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**VIA E-MAIL ONLY**

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***Novartis Comments on Improving Patent Quality Measurement/Proposed Master Review Form (MRF) (Fed. Reg. Vol. 81, No. 58; p. 16142-45, March 25, 2016)***

Novartis is a global healthcare company whose mission is to discover new ways to extend and improve patients' lives. Like others in our industry, we depend heavily on the patent system to provide the incentives necessary to enable the work that we do to invent, develop and bring our medicines to patients. The quality of the system, and of the patents that emerge from it, are therefore of utmost importance, not only to us as a frequent user of the system, but to the patients whose lives are ultimately impacted in very real ways by the strength, consistency and reliability of the system that fuels the development of their treatments and cures. We thus have a keen interest in the Office's efforts to improve not only the quality of the system itself, but the quality and efficiency of the metrics that it uses to measure and assess its own performance, and are pleased that it is now taking additional actions to ensure clarity of the record and quality in examination. We are also pleased with the Office's continuous engagement with its stakeholders throughout the Enhanced Patent Quality Initiative (EPQI), and thank the Office for this opportunity to assist now in developing the implementation and guidance for use of the Office's new proposed Master Review Form (MRF). Our specific comments at this time with respect to the MRF are as follows:

**I. General Comments on the Overall Content and Form of the MRF**

*1) The Office Should Clarify How and When the MRF will be Used to Review Examiners' Work Product*

From the current information provided to stakeholders, it is unclear exactly how and when the Office will utilize the MRF. The MRF appears to be designed for a reviewer to use to analyze the complete file history of a particular application, e.g., upon allowance, after a final rejection, or upon abandonment. If that is the case, however, it is not clear whether the form is intended to be used only to provide metrics of the quality of the examination, or if the Office could/would further use the results of the review to revise the outcome of the examination. Moreover, if a review did change the outcome, it does not appear that the Office has developed a mechanism to notify an applicant that a change has occurred due to an independent review. Such a mechanism should be put in place if this is the Office's intent. The timing, moreover, of MRF-based reviews should also be clarified, and in our view

should be completed before an official action is mailed to an applicant, since examiners in other countries often make decisions based on indications of rejection or allowance by U.S. patent examiners. Completing MRF-based reviews before official actions are mailed will help to prevent any harm that a poorly constructed and/or reasoned official action may otherwise create within the same family of patent applications in other countries.

If, on the other hand, the MRF is intended to be used to review a variety of single ‘actions’ by an examiner, this objective might better be served by creating a set of separate forms specific to each type of action to be reviewed (e.g., restriction vs. non-final action vs. final action vs advisory action). This would allow reviews to be customized to each type of action, without becoming unwieldy in size and scope. As currently proposed, the MRF is so extensive that it does not seem well-suited or efficient for individual action review, as much of the form would be irrelevant to the particular action being assessed.

2) *The Office Should Consider Shortening the MRF to Ensure That Users’ Engagement is Maintained*

a) The Office Should Consider “Splitting” the MRF into Separate Search and Examination MRFs

As noted above, the comprehensive nature of the proposed MRF suggests that it will be used to review an entire examination process from start to finish. If that is the Office’s intention, we ask the Office to consider at least separating review of Search from review of Examination. This would improve the efficiency of the process, particularly where a Search is found to be materially incomplete or misdirected for a given claim set, since reviewing the subsequent Examination in such a case would not be particularly useful. While we recognize that, in such a situation, a reviewer would still be able to analyze an examiner’s application of law to the misidentified facts, the reviewer in such case would also need to spend extensive time criticizing rejections of record and identifying ‘omitted rejections’ that are truly only reflective of search deficiencies. In our view, it is far more logical for a reviewer to first perform a separate Search review. If the Search results (and subsequently selected prior art) are correct, only then should the Office proceed to perform an Examination review.

b) Alternatively, the Office Should Consider Creating a Long and Short Version of an Examination MRF

As an alternative to separating the Search and Examination reviews and forms, we suggest that the Office consider having a long, relatively comprehensive version of the MRF, and a shorter, simpler version that would allow a Reviewer to examine more cases in less detail. As currently proposed, while a long version may be useful for reviewing all aspects of an examination proceeding, its length is likely to result in a reviewer giving only brief attention to most topics. Creating a second, shorter version of the MRF would address that concern by enabling a reviewer to

focus mainly on prior art-based rejections, e.g., looking at whether grounds for rejection are well reasoned and adequately conveyed, and whether an examiner gave due consideration and response to an applicant's arguments offered in reply to initial rejections.

