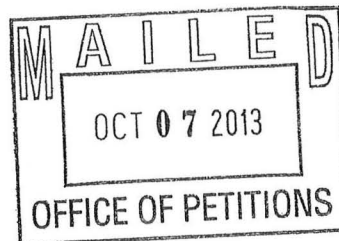




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In re Application of
Michael A. BOSS et al
Application No. 08/453,449
Filed: May 30, 1995
Attorney Docket No.: CARP0018-106

ON PETITION

This is a decision on the petition, filed March 6, 2013, under 37 CFR § 1.181 requesting supervisory review of the decision of the Director of Technology Center 1600 (Technology Center Director) dated January 7, 2013, and under 37 CFR § 1.183 requesting waiver of 37 CFR § 1.142 and 37 CFR § 1.116. The instant petition requests the examiner be directed to withdraw the restriction requirement and the amendment filed November 7, 2011 to be entered.

The petition to withdraw the restriction requirement and enter the amendment dated November 7, 2011 in the above-identified application is **DENIED**.

RELEVANT BACKGROUND

The file history has been carefully considered. Relevant portions of the extensive prosecution of this application are summarized below.

- On August 22, 1996, during a telephone interview with the attorney of record for the above-referenced application, restriction was required under 35 USC § 121 between Group 1, claims 34-41 drawn to recombinant antibodies, classified in Class 530, subclass 387.3 and Group II, claims 42 and 43 drawn to methods of therapy using recombinant antibodies, classified in Class 424, subclass 133.1.
- On August 22, 1996 a provisional election was made without traverse to prosecute the invention of Group I, claims 34-41.
- On September 18, 1996, the examiner assigned to the application began prosecution on the merits of the elected Group 1, claims 34-41. Method claims 42 and 43 were withdrawn from further consideration by the examiner pursuant to 37 CFR § 1.142(b), as being drawn to the non-elected invention.

- On September 27, 1996 a supplemental Office action on the merits was mailed.
- On March 28, 1997, applicant filed a response to the Office action and cancelled claims 42 and 43.
- A non-final Office action was mailed September 21, 2007, rejecting all pending claims, claim 34-41 and 44-59, drawn to product claims.
- A response was filed on April 25, 2008 canceling claims 34-41 and 44-59 and presenting new claims 60-86. Claims 60-82 were directed to methods of producing an altered antibody and associated transformed cells, previously not claimed.
- In a final Office action mailed August 6, 2008, the examiner withdrew claims 60-82, on the grounds of election by original presentation. Examiner noted that since applicant had previously received an action on the merits of the originally presented invention, that invention has been constructively elected by original presentation for prosecution on the merits. Claims 60-82 were withdrawn from consideration as being directed to a nonelected invention. 37 CFR § 1.142(b) and MPEP § 821.03. Claims 83-86, drawn to the elected invention, were rejected.
- A Notice of Appeal was filed on February 6, 2009 directed to rejected claims 83-86.
- An amendment after final was filed on April 3, 2009. Petitioner cancelled claims 60-82, amended claims 83-86 and presented new claim 87. New claim 87 was directed to the elected invention and depended from claims 83-86.
- An Advisory Action was mailed in response to the amendment after final on April 15, 2009, indicating that the amendment was not entered. Petitioner was advised that the proposed amendment raises new matter issues that would require further reconsideration and/or search, that the amendment raises the issue of new matter by the addition of the limitation that the claimed antibody was not naturally occurring. The amendments to claims 83-86 and newly added claim 87 were not entered.
- A second amendment after final was filed on August 25, 2009 attempting to further amend claims 83-86 and add new claim 87.
- On September 8, 2009, petitioner filed an Appeal Brief in support of the appeal from the finally rejected claims 83-86.

