving the second non-final action and final rejection, when Mr. Speeg tested the GELFOAM material, that the patent owner discovered that GELFOAM did not in fact swell.<sup>14</sup> The patent owner argued that this discovery could not reasonably have been anticipated by or expected to have been discovered by the patent owner earlier, since the Nabai patent expressly characterized the sponge used in its skin biopsy as being swellable and that GELFOAM was the only example of a swellable sponge disclosed in the Nabai reference.<sup>15</sup> The patent owner further contended that given the sworn nature of U.S. patent applications, it was reasonable for the patent owner to rely upon this express teaching of the Nabai reference as true in responding to the second non-final action initially citing Nabai.<sup>16</sup>

In addition, the patent owner stated that the examiner in the advisory action (1) denied entry of

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<sup>10</sup> October 27, 2009 decision at page 6.

<sup>11</sup> October 27, 2009 decision at page 6.

<sup>12</sup> Renewed petition at page 2.

<sup>13</sup> Renewed petition at page 4.

<sup>14</sup> Renewed petition at page 4.

<sup>15</sup> Renewed petition at page 4.

<sup>16</sup> Renewed petition at page 4.

the Speeg declaration, and (2) stated that the declaration was not persuasive because the response did not establish a nexus between the isotonic solution in which Mr. Speeg tested the GELFOAM and the claimed subject matter, namely, a method for performing a breast biopsy.<sup>17</sup> The patent owner argued that the Nabai reference may not be enabling as to what was a swellable sponge and that granting the petition would give the patent owner the opportunity to respond to the position the Examiner had taken in the advisory action and to develop the record regarding the Nabai teachings in order to advance the prosecution of the reexamination.<sup>18</sup> Patent owner alleged that the teaching of the Nabai reference was clearly in dispute and should be resolved in an orderly fashion through continued reexamination.<sup>19</sup>

## 5. Decision of December 18, 2009 Dismissing the Renewed Petition

In its December 18, 2009 dismissal of patent owner's renewed petition under 37 CFR 1.182 to request continued reexamination, the Office stated the following:<sup>20</sup>

What the petition does not explain, is why Mr. Speeg did not test the GELFOAM material immediately after the issuance of the second non-final Office action, to address the issue with special dispatch. While petitioner patent owner states that it was reasonable for the patent owner to rely upon this express teaching of the Nabai reference as true in responding to the second non-final action, it is not clear why it became unreasonable for the patent owner to rely upon this express teaching of the Nabai reference as true – only after final Office action. Thus, the petition does not present a persuasive reason why the need for the declarations could not have been earlier anticipated. As such, the petition again fails for want of a persuasive explanation of why the patent owner did not anticipate the need for the new evidence earlier in the prosecution.

The dismissal further stated that if the “sworn” nature of the teaching of the Nabai reference was deemed unreliable (by the patent owner) after final Office action, it would have been deemed just as unreliable after the second non-final Office action – nothing in the final Office action was shown to suddenly address the reliability of the “sworn” nature of the teaching of the Nabai reference. The dismissal reiterated that given the statutory mandate of 35 U.S.C. § 305 for special dispatch in reexamination, patent owner could have, and should have, submitted declaratory evidence regarding this finding of fact to support the argument made (and further special dispatch by placing everything before the examiner in the response) after the second action non-final, but patent owner chose not to do so.<sup>21</sup>

With respect to patent owner's argument in the renewed petition that the Nabai reference may

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<sup>17</sup> Renewed petition at page 4. As pointed out by the examiner in the advisory Office action, the Speeg declaration only provided evidence that GELFOAM immersed in saline did not swell and that the claims did not pertain to having the material immersed in a saline solution, but instead the material was placed in a biopsy site within a human body. Therefore, the examiner concluded that the Speeg declaration did not establish a nexus between the evidence and the claims.

<sup>18</sup> Renewed petition at page 5.

<sup>19</sup> Renewed petition at page 5.

<sup>20</sup> December 18, 2009 decision at page 7.