*3) The Office Should Consider Adding More Granularity to the Scale Used in the MRF*

The Office could also improve the MRF by providing a selection of responses with greater depth than what is currently offered. At present, the statements in the MRF typically offer a choice of only i) yes; ii) in-part; or iii) no, as responses. Providing only these three choices does not seem to provide sufficient granularity to allow the data harvested by the MRF to be as useful as it could be. The response "in-part" covers a very wide range of potential shortcomings, from those that are very minor to those that are much more severe. In our view, the MRF would provide much better data to the Office and to Examiners if the choice of responses better identified different levels of "in-part." As an example, the choice of responses could be revised to include: i) fully; ii) mostly; iii) partially; iv) slightly; or v) not at all. This set of questions would essentially require a reviewer to identify whether an examiner is closer to "right" or closer to "wrong." These types of choices will also more clearly convey whether a particular issue raised by a particular statement was addressed and the extent of detail and precision that was used in addressing that issue.

*4) The Office Should Consider Reordering/Removing Certain Items*

Several sections of the MRF are somewhat difficult to follow as currently arranged, and could benefit from either being removed or rearranged in a way that would make them more valuable or easier to complete. For example, in our view, the "Overview" section as currently written is somewhat confusing. Initially, it asks which rejections were made in a particular action. While this is straightforward and simple to answer, the second question, asking which rejections were omitted, requires a very substantive review. It would be quite difficult for a reviewer to answer these questions accurately until he/she has considered and answered all of the questions in the MRF. To make this second question more useful, it might best be moved to the end of the MRF. Alternatively, this question might be revised to instruct a reviewer to answer the second question only after completion of the MRF. In such case, a further note could be placed at the end of the MRF to remind the reviewer that he/she should return to the beginning to complete the "Overview" section.

We further suggest that the Office consider grouping "Omitted Rejections" within each statutory section (e.g., omitted novelty rejections should be included under the analysis of 35 U.S.C. §102). In many cases, addressing an Omitted Rejection may merely require a reviewer to indicate that a certain rejection of record should have been made applicable to additional claims. We believe this change in grouping will reduce the length and complexity of the MRF.

Additionally, the Office should consider removing the question about the source of art upon which an “Omitted Rejection” is based, as it is unclear why the source is relevant to the rejection. Alternatively, should the Office perform a separate Search review, the source of art overlooked by an examiner could be included in the separate Search review. In our view, removal of this question would reduce the length and complexity of the form.

#### *5) Consider Adding Several Additional Questions*

In our view, there are several additional questions that could be added to the MRF to further enhance its value as a quality assessment tool. One such set of questions should be aimed at assessing an examiner’s proper use of the Broadest Reasonable Interpretation (BRI) standard when interpreting patent claims. Such a set could, for example, be structured to allow a reviewer to select one of the following choices: **i) The rejection properly interpreted the claim under the BRI standard; ii) the rejection interpreted the claims too narrowly under the BRI standard; or iii) the rejection interpreted the claims too broadly under the BRI standard.** Interpreting the language of claims properly is of course of critical importance, because it defines the scope of what is assessed for patentability and patent eligibility, and provides clarity as to the subject matter claimed once a patent issues. In our view, it is therefore important to include questions along these lines in the MRF.

Another question that the Office should consider adding is an additional question in the “Correctness” subsections asking if an examiner properly considered all rebuttal arguments and/or evidence presented to the Office to overcome the statutory rejection. While the Office proposes a similar question in the catch-all section “Reply to Applicant,” we believe that including this question in the “Correctness” subsection for each rejection made would ensure that this data can be captured and parsed for each statutory section.

A third question that might be added is an additional question in the “Clarity” subsections asking if an examiner provided an explanation as to why any rebuttal arguments and/or evidence presented to the Office were insufficient to overcome a rejection. Including this question in the “Clarity” subsection for each rejection made would ensure that this data can be captured and parsed for each statutory section.

Last, the Office should consider adding a question to all “Clarity” subsections asking if an examiner has made a suggestion to overcome a particular rejection. While the Office proposes a similar question in the catch-all section “Other Quality Related Items,” we believe including this question in the “Correctness” subsection for each rejection made will ensure that this data can be captured and parsed for each statutory section.

## **II. Comments on Specific Portions of the MRF:**

In addition to the above General Comments, we believe that specific sections of the MRF could benefit from some changes to provide further clarity to reviewers. As an initial matter, we believe that the MRF would be clearer if all portions of the

form were presented consistently. For instance, all statements should be converted to either questions OR statements, and in any event, they should all be stated similarly without double negatives, which make some the statements unnecessarily confusing. We address the specific sections for which we have comments below in the order in which they appear in the MRF.