- A Notification of Non-Compliant Appeal Brief was mailed September 29, 2009 requesting that petitioner provide the status of all claims.
- Petitioner responded with a corrected Appeal Brief, filed October 19, 2009, indicating that claims 1-59 were cancelled, 60-86 were pending. Claims 60-82 are withdrawn and claims 83-86 stand rejected and are on appeal.
- A second Notification of Non-Compliant Appeal Brief was mailed January 20, 2010 indicating that that the Appeal Brief did not include the judgment on appeal of interference decision from the Board of Patent Appeals and Interferences by the Court of Appeals for the Federal Circuit (CAFC), dated December 11, 2009.
- Petitioner responded on February 22, 2010 and provided a copy of the judgment of the CAFC entered on December 11, 2009.
- In view of the judgment of the CAFC on December 11, 2009, the examiner on May 11, 2010, issued new grounds of rejection in a non-final Office action. The examiner indicated that the amendment filed August 25, 2009 had not been entered. However, per MPEP § 1207.04, the amendment should have been entered.
- An amendment was filed on November 10, 2010. The amendment presented new claims 87-106.
- A Notice of Non-Compliant amendment was mailed February 1, 2011. The examiner indicated that claims 87-106 were directed to distinct inventions from the invention previously elected and examined.
- An amendment was filed on March 1, 2011. The amendment presented claims 87-106, and added claims 107-110. Claims 107-110 were drawn to the elected invention.
- On March 4, 2011, the examiner held the amendment of March 1, 2011 non-responsive for failure to submit a complete listing of the claims.
- On March 29, 2011, petitioner replied with a complete listing of the claims, now new claims 87-110 (originally filed on November 10, 2010) were entered.
- On June 6, 2011, a final Office action was mailed. Claims 87-106 were withdrawn as being directed to a non-elected invention. Claims 107-110 were rejected.

- An amendment after final was received on November 7, 2011. The amendment amended claims 87-93 and 102-110 and submitted previously presented claims 94-101.
- An Advisory Action refusing entry of the amendment was mailed November 14, 2011. The advisory indicated that the proposed amendment would not be entered because the amendment raise new issues that would require further consideration and/or search, they raise the issue of new matter and they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- A Notice of Appeal and Pre-Appeal Request for Review were filed on December 7, 2011. The Pre-Appeal Request for Review did not address any of the rejections given in the final rejection mailed June 6, 2011.
- A response to the Pre-Appeal Request for Review was mailed February 3, 2012. Claims 107-110 remain rejected and claims 87-106 remain withdrawn from consideration. Applicant was required to submit an appeal brief.
- On May 31, 2012, a petition to the Director under 37 CFR § 1.181 and 37 CFR § 1.183 was filed. The petition requested Director review of the examiner's refusal to examine process of making claims 87-106 and the refusal to enter the amendment after final filed November 7, 2011.
- On July 3, 2012 an appeal brief was filed with claims 107-110 as the appealed claims.
- The petition was dismissed as untimely on July 3, 2012 since 37 CFR 1.181(f) indicates that any petition not filed within two months of the mailing date of the action from which relief is requested may be dismissed.
- A revised petition to the Director under 37 CFR § 1.181 and 37 CFR § 1.183 was filed on July 11, 2012. The revised petition requested waiver of 37 CFR § 1.181(f) and a review on the merits of the request to review the examiner's refusal to examine process of making claims and the refusal to enter the amendment filed November 7, 2011.
- On July 30, 2012, the Office of Petitions considered and dismissed the petition filed July 11, 2012. The petition failed to provide any convincing arguments why the first petition was not timely filed, nor did petitioner provide convincing evidence of an extraordinary situation where justice requires waiver of the rules.

- Reconsideration of the dismissal of the petition was filed on September 25, 2012. Petitioner argues that 37 CFR § 1.144 permits the filing of the petition before appeal. Petitioner again requested review of the restriction requirement.
- On December 20, 2012, the Office of Petitions granted the petition for review of the restriction requirement and referred the application to Technology Center 1600 for reconsideration on the merits of the petitions filed May 31, 2012 and July 11, 2012.
- On January 7, 2013, the Director of Technology Center 1600 denied the petition filed September 25, 2012. The restriction (withdrawn by original presentation) required between the examined product claims and later-added claims to the process of making the product was maintained. The amendment after final was refused entry on the basis that similar and/or comparable claim limitations were not presented prior to the mailing of the final rejection.
- Applicant now request review of the Director's decision refusing to withdraw the restriction requirement and refusing to require the examiner to enter the amendment filed November 7, 2011.