<sup>21</sup> December 18, 2009 decision at page 8.



not be enabling as to what was a swellable sponge and that granting the petition would give the patent owner the opportunity to respond to the position the examiner had taken in the advisory action,<sup>22</sup> the Office's position was that such arguments regarding the correctness of examiner's actions were not appropriate under a 37 CFR 1.182 petition.<sup>23</sup> Rather, such arguments may be presented for appeal. The decision at page 8 provided advisory comments on this § 1.181 aspect of the petition as follows:

The Nabai reference is a U.S. Patent, and all U.S. Patents are presumed valid. It is very high bar to show that a U.S. Patent is not enabled. In any event, the present renewed petition is not the proper vehicle to provide a showing by arguments alone regarding the operability of a U.S. patent. See MPEP 716.07.

## **II. Patent Owner's Present Petition filed December 24, 2009 for Reconsideration of the December 18, 2009 Dismissal of the Renewed Petition**

In its present petition for reconsideration, patent owner's arguments are directed to (1) reasons for not questioning the teachings of the Nabai reference earlier and (2) circumstances under which a request for continued reexamination (by filing a petition under 37 CFR 1.182) is warranted as set forth in the Notice of March 1, 2005 titled "Notice of Changes in Requirement for a Substantial New Question of Patentability for a Second or Subsequent Request for Reexamination While an Earlier Filed Reexamination is Pending."<sup>24</sup>

### **1. The Nabai Reference**

With respect to patent owner's reasons for not questioning the teachings of the Nabai reference earlier, patent owner asserts the following:<sup>25</sup>

The patent owner did not know, and based on the express teachings of Nabai, the patent owner had no reason to suspect that the GELFOAM material would not swell as expressly represented in the Nabai reference.

Therefore, patent owner argues that it did not choose not to seek evidence earlier and in fact did not make any choice.<sup>26</sup>

Patent owner further argues at page 2 of the present petition that "the same policies that justify a 'very high bar to show that a U.S. Patent is not enabled' should also explain the patent owner's failure to even consider questioning the accuracy of the technical underpinnings of the Nabai reference (i.e., the swellability of the GELFOAM material)."<sup>27</sup> Patent owner also asserts that the failure of a respondent to a non-final rejection to "not have in his or her possession information

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<sup>22</sup> Renewed petition at page 5.

<sup>23</sup> Insofar as the petition continues to argue as to the propriety of the examiner's action, this is subject to either supervisory review under 37 CFR 1.181 or substantive review by way of appeal. Relief under 37 CFR 1.182 is not available for either of these situations and thus, these arguments will not be addressed here.

<sup>24</sup> 1292 *Off. Gaz. Pat. Office* 20, March 1, 2005.

<sup>25</sup> Petition for reconsideration at pages 1-2.

<sup>26</sup> Petition for reconsideration at page 1.

<sup>27</sup> Petition for reconsideration at page 2.

enabling him or her to challenge the express teachings of a reference cannot *per se* constitute a failure to act with 'special dispatch' and preclude consideration of newly discovered information - especially when the express disclosure in the reference indicates that such information should not, in fact, exist."<sup>28</sup> Patent owner alleges that the December 18, 2009 Office decision appears to be internally inconsistent in that "[o]n the one hand, the Decision indicates that the Office places issued patents on a pedestal such that it is a 'very high bar to show that a U.S. Patent is not enabled,' but on the other hand this pedestal is ignored and is of no probative value or justification when it comes to challenging the accuracy of express teachings in a U.S. Patent reference."<sup>29</sup>

## 2. The March 1, 2005 Notice Regarding RCR

With respect to the Notice of March 1, 2005, the patent owner alleges that it is being denied access to the process outlined in the Notice regarding continued reexamination and that the present situation is exactly the situation contemplated by the Notice for which continued reexamination is warranted.<sup>30</sup> Specifically, patent owner asserts that the "Notice only mentions situations in which response after final has been denied entry as would be the case with analogous RCE in standard prosecution," and "[a]ccordingly, the patent owner submits it is not correct to deny it access to continued reexamination when the Notice contemplates that responses not enterable under 37 CFR § 1.116 will be considered via continued reexamination."<sup>31</sup>

