From:
Sent: Friday, August 13, 2010 3:21 PM
To: Restriction_Comments
Subject: GlaxoSmithKline Comments on Proposed Changes to Restriction Practice in Patent Applications

Dear sirs:

Attached please find the comments offered on behalf of GlaxoSmithKline.

Best regards,

J. Michael Strickland
Senior Patent Counsel

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Comments on Proposed Changes to Restriction Practice in Patent Applications

The Honorable David Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

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

Attn: Linda S. Therkorn

Comments Proposed Changes to Restriction Practice
in Patent Applications, 75 Fed. Reg. 33584 (June 14, 2010)

Dear Under Secretary Kappos:

In response to the Request for Comments published June 14, 2010, at Federal Register, Vol. 75, No. 113, p. 33584-33587, GlaxoSmithKline ("GSK") submits the following comments.

Executive Summary:

As one of the world's leading research-based pharmaceutical and healthcare companies, GSK has a keen appreciation for the importance of a strong and effective patent system that efficiently produces patents of the highest quality. GSK is encouraged that the Patent Office has requested comments on ways to improve the quality and consistency of restriction requirements. Improper restriction requirements can lead to the filing of numerous divisional applications in order to protect the subject matter that the applicant is entitled to have examined in a single application. Improving the quality and consistency of restriction requirements can therefore reduce the expense of obtaining and maintaining patent protection. Additionally, improving the quality and consistency of restriction requirements can improve the efficiency of the patent system by reducing the number of applications that must be examined by the patent office resulting in a reduction in the backlog.

GSK addresses each of the enumerated proposals in turn.

Comments on Proposed Changes to Restriction Practice

1. **PTO proposal: Restriction requirement must set forth reasons why lack of restriction would pose serious burden to the examiner.**

   GSK agrees with the PTO that the MPEP should be clarified to indicate that a restriction requirement, including an election of species requirement, must always set forth the reasons why the inventions are independent or distinct and why there would be a serious burden on the examiner in the absence of a restriction requirement.

2. **PTO proposal: An additional examination prong based on the rationale that the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 USC 112 should be added to the search prong to support an argument that lack of restriction would pose a serious burden to the examiner.**

   GSK does not believe that the burden requirement should include an examination burden requirement. The prior art search prong of the burden requirement is grounded in the classification system, an objective measure of whether a search would be burdensome. The proposed examination prong would be subjective and allow examiners to issue restriction requirement for inventions even falling within the same class. GSK believes such an examination prong in the burden requirement would be too subjective such that there could rarely be a successful challenge to a restriction requirement.

   In addition, the subjectivity associated with assessing an examination burden would result in inconsistent practice among examiners. Even if the MPEP indicates that the rationale for such restriction is limited to non-prior art issues under 35 USC 101 and/or 35 USC 112 as suggested, the reasons for restriction will still be subjective. Additionally, GSK believes there are rare instances when such non-prior art issues will greatly add to the burden on the examiner. The savings incurred in avoiding such rare instances is outweighed by the increased costs to the public and to the PTO.

   The consequences of adding an examination prong could be an increase in the number of allegedly distinct inventions identified in restriction practice, with the concomitant increase in divisional filings needed to adequately protect an invention that should have been examined and disposed of in a single filing. Such an increase will impose undue costs on the patent

applicant to protect in multiple applications an invention that should have been protected in one. In the case of small inventors and even some large corporations that are faced with tight economic times, such an increase in costs may result in applicants not being able to afford to protect the full scope of their inventions. To the extent that applicants can afford to file the divisional applications necessary to protect their inventions, this change will also result in an unwarranted and undesirable increase in the application backlog.

3. **PTO proposal: Revise the burden requirement to indicate that there would be a serious burden if restriction is not required when the prior art applicable to one invention would not likely be applicable to another invention (e.g., because of different field of art or different effective filing date).**

   GSK does not believe that such a revision is necessary as a different field of art is encompassed by the current different field of search justification for imposing a restriction requirement. GSK does not agree that a different effective filing date could support a need for a restriction requirement. Additionally, GSK believes that such a revision may serve to hinder prosecution on the merits in certain circumstances. For example, in the chemical arts, one piece of prior art may be more relevant to one chemical subgenus than to another subgenus, while another piece of prior art could be relevant to the genus, but not to a species. Under current practice, this circumstance could be addressed by rejecting a claim or group of claims, while finding other claims to be allowable. This approach advances prosecution on the merits. GSK believes that the revising the burden requirement as suggested may have a negative impact on efficient prosecution is circumstances such as these.