STATUTE, REGULATION, AND EXAMINING PROCEDURE

35 U.S.C. § 121 states:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

37 CFR § 1.116(b) states:

After a final rejection or other final action (§ 1.113) in an application or in an ex parte reexamination filed under § 1.510 or an action closing prosecution (§1.949) in an inter partes reexamination filed under §1.913, but before or on the same date of filing an appeal (§ 41.31 or § 41.61 of this title):

- (1) An amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action;
- (2) An amendment presenting rejected claims in better form for consideration on appeal may be admitted; or
- (3) An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented

37 CFR § 1.142 states:

- (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.
- (b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

37 CFR § 1.145 states:

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 ,1.144 and 1.183.

37 CFR § 1.181(f) states:

The mere filing of a petition will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings. Any petition under this part not filed within two months of the mailing date of the action or notice from which relief is requested may be dismissed as untimely, except as otherwise provided. This two-month period is not extendable.

37 CFR 1.183 states:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed. Any petition under this section must be accompanied by the petition fee set forth in 37 CFR 1.17(f).

MPEP § 806.05(f) states:

A process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make another materially different product; or (B) that the product as claimed can be made by another materially different process. Allegations of different processes or products need not be documented. A product defined by the process by which it can be made is still a product claim (*In re Bridgeford*, 357 F.2d 679, 149 USPQ 55 (CCPA 1966)) and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process; defining the product in terms of a process by which it is made is nothing more than a permissible technique that applicant may use to define the invention.

MPEP § 806.05(j) states:

To support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, both two-way distinctness and reasons for insisting on restriction are necessary, i.e., separate classification, status in the art, or field of search. See MPEP § 808.02. See MPEP § 806.05(c) for an explanation of the requirements to establish two-way distinctness as it applies to inventions in a combination/subcombination relationship. For other related product inventions, or related process inventions, the inventions are distinct if:

- (A) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive;
- (B) the inventions as claimed are not obvious variants; and
- (C) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 802.01.

MPEP § 808.02 states:

Where the inventions as claimed are shown to be independent or distinct under the criteria of MPEP § 806.05(c) - § 806.06, the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following:

(A) Separate classification thereof: This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(B) A separate status in the art when they are classifiable together: Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(C) A different field of search: Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

MPEP § 818.02(a) states:

Where claims to another invention are properly added and entered in the application before an action is given, they are treated as original claims for purposes of restriction only.

The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination (RCE) which has been filed for the application. Subsequently presented claims to an invention other than that acted upon should be treated as provided in MPEP § 821.03.

MPEP § 821.04(b) states:

Where claims directed to a product and to a process of making and/or using the product are presented in the same application, applicant may be called upon

under 35 U.S.C. § 121 to elect claims to either the product or a process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR § 1.142. See MPEP § 821 through § 821.03. However, if applicant elects a claim(s) directed to a product which is subsequently found allowable, withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must depend from or otherwise require all the limitations of an allowable product claim for that process invention to be rejoined. Upon rejoinder of claims directed to a previously nonelected process invention, the restriction requirement between the elected product and rejoined process(es) will be withdrawn. If applicant cancels all the claims directed to a nonelected process invention before rejoinder occurs, the examiner should not withdraw the restriction requirement. This will preserve applicant's rights under 35 U.S.C. § 121. Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, applicant may present claims directed to the process of making and/or using the allowable product by way of amendment pursuant to 37 CFR § 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise require all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. However, if applicant files an amendment adding claims to a process invention, and the amendment includes process claims which do not depend from or otherwise require all the limitations of an allowable product, all claims directed to that newly added invention may be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03).