The patent owner requests that if the Office is changing its practice and abandoning the Notice of March 1, 2005, the Office should inform the patent bar. The patent owner cites and includes as support for this allegation, a petition under § 1.182 for continued reexamination, which was accompanied by a declaration, that was granted in a July 18, 2006 decision in the 90/006,802 (hereinafter '6802) reexamination proceeding. The patent owner alleges that the petition there was granted without any scrutiny into why the declaration had not been submitted earlier. The patent owner also points out that, in the '6802 proceeding, the patent owner of that proceeding had responded to a final rejection without the declaration whereas in the present reexamination proceeding, the patent owner has been more diligent than the patent owner in '6802 proceeding in that the declaration was submitted in response to the final action.<sup>32</sup>

The patent owner questions why there is "a grantable basis for continuing reexamination to consider evidence that the patent owner did not even get around to submitting in response to the final action in" the '6802 proceeding, whereas there is not a grantable basis in the present proceeding "where the patent owner submitted the evidence in response to the final action."<sup>33</sup> The patent owner alleges that, while the Office may not be bound by its action in the '6802, that a basic rule of fairness seems to be violated.<sup>34</sup> The patent owner believes that the purpose of the

<sup>28</sup> Petition for reconsideration at page 2.

<sup>29</sup> Petition for reconsideration at pages 1-2.

<sup>30</sup> Petition for reconsideration at page 2.

<sup>31</sup> Petition for reconsideration at pages 2-3.

<sup>32</sup> Petition for reconsideration at page 3.

<sup>33</sup> Petition for reconsideration at page 3.

<sup>34</sup> Petition for reconsideration at page 3.

Notice appears to have been implemented in the '6802 proceeding whereas in the present situation, it is being superseded "by excruciating inquiry into issues relating to Rule 116 from which the Notice was expressly intended to provide relief."<sup>35</sup>

### III. ANALYSIS AND FINDINGS

#### 1. Patent Owner's Arguments for not Questioning the Teachings of the Nabai Reference Earlier

With respect to patent owner's arguments in the present request for reconsideration regarding why the declaration evidence was not earlier submitted, patent owner's response again fails to explain why patent owner began to question the enablement of the teachings of the Nabai reference only after the final Office action was issued; no new grounds of rejection were made in the final rejection and the issue was not newly raised in that action (or even discussed there). It is noted that page 14 of patent owner's remarks filed on January 6, 2009 *in response to the second non-final Office action* stated "[w]hile it may be correct that GELFOAM is known to swell, where is it taught that the specific percentages desired by the method of Applicant are to be employed in any of the cited reference?" There, patent owner, in response to the second non-final Office action, did not question the correctness of whether the GELFOAM material actually swelled, but instead questioned the specific percentage of swelling taught by the prior art. The subsequent final Office action did not raise any new issues that could have prompted the patent owner to question the reliability of the teachings of the Nabai reference.

As stated by patent owner in its July 30, 2009 petition, it was only after the examiner had responded to the patent owner's arguments in the March 9, 2009 final Office action that patent owner considered the submission of additional data and testimony to be warranted<sup>36</sup> – clearly by this statement, patent owner chose not to consider submitting the 37 CFR 1.132 declarations until after the examiner was not persuaded by patent owner's arguments and issued a final Office action.

Although patent owner disagrees that submitting the evidence later was a "choice," the evidence submitted to overcome the rejections made in the November 6, 2008 second non-final Office action, was not made in patent owner's next responsive reply, but rather was presented only after a final rejection was issued. MPEP 2272 states (in pertinent part):

It is intended that prosecution before the examiner in a reexamination proceeding will be concluded with the final action. . . . Accordingly, both the examiner and the patent owner should identify and develop all issues prior to the final Office action, including the presentation of evidence under 37 CFR 1.131 and 1.132.