4. **PTO proposal: Revise election of species practice to require the examiner to set forth groupings of species that the examiner considers to be patentably distinct from one another, but within which the examiner considers the species to be patentably indistinct. The Applicant would then be required to elect either a single species or an identified group of species.**

   GSK does not agree with the suggested change to election of species practice. In some circumstances, particularly in the pharmaceutical arts, species that possess a fair degree of structural similarity can still be patentably distinct from one another. .

5. **PTO requests suggestions for improving higher level review of restriction requirements.**

Under the current system of review, an examiner with partial signatory authority may sign non-final Office actions containing the final requirement for restriction, and the applicant is required to petition the Director in order to obtain review of this final determination. If the Director finds that the restriction was improper and prosecution has not delayed to allow the Director to act on the petition, there is a risk that the prosecution would have advanced to a first or even final office action, resulting in the need for the examiner to rework the application.

GSK believes that there should be an improved and clear path for seeking expedited higher level review of restriction requirements and offers the following suggestion as an example of such review. In instances when the applicant has argued that the restriction requirement is improper either because the inventions are not patentably distinct or because, though patentably distinct, an examination would not pose an undue burden, if the examiner intends to make the restriction final, the examiner is required to contact the applicant to afford the applicant an opportunity to request an interview with the examiner and the examiner's supervisor to discuss the propriety of the restriction requirement.

6. **PTO proposal: The PTO is considering explaining that to support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, that are not otherwise provided for in MPEP §§ 806 through 806.05(j), there must be two-way distinctness (*see* MPEP § 802.01) and a serious burden if restriction were not required.**

GSK agrees with the PTO's proposal.

7. **PTO proposal: If the examiner determines that the elected species is allowable, the PTO would specify that the examination of the Markush-type claim be extended to the extent necessary to determine the patentability of the claim (e.g., examination of non-elected species). If any non-elected species is determined to be unpatentable, the Markush-type claim would be rejected, and the search and examination would not be extended to cover all non-elected species.**

GSK believes that, in an effort to promote expedient prosecution, the examiner should be required to report to the applicant with specificity all species that the examiner found to be patentable and the one or more species that the examiner found to be unpatentable to allow the applicant an opportunity to argue for the patentability of the species found to be

unpatentable and/or amend the claim to recite a genus that encompasses only patentable species. GSK believes that it should be made clear that the applicant will have the ability to amend a genus to delete subject matter that has been found to be unpatentable, allowing a subgenus that encompasses the species found to be patentable to pass to issue.

8. **PTO proposal: clarify that standard rules governing when a final action is appropriately apply to amended Markush-type claims and that whether an action can be made final does not depend upon whether the examiner previously required a provisional election of species.**

   GSK has no comments.

9. **PTO Query: Would restriction be proper between a subcombination and a combination when a subcombination sets forth a Markush grouping of alternatives (e.g., a subcombination claim to an individual DNA molecule selected from a list of alternative embodiments and a combination claim to an array comprising a plurality of DNA molecules wherein one or more of the DNA molecules are selected from the list of alternative embodiments set forth in the subcombination claim – issue: the combination claim does not require all the elements of any particular claimed subcombination to be present in the claimed array)**

   GSK has no comments.

10. **PTO Request: Any suggestions regarding changes to restriction practice as it relates to Markush claims**

    GSK has noticed an inconsistency in the way restriction practice is applied to Markush claims. One examiner may give a 20+ restriction requirement while another examiner may not issue a restriction requirement for similar claims.