MPEP 1207.04 states:

The examiner may, with approval from the supervisory patent examiner, reopen prosecution to enter a new ground of rejection after appellant's brief or reply brief has been filed. The Office action containing a new ground of rejection may be made final if the new ground of rejection was (A) necessitated by amendment, or (B) based on information presented in an information disclosure statement under 37 CFR 1.97(c) where no statement under 37 CFR 1.97(e) was filed. See MPEP § 706.07(a). Any after final amendment or affidavit or other evidence that was not entered before must be entered and considered on the merits.

MPEP § 2113 states:

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

OPINION

Petitioner requests supervisory review of the Technology Center Director's decision. Petitioner further requests that the examiner be directed to withdraw the restriction requirement presented in the final rejection dated August 6, 2008 and enter the amendment filed November 7, 2011.

Restriction Requirement

Petitioner argues: (1) a restriction is not required if claims are distinct from or independent of the invention previously claimed. Petitioner submits that the claims presented must be both distinct from and independent of the invention previously

claimed; (2) the process of making claims are not distinct and independent of the product claims; (3) applications stemming from a divisional application are not limited to the invention claimed in that division; (4) constructive elections are not required by statute; and (5) the situation here is extraordinary because petitioner cannot now file a continuation application to pursue the process claims because the 20-year term will have long expired.

With respect to petitioner's argument that restrictions are not required if claims are distinct from or independent, petitioner is reminded that applicants are entitled to a patent to a single invention. In the instant case, the examiner properly restricted the claims in the application to a single invention. The examiner has established on the record and the record is clear that the product and methods of making the product are distinct.

Under 35 USC § 1.121 the claims of an application may properly be restricted to one of two claimed inventions if it can be shown that each invention is capable of supporting separate patents and they are either independent, MPEP § 806.06 or distinct, MPEP § 806.05. Although the product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. Hence a process of making the product claim is capable of supporting a separate patent apart from the product claims.

A process of making the product and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make another materially different product; or (B) that the product as claimed can be made by another materially different process. See MPEP § 806.05(f), above. As set forth in the restriction requirement, the product as claimed can be made by another materially different process. The petitioner asserts that the distinction made by the Office glosses over the first step recited in the method claims and the product-by-process limitations. As indicated by the examiner, the product can be produced via various recombinant and non-recombinant means such as phage display libraries and in vitro immunization. Phage display libraries and in vitro immunization require different ingredients and process steps that do not rely solely upon the specific steps of the newly submitted claims. Accordingly, restriction is proper. Moreover, petitioner is reminded that the patentability of a product does not depend on its method of production. See MPEP § 2113, above. The examiner set forth proper reasons for restriction as there are processes of making and product by process claims present in this application. For these reasons set forth above, the restriction is maintained.

The Office action of August 6, 2008 referenced the presence of claims 60-86. "Newly submitted claims 60-82 were deemed to be drawn to an invention that is independent or

distinct from the invention originally elected in the Office action of 1996. Claims 60-82 were drawn to methods of producing altered antibodies and associated transformed cells previously not claimed. Methods of producing altered antibodies are related to altered antibodies as process of making and products made. The claimed altered antibodies can be produced by other biological, chemical and recombinant methods, other than that claimed. Transformed cells are drawn to products which differ in structure and mode of action. Altered antibodies and transformed cells do not share a substantial structural feature essential to a common utility. Since applicant has received an action on the merits for the originally elected invention this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60-82 were properly withdrawn from consideration as being drawn to a non-elected invention." Since petitioner received an action on the merits for the originally presented invention in claims 83-86, this invention was properly constructively elected by original presentation for prosecution on the merits.