In this case, patent owner failed to submit evidence at the earliest possible point, despite the clear notice in MPEP 2272 that evidence submissions should be filed before final action and despite the statutory mandate for special dispatch in reexamination. Patent owner argues that the "very high bar to show that a U.S. Patent is not enabled" should also explain its failure to even consider

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<sup>35</sup> Petition for reconsideration at page 3.

<sup>36</sup> July 30, 2009 petition at page 4.

questioning the accuracy of the technical teaching of the Nabai reference;<sup>37</sup> however, this is unpersuasive. Given that patent owner should have been aware of both the high threshold requirement to show that a patent is not enabled and the Office's mandate for special dispatch, patent owner should have begun rigorously seeking to obtain evidence challenging the Nabai reference sooner (i.e., before final Office action) rather than later (i.e., after final Office action). This particular argument only distracts from the issue at hand - that patent owner's evidence after final was not responsive to any new ground of rejection made or new issues raised in the final Office action. The statement in the December 18, 2009 Office decision regarding the very high bar to show that a U.S. patent is not enabled was not the basis of that decision, but instead was an advisory comment on a position that should have been asserted via a § 1.181 petition, rather than in the petition being addressed.

Patent owner had explained in its July 30, 2009 petition that the *costs and substantial efforts* that went into preparing these declarations impeded the patent owner's ability to submit such declarations at an earlier date.<sup>38</sup> However, the October 27, 2009 Office decision stated that it appeared that the patent owner did not make any efforts to seek evidence until after the final Office action was mailed.<sup>39</sup> Patent owner has not returned to this argument nor rebutted the Office's determination regarding patent owner's lack of effort to at least begin the process of obtaining evidence prior to the final Office action.

As such, the petition again fails for want of a persuasive explanation of why the patent owner did not consider and explore the need for the new evidence earlier in the prosecution of the present reexamination proceeding, which would have led to an earlier submission of the evidence to advance the Office's need for special dispatch in reexamination.

## **2. Patent Owner's Arguments for Situations Warranting Continued Reexamination Contemplated in the March 1, 2005 Notice**

As an initial matter, the Request for Continued Reexamination (RCR) analogous rule package contemplated and referred to in the Notice was never promulgated, even as a proposed rule. A review of the March 1, 2005 Notice shows that the intent of the Notice is to advise patent owners to use "the petition procedure under 37 CFR 1.182;" i.e., the currently existing procedure set forth for "situations not specifically provided for" in the regulations. The Notice does not provide its own specialized new petition procedure. For this reason, each petition submitted under § 1.182 seeks its own individualized relief based on the equities of the individualized fact situation, and decisions on such petitions do not create any body of generalized expectations that could be applied to any individual petition submission.

The grant of relief for such a § 1.182 petition is strictly controlled by the Office so as to further the statutory mandate of 35 U.S.C. § 305 that "[a]ll reexamination proceedings under this section . . . will be conducted with **special dispatch** within the Office" [emphasis added]. In keeping with the requirement of special dispatch, a petition under 37 CFR 1.182 for continued reexamination must show how granting the petition would further the prosecution of the reexamination proceeding.

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<sup>37</sup> Petition for reconsideration at page 2.

<sup>38</sup> July 30, 2009 petition at page 5.

<sup>39</sup> October 27, 2009 decision at page 6.

Prosecution may be furthered by reducing issues, by better defining the issues for appeal (not raising new ones), or by placing the claims in condition for the issuance of a reexamination certificate. In support of the relief requested, a patent owner is to set forth reasons why the submission could not have been presented at an earlier point in the proceeding.

With respect to the ability of the submission to further the prosecution by its entry, patent owner fails to provide specific rationale explaining how entry of the July 8, 2009 declarations would act to better define the issues for appeal, or the issuance of a reexamination certificate. Patent owner only states that without the entry of the Bernie declaration, "the issues relating to the Nabai reference cannot be resolved."<sup>40</sup> In neither the petition, nor elsewhere in the prosecution record, has patent owner set forth with specificity the manner in which the evidence submission would advance prosecution towards issuance of a reexamination certificate or towards appeal. Irrespective of the merits of the evidence submission, the instant petition fails to clearly show how the submission is a *bona fide* effort to address the rejections of the claims so as to define the issues for appeal, or the issuance of a reexamination certificate. Reopening of the prosecution to consider the declarations absent a showing of a *bona fide* effort to advance prosecution by better defining the issues for appeal or the issuance of a reexamination certificate would validate the patent owner's unnecessary delay in presenting the declarations in this proceeding, contrary to the statutory requirement for "special dispatch within the Office."