1) *102 Rejection Made (Correctness):*

This section alternatively refers to “claim features” or “claim limitations,” and in our view, would be clearer if a single term were used consistently, not only in this section, but throughout the entire MRF. Ideally, the term “element” should be used, as referred to in 37 C.F.R. §1.75.

Additionally, the first two statements in this section, as well as the first two statements in the corresponding “Correctness” subsection under “103 Rejection Made,” could be improved with mention of the BRI standard. The first question could be rewritten to read as follows: “Under the BRI standard, the elements of the claims can be said to be found in the prior art relied upon.” The second question could be rewritten to read as follows: “Under the BRI standard, the elements of the claims are properly matched to the prior art relied upon.” Rephrasing these statements in this or a similar manner will remind the reviewer that an examiner must match claim elements to elements found in the prior art, while always assuring that those claim elements are assigned their BRI.

The Office should also consider including in this section, as well as the corresponding “Correctness” subsection under “103 Rejection Made,” a question asking whether an examiner has properly analyzed and/or applied any prior art exceptions under 35 U.S.C. §102(b) (AIA). The new AIA exceptions are quite complex, and practitioners and the Office will benefit from understanding whether the current AIA exceptions are correctly considered and applied.

2) *103 Rejection Made (Correctness):*

The first statement in this subsection would be more accurate if rewritten as follows:

“Does the combination of cited art teach or suggest all of the claim elements?”

We provide this suggestion, because, in order to establish prima facie obviousness of a claimed invention, all of the claim features must be taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981 (CCPA 1974). Indeed, the Board of Patent Appeal and Interferences has confirmed that a proper obviousness determination requires that the Office make “a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art.” *In re Wada and Murphy*, Appeal 2007-3733, citing *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). The necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of

law based on underlying factual inquiries, including ascertaining the differences between the claimed invention and the prior art. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Indeed, MPEP §904 instructs examiners to conduct a search that covers “the invention as described and claimed.” In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim, which should be appropriately reflected in the MRF.

### 3) 103 Rejection Made (Clarity):

*KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), the most recent Supreme Court case analyzing obviousness under 35 USC §103, makes clear that the analysis set forth in *Graham v. John Deere Co.* still governs all obviousness determinations. Thus, we believe that it is vitally important that the Office revise the *Graham v. John Deere Co.* set of questions to further include the following:

- Did the examiner establish and clearly set forth the level of skill in the relevant art?;
- Did the examiner analyze all secondary considerations of record prior to forming a conclusion of obviousness?
- Did the examiner consider all secondary indicia of non-obviousness found in the original application? and
- Did the examiner consider all secondary indicia of non-obviousness submitted by the Applicant(s)?

### 4) 101 Rejection Made (Correctness):

For utility-based rejections under 35 U.S.C. §101, in our view this MRF section should ask whether a Section 101 rejection is properly accompanied by a rejection under 35 U.S.C. §112(a) (lack of enablement) for failure to teach “how to use” a claimed invention.

With respect to subject matter eligibility under Section 101, we believe that it is imperative to emphasize in this section that each claim must be considered as a whole when an examiner undertakes the §101 analysis. To achieve this, we propose that the Office include the following question in this section: “**For each claim receiving a rejection under 101, did the Examiner analyze the claim as a whole, rather than dissecting it into individual elements or steps?**” While we understand that the Office may not wish to expand the number of questions around subject matter eligibility given the evolving state and increasing unpredictability of the case law in this area, we believe that this fundamental principle should be reflected, as this approach has been consistently reaffirmed in the Supreme Court precedents in this area. *See, e.g., Diamond v. Diehr*, 450 U.S. 175 (1981); *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289, 1298 (2012) (reaffirming *Diehr* and inquiring whether “the three steps *as an ordered combination* adds [something more] to the laws of nature that is not already present when the steps are considered separately.”) (emphasis added).

5) *Double Patenting (Statutory) Rejection Made (Correctness):*

In our view, this section, as well as the “Double Patenting (Non-Statutory) Rejection Made” section, should include a question asking whether an examiner focused *solely on the claims* of the reference patent (or application), rather than relying on the disclosure of the reference patent (or application). In addition, it would be useful to include a sub-question that asks whether any reliance on the specification was proper, e.g., for definition of a claim term or to identify the utility of a claimed composition. Together, both of these questions will provide data that the Office may use to determine whether examiners have a proper understanding of the role of the claims (vs. the specification) in obviousness-type double patenting rejections.