    For example, some examiners in the chemical arts will seek to restrict out every subgenus that includes a heterocycle. Thus, if a genus includes a core molecule having either a carbon ring or heterocycle and having four different R groups, $R_1 - R_4$, that could be either carbon rings or heterocycles, the examiner could issue a restriction requirement where: (1) the core is a carbon ring and each of the R groups are carbon rings; (2) the core is a heterocycle and each of the R groups is a carbon ring; (3) the core is a carbon ring, R_1 is a heterocycle, and $R_2 - R_4$ are each carbon rings, etc. Other examiners will not take this granular approach.

As a general matter, GSK believes that proper Markush claims (e.g., claims in which members of the Markush group ordinarily belong to a recognized physical or chemical class or to an art-recognized class, or, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, where it is clear from their very nature or from the prior art that all of them possess this property) should not be subject to restriction.

GSK notes that the Patent Office now utilizes chemical searching tools that allow the examiner to perform structure searches in which a core of a molecule is specified and positions for R groups are not specified, thereby searching for any molecules with the specified core regardless of the R groups that may be attached at the various positions. Other more narrow searches can be constructed when one or more of the R groups have a reasonable number of substituents such that the search can be directed to the core and any one or more of the specified R groups. Such searches are not confined to traditional U.S. classes and subclasses.

In situations where the number of hits retrieved from such a search is reasonable, GSK believes that restriction to a limited subset of R groups, even if such R groups fall within different classes or subclasses, results in inefficient examination as there is no additional search and examination burden on the examiner.

GSK believes the Patent Office should issue guidelines to promote consistency in the restriction of Markush groups in the chemical arts. For example, in instances when the applicant has claimed a specified chemical core related to a pharmaceutical activity with various R groups that will facilitate a chemical structure search, the applicant should be entitled to have the entire scope of the claim examined unless the structure search on the claimed core, narrowed by any reasonable R groups, reveals an inordinate amount of hits.

Such an approach will be more in-line with the "unity of invention" practice followed by most other countries. The PTO presently follows unity of invention practices in connection with international applications filed under the Patent Cooperation Treaty (PCT) and has employed the unity of invention model in establishing worksharing arrangements with other patent offices. Given the Office's considerable experience applying the unity of invention standard, GSK

believes the PTO should consider adopting the "unity of invention" approach for US originating applications.

11. **PTO proposal: Define "rejoinder" to be appropriate when (1) all claims to the elected invention are allowable; and (2) it is readily apparent that all claims to one or more nonelected inventions are allowable for the same reasons that the elected claims are allowable. Claims not subject to rejoinder would include those that require additional consideration of prior art or raise utility, enablement, or written description issues not considered during examination of the allowable elected claims.**

    GSK believes that this is a reasonable proposal and suggests that the examiner be required to give a specific reason as to why the non-elected withdrawn claims will not be rejoined.

12. **PTO proposal: Instruct examiners that when all claims directed to an elected invention are allowable, nonelected claims must be considered for rejoinder and withdrawal of the restriction requirement – whether the nonelected claims are distinct from the allowed claims and whether there would be a serious burden if the nonelected claims were rejoined**

    GSK believes that the PTO should adopt this proposal as it could lead to an increase in rejoined claims with a corresponding decrease in the need for unnecessary divisional filings.

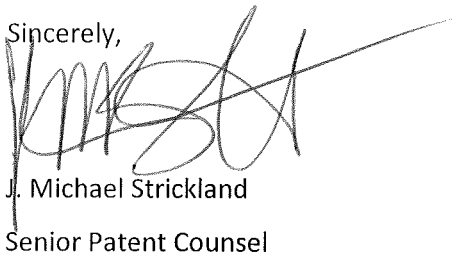
13. **PTO Query: Any other ways restriction practice could be improved?**

    GSK takes this opportunity to request that the Patent Office remind examiners that applications filed under 35 U.S.C. § 371 are examined under the unity of invention standard, Chapter 1800 of the M.P.E.P., rather than under U.S. restriction practice outlined in Chapter 800 of the M.P.E.P. In many cases examiners ignore the unity of invention determination at the PCT stage, and proceed to apply US restriction practice.

Conclusion

GSK understands the need for a strong and effective patent system that efficiently produces patents of the highest quality and appreciates the efforts undertaken by the Patent Office to improve the patent system. GSK appreciates the opportunity to provide comments on the proposed changes to restriction practice.

Sincerely,



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