Patent owner argues in the present request for reconsideration that the Office has violated a basic rule of fairness by granting the April 19, 2006 petition for continued reexamination filed in the '6802 proceeding (see the July 18, 2006 Office decision in the '6802 proceeding attached to the December 24, 2009 petition), but not granting the § 1.182 petition for continued reexamination in the present proceeding. In response, the facts and circumstances that were considered in support of continued reexamination in the '6802 proceeding are different from the facts and circumstances of the present proceeding. In the '6802 proceeding, patent owner submitted a proposed after-final amendment and accompanying declaration in response to new grounds of rejection that applied a newly cited reference in the final Office action.<sup>41</sup> In contrast, the final Office action here did not include a new ground of rejection and did not rely on a new reference. It was only after the examiner issued the same rejections twice, and did not accept the patent owner's arguments in response to the November 6, 2008 non-final Office action that patent owner elected to submit evidence in response to the final Office action where no new grounds of rejection were made. In this case, patent owner failed to seasonably submit evidence, despite the clear notice in MPEP 2272 that evidence submissions should be filed before final action, and despite the statutory mandate for special dispatch in reexamination. That failure is particularly stark here, where the final Office action did not differ from the second non-final Office action. Therefore, contrary to patent owner's allegations in the present petition, the July 18, 2006 decision in the '6802 proceeding is not on point. Simply put, in the instant proceeding, patent owner in this instance failed to prosecute the proceeding in a manner that would support the unequivocal mandated of 35 U.S.C. § 305 for the Office to carry out an *ex parte* reexamination proceeding with special dispatch. And, the requested reopening of the prosecution to consider declarations that were not submitted at the earliest possible point in the proceeding would be contrary to the Office's mandate for special dispatch. Aside from these points, each situation

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<sup>40</sup> Petition for reconsideration at page 3.

<sup>41</sup> September 27, 2005 final Office action, newly applying the Wardlaw reference, in the '6802 proceeding at page 11.

under § 1.182 stands on its own merits; and, as stated above, the equities here are not the same as there.

For the reasons set forth above, the patent owner's arguments and explanations regarding why the July 8, 2009 response after final accompanied by the §1.132 declarations could not have been presented earlier are not persuasive.

Accordingly, patent owner's December 24, 2009 petition requesting reconsideration of the dismissal of the November 4, 2009 renewed petition requesting continued reexamination of the present reexamination proceeding is denied as to the underlying relief requested. Further, given the extensive treatment of this issue (this is the third decision on the matter), the decision is designated a **final agency action** within the meaning of 5 U.S.C. § 704.

### CONCLUSION

1. The present petition for reconsideration is granted to the extent that the prior decision has been reconsidered, but it is denied as to the underlying relief requested. The prosecution of the present *ex parte* reexamination proceeding is not being reopened for continued reexamination to consider the July 8, 2009 after final response and declarations.
2. This decision is a final agency action within the meaning of 5 U.S.C. § 704.
3. Further correspondence with respect to this matter should be addressed as follows:  
  
By mail: Mail Stop  
Commissioner for Patents  
Post Office Box 1450  
Alexandria, VA 22313-1450
4. Jurisdiction over the proceeding is returned to the Central Reexamination Unit
5. Any questions concerning this communication should be directed to Susy Tsang-Foster, Legal Advisor, at (571) 272-7711 or, in her absence, to Kenneth M. Schor, Senior Legal Advisor at (571) 272-7710.



Brian E. Hanlon  
Director  
Office of Patent Legal Administration

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