Regarding applications stemming from a divisional application, 35 U.S.C. § 121 shields claims against a double challenge if consonance exists between the divided group of claims and an earlier restriction requirement. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579, 19 USPQ2d 1241 (Fed. Cir. 1991). Consonance requires that the line of demarcation between the independent and distinct inventions that prompted the restriction be maintained. If a restriction requirement does not set forth the line of demarcation then challenged claims could not satisfy the consonance requirement. Therefore restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that the claims in continuing applications are consonant and therefore deserving of 35 U.S.C. § 121 protections. Here, as discussed above, the examiner in the final rejection of August 6, 2008 established that the applicant by constructive election, elected product claims. Petitioner's arguments appear to be somewhat speculative as to unstated reasons of judges. With regard to the petitioner cited *Beohringer Ingelheim Int'l GMBH v Barr Laboratories, Inc.*, 592 F.3d, 1340 (Fed. Cir. 2010), presented was only a holding in the case as to whether to have an en banc hearing or not. A per curium decision does not give a written opinion as to the facts expressed by petitioner.

With respect to petitioner's request that the requirement for restriction pursuant to constructive election be waived based on an extraordinary circumstance that now prevents the filing of a continuation or divisional application for process claims, the issue at hand is not that petitioner cannot now file process claims in another application, rather, it is whether petitioner has properly followed the statutes and regulations with exercise of reasonable care and diligence herein. In the instant case, a review of the record indicates that the petitioner knew or should have known, based on the examiner's actions regarding restrictions that no process claims were pending before the Office.

37 CFR § 1.183

In order for grant of a petition under 37 CFR § 1.183, petitioner must show (1) that this is an extraordinary situation where (2) justice requires waiver of the rules. *In re Sivertz*, 227 U.S.P.Q. 255, 256 (Comm'r Pat. 1985). Petitioner has not shown that either condition exists in this case, much less that the failure to obtain an earlier date of abandonment in the instant application would have an effect on another application. There is no requirement that any application contain process claims. Additionally, petitioner should have known that he did not have pending process claims on record with the USPTO in the instant or another application. The filing of divisional or continuation applications is always within the control of applicants. Therefore, it is not seen where justice would require waiver of the rules since there is nothing extraordinary in this situation. If anything, extending the potential patent term would be extraordinary and detrimental to the general public. Petitioner voluntarily chose his representative in this action, and he cannot now avoid the consequences of the acts or omission of their freely selected agent. *Link v. Wabash R. Co.*, 370 U.S. 626 (1962). Any other notion would be wholly inconsistent with our system of representation, in which each party is deemed bound by the actions or inactions of his agent.

Circumstances resulting from petitioner's, or petitioner's counsel's, failure to exercise due care, or lack of knowledge of, or failure to properly apply, the patent statutes or rules of practice are not, in any event, extraordinary circumstances where the interests of justice require the granting of relief. See *In re Tetrafluor, Inc.*, 17 USPQ2d 1160, 1162 (Comm'r Pats. 1990); *In re Bird & Son, Inc.*, 195 USPQ 586, 588 (Comm'r Pats. 1977). The Patent and Trademark Office must rely on the actions or inactions of duly authorized and voluntarily chosen representatives of the applicant, and petitioner is bound by the consequences of those actions or inactions. *Link v. Wabash R. Co.*, 370 U.S. 626, 633-34 (1962); *Huston v. Ladner*, 973 F.2d 1564, 1567, 23 USPQ2d 1910, 1913 (Fed. Cir. 1992); see also *Haines v. Quigg*, 673 F. Supp. 314, 317, 5 USPQ2d 1130, 1132 (D.N. Ind. 1987); *Stevens v. Tamai*, 366F.3d 1325 (Fed. Cir. 2004) (court denying priority due to counsel's admitted failure to follow the Rules of Practice of the USPTO); *Gustafson v. Strange*, 227 USPQ 174 (Comm'r Pats. 1985) (counsel's unawareness of 37 C.F.R. § 1.8 not extraordinary situation warranting waiver of a rule). Indeed, it is well settled that a party's inadvertent failure to comply with the requirements of the rules or procedures before the USPTO is not deemed to be an extraordinary situation that would warrant waiver of the rules or procedures under 37 CFR § 1.183. See *Honigsbaum v. Lehman*, 903 F. Supp. 8, 37 USPQ2d 1799 (D.D.C. 1995). Even assuming, arguendo, that clerical inadvertence or mistake led to petitioner's failure to submit a timely and proper reply, such is not a grounds for requesting waiver of the regulations. See *In re Kabushiki Kaisha Hitachi Seisakusho*, 39 USPQ2d 1319, 1320 (Comm'r Pat. 1994) (clerical error causing delay leading to a loss of right does not warrant suspension of the rules).