We further suggest that this section, as well as the “Double Patenting (Non-Statutory) Rejection Made” section, be amended to include a question asking whether an examiner has properly set forth the procedural basis for the obviousness-type double patenting rejection, i.e., same inventor type, common owner type, or joint research agreement type-double patenting. This question will provide data that the Office may use to determine whether examiners have a proper understanding of the threshold basis for making obviousness-type double patenting rejections.

6) *Double Patenting (Non-Statutory) Rejection Made (Clarity):*

To accurately reflect Supreme Court case law, it is vitally important that the Office revise the *Graham v. John Deere Co.* question in this portion of the MRF to individually review each of the Graham factors. Therefore, the question “Was a complete *Graham v. John Deere Co.* analysis performed, if claims are obvious variants?” should be expanded to include the same sub-questions found in the “103 Rejection Made” portion of the MRF.

Additionally, the question “Was a genus/species analysis clearly explained?” in this section is not clear. It appears that the intent of this question is to assess whether examiners are properly including an explanation as to why a particularly species is considered unpatentable under obviousness-type double patenting over a co-pending (or prior issued) genus claim. If this is the case, the question should be clarified to reflect this intent.

7) *Reply to Applicant*

This section should ask whether an examiner, having been adequately challenged by an applicant on taking Official Notice of some fact or relying upon “common knowledge” in making a rejection, has properly responded with supporting documentary evidence (e.g., an examiner’s declaration or literature) to support the finding. Including this question will allow the Office to ascertain whether examiners understand and apply the proper procedures set forth in MPEP 2144.03.

#### 8) *Final Rejection*

The question “Was the final rejection premature?” in this section should be expanded to include a more complete set of the possible sub-reasons that would inform whether a final rejection is premature. The MPEP provides that a second or subsequent action on the merits may be made final unless an examiner introduces a “new ground of rejection” that is neither necessitated by an applicant’s amendment, nor based on information submitted in an information disclosure statement. MPEP 706.07(A). According to the courts, “the ultimate criterion of whether a rejection is considered ‘new’ ... is whether appellants have had fair opportunity to react to the thrust of the rejection.” *In re Kronig*, 539 F.2d 1300, 1302 (CCPA 1976); *accord* MPEP 1207.03(A). Thus, a change in the discussion of, or rationale in support of, a rejection can constitute “new grounds” if an applicant has not had a fair opportunity to react to these revisions, even absent a change in the statutory basis for a rejection or a change in the art used to support a rejection. The existence of “new grounds” is therefore highly fact dependent and can include, among other things, new evidence or art, a new statutory basis, reliance on a new part of existing evidence, a new analysis of existing evidence, a new inference drawn from an existing reference, a new legal theory, a new application of law to facts, etc. In light of this, the sub-reasons for premature finality should be expanded in this question, at least by including a catch-all question, with an explanation box such as the following:

*A ‘new ground of rejection,’ not specified above (e.g., reliance on a new part of existing evidence, a new analysis of existing evidence, a new inference drawn from an existing reference, a new legal theory, a new application of law to facts, etc.), was improperly introduced.*

*Please explain:* \_\_\_\_\_.

#### 9) *Other Quality Related Items*

The MRF would also benefit from a new section addressing an examiner’s actions in response to any after-final amendments presented by an applicant. For example, this section could ask whether an examiner properly explained his/her reasons for refusing to enter amendments presented after a final rejection, whether an examiner properly responded to any new arguments from an applicant, and whether rejections were appropriately maintained or withdrawn.

Also beneficial for assessing the overall quality of examination would be a section asking whether any Objections to the claims or the specification were reasonable and clearly conveyed, and a further question assessing whether an examiner addressed each and every claim of record.

Last, in our view, the MRF should ask whether an examiner issued a Notice of Non-Compliant Amendment for minor issues that could have been resolved by a telephone call with an applicant (e.g., an incorrect claim identifier). It is in the interest of compact prosecution to resolve such minor issues expediently, and the Office, in fact, already encourages examiners to address minor issues in this manner.

Gathering data as to whether examiners utilize such notices for minor issues will allow the Office to determine whether compact prosecution recommendations are heeded, and would allow the Office to adapt its rules (if necessary) to encourage the use of telephone interviews, rather than generating unnecessary paperwork.

Novartis again thanks the Office for its continued engagement with stakeholders throughout the EPQI, and for this opportunity to provide feedback on the proposed MRF. Efforts like these are important steps in continuing to improve and ensure the integrity of the patent system that enables the work that we do. We look forward to continuing to participate in the ongoing quality-related dialogue with the Office.

Respectfully submitted,  
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