In the instance case, petitioner had the option of filing a divisional or continuation application within the 20-year term to pursue the process claims, but chose not to do so. Petitioner's failure to file a divisional or continuation within the 20-year term, which precludes it from now filing a divisional or continuation, does not justify suspension or waiver of the rules under 37 CFR § 1.183 because it does not rise to the level of an extraordinary event within the meaning of 37 CFR § 1.183. See, *Nitto Chemical Industry Co., Ltd. V. Comer*, 37 USPQ2d 1778 (1994). (Commissioner's refusal to waive requirements of 37 C.F.R. § 1.10 in order to grant priority filing date to patent application not arbitrary and capricious, because failure to comply with the requirements of 37 CFR § 1.10 is an "avoidable" oversight that could have been prevented by the exercise of ordinary care or diligence, and thus not an extraordinary situation under 37 CFR § 1.183). *Gustafson v. Strange*, 227 USPQ 174 (Comm'r Pats. 1985) (counsel's unawareness of 37 C.F.R. § 1.8 not extraordinary situation warranting waiver of a rule).

Moreover, no extraordinary circumstance has been shown to have occurred that precluded petitioner from filing process claims in another application at an earlier time. See *Vincent v. Mossinghoff*, 230 USPQ 621, 625 (D.D.C. 1985) (petitioner's failure to take adequate notice of USPTO procedures will not be permitted to shift, in equity, his lack of diligence onto the USPTO).

Amendment after Final

Petitioner requests entry of the amendment filed November 7, 2011 requesting that the rule prohibiting entry of amendments after final be waived since it is not required by statute. Petitioner again submits that: (1) the situation is extraordinary; (2) the amendment would overcome most of the outstanding rejections; and (3) petitioner cannot file a continuation application because the 20-year term will have long expired. Petitioner seeks waiver of the rule prohibiting entry of after final amendments such that the November 7, 2011 amendments can be entered.

A review of the file history indicates that petitioner, in response to the final rejection dated June 7, 2011, filed an amendment 5 months later. Petitioner was notified on November 14, 2011 that the amendment after final dated November 7, 2011 would not be entered. On May 29, 2012, more than 6 months later, petitioner filed a petition to have the amendment entered. The history also reveals that there is nothing of record indicating that the amendment overcomes the rejections of record.

Petitioner is advised that 1) 37 CFR § 1.181(f) permits the dismissal of a petition not filed within two months of the mailing date of the action or notice from which relief is requested; (2) the instant petition appears to argue issues presented in the Office letter mailed November 14, 2011; (3) as over 6 months passed between the action dated November 14, 2011 and the petition filed on May 29, 2012, the instant petition is dismissed as untimely; and (4) as noted in *Korsinsky v. Godici*, 2005 U.S. Dist. LEXIS

20850, (S.D.N.Y. 2005), by operation of regulation, the Commissioner was entitled to dismiss Korsinsky's petition as untimely.

Accordingly, the amendment filed November 7, 2011 is denied entry.

Claim 87 filed August 25, 2009

Petitioner finally indicates it has come to the applicant's attention that a product claim, reciting limitations similar to the examined product claims, submitted as new claim 87 in response to the final office action dated August 6, 2008, should have been examined. Petitioner relies on MPEP § 706.07(e) which indicates that all amendments submitted after final rejection are ordinarily entered when a final rejection is withdrawn. Petitioner now request examination of product claim 87.

Claim 87 was originally filed in an amendment after final, dated April 3, 2009, and was directed to the elected invention, an altered antibody of any one of examined claims 83-86. In the advisory mailed April 15, 2009, the examiner refused entry of the amendment. Subsequently, the examiner reopened prosecution of the application after applicant filed an appeal brief, in an Office action mailed May 11, 2010. Upon reopening of prosecution the amendment dated April 3, 2009 should have been entered as provided by MPEP § 1207.04, however the amendment was not entered and claim 87 was not treated on the merits. With prosecution being reopened, the applicant had the opportunity to either request that previously filed claim 87 be entered, or re-submit previously submitted claim 87. Applicant did neither, and in fact, later added a different claim 87.

The consideration of claim 87 filed August 25, 2009 is clearly untimely here. A review of the record indicates that petitioner responded to the non-final Office action, and continued prosecution traversing the rejections, filing amendments to the claims, submitting amendments after final, filing Notice of Appeals and requesting a pre-appeal review during a period of more than 2 years. The failure of the examiner and petitioner to recognize that claim 87, filed August 25, 2009, was a claim directed to the elected invention, cannot be relied upon now to request examination of that claim 87. When the claim was not entered, applicant failed to timely petition to have claim 87 examined as being directed to the elected invention. Alternatively, as stated above, petitioner was not precluded from, once the final rejection was withdrawn, resubmitting claim 87 as a product claim to be examined with the elected invention.

Furthermore, it is noted that: (1) 37 CFR § 1.181(f) permits the dismissal of a petition not filed within two months of the mailing date of the action or notice from which relief is requested; (2) the instant petitions appear to argue about the Office letter mailed May 11, 2010; (3) as over 2 years passed between that action and the instant petition, the instant petition is dismissed as untimely; and (4) as noted in *Korsinsky v. Godici*, 2005

U.S. Dist. LEXIS 20850, (S.D.N.Y. 2005), by operation of regulation, the Commissioner was entitled to dismiss Korsinsky's petition as untimely. Accordingly, petitioners request to have the product claim 87 reinstated is denied.

For the reasons set forth above, with respect to petitioner's request to waive 37 CFR § 1.145, waiver of 37 CFR § 1.116 to allow entry of the process claims would not be appropriate. Circumstances resulting from petitioner's, or petitioner's counsel's failure to exercise due care, or lack of knowledge of, or failure to properly apply the patent statutes or rules of practice are not, in any event extraordinary circumstances where the interests of justice require the granting of relief. See *In re Tetrafluor, Inc.*, 17 USPQ2d 1160, 1162 (Comm'r Pats. 1990).

DECISION

The instant petition is granted to the extent that the action of the Technology Center Director has been reviewed, but is **denied** with respect to directing withdrawal of the restriction requirement, and denied with respect to the entry of the amendment filed November 7, 2011.

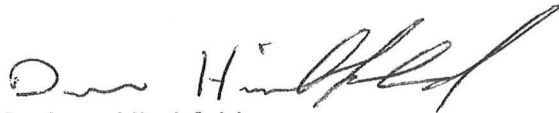
A review of the record indicates that the Technology Center Director did not abuse his discretion or act in an arbitrary and capricious manner in the petition decision of January 7, 2013. The record establishes that the Technology Center Director had a reasonable basis to support her findings and conclusions. In addition, petitioner has not shown the existence of an extraordinary situation in which justice requires waiver of the rules to permit claims to a process of making and/or entry of the after final amendment.

This decision is a final agency action within the meaning of 5 U.S.C. § 704 for purposes of seeking judicial review. See MPEP § 1002.02.

The petition fee under 37 CFR § 1.17(f) required for a petition under 37 CFR § 1.183 has been charged to petitioner's Deposit Account 50-4364.

The above-identified application is being referred to Technology Center 1600 for further processing consistent with this decision.

Telephone inquiries concerning this decision may be directed to Supervisory Petitions Examiner Thurman K. Page at (571) 272-0602.

A handwritten signature in black ink, appearing to read "Andrew Hirshfeld", is written over the printed name.

Andrew Hirshfeld
Deputy Commissioner for
Patent Examination Policy/
Petitions Officer