-----Original Message-----
**From:** Charles.M.Kinzig@gsk.com
**Sent:** Monday, October 15, 2007 11:59 PM
**To:** Markush.Comments
**Subject:** ?Examination of Patent Applications That Include Claims Containing Alternative Language? - Comments on Notice of Proposed Rulemaking

Kathleen Kahler Fonda
Legal Advisor
Office of the Deputy Commissioner for Patent Examination Policy
Alexandria, VA 22313–1450

Dear Ms. Fonda,

Attached please find the comments of GlaxoSmithKline on the Notice of Proposed Rulemaking entitled “Examination of Patent Applications That Include Claims Containing Alternative Language.”

GlaxoSmithKline appreciates the opportunity to comment on the proposed rules. Thank you for thoughtful consideration.

Respectfully yours,

Charles Kinzig

Charles M. Kinzig
VP, Corporate Intel. Prop. - U.S.
GlaxoSmithKline
709 Swedeland Road
King of Prussia, PA 19046
phone: 610-270-5021 / fax: 610-270-5073
e-mail: charles.m.kinzig@gsk.com
Admin. Asst.: Mary T. Fenerty

October 15, 2007

*By Electronic Mail to markush.comments@uspto.gov*

**Comments of GlaxoSmithKline in response to U.S. Patent and Trademark Office Notice of Proposed Rulemaking --**

**"Examination of Patent Applications That Include Claims Containing Alternative Language"**

Docket No. PTO–P–2006–0004
RIN 0651–AC00

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

Attn: Kathleen Kahler Fonda
Legal Advisor
Office of the Deputy Commissioner for Patent Examination Policy

Dear Ms. Fonda:

In response to the Proposed Rulemaking published August 10, 2007, at Federal Register, Vol. 72, No. 154, 44992-45001, GlaxoSmithKline submits the following comments.

***Introduction:***

GlaxoSmithKline ("GSK") is one of the world's leading research-based pharmaceutical and healthcare companies. GSK invested over $6 billion in researching and developing new medicines in 2006, and is investing even more in 2007. These medicines improve the quality of human life by enabling people to do more, feel better and live longer. Typically it takes 8-15 years to discover, develop, and obtain approval for a new medicine – and it requires over $1 B to bring a single new chemical entity to market. GSK relies heavily upon patent protection to recoup its investment in research and development and to continue the search for new and improved medicines.

The subject matter of GSK's patents is primarily in the area of new chemical compounds and compositions, including biomolecules and vaccines, and their use in treating or preventing disease. Chemical compounds are the very type of invention that

alternative (or Markush) claiming was developed to address. Accordingly, the changes to claiming practices embodied in the proposed rules will disproportionately affect GSK and it patent applications, and others similarly situated in the pharmaceutical and biotechnology industries.

As more fully discussed below, GSK believes many of the proposed rules are bad policy, and will adversely affect the security and confidence of stakeholders in the patent system if enacted in their present form. GSK acknowledges the tension between the Office's need to control its search and examination practices and the rights of patent holders to obtain full and effective patent protection. However, GSK believes that the societal benefit of protecting the rights of inventors and the consequent positive effect on innovation should be paramount – and that the Office has at its disposal less drastic methods that may be used to accomplish its objectives.

## I. Policy Concerns/Recommendations

1. The changes to practice would affect the substantive rights of applicants

Although styled as procedural, the changes to practice mandated by the new rules are in fact substantive. The rules mandate certain changes in claiming practices that will limit how an inventor may claim his invention, and inevitably how broad and effective the resulting patent protection will be.

35 U.S.C. § 112 requires that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." (emphasis added) Accordingly, the applicant is entitled to claim his invention as he sees fit, subject to the requirements that he must "particularly point out and distinctly claim" the invention. While GSK recognizes the Office's interest in exercising control over certain administrative matters, it is not the prerogative of the Office to diminish the patentee's substantive rights for the convenience of its examination policy.[1]

As a practical matter, the proposed changes will create an obstacle to applicants describing and adequately claiming what they consider their invention. In addition, the rules will allow the Office to restrict the scope of individual generic claims to essentially species claims. The resulting inadequate or piecemeal protection will allow others to more easily appropriate the essence of an inventor's work while skirting his patent. This will mean that inventors will not obtain the full value of their invention; they will not recoup

[1] *In re Weber*, 580 F.2d 455, 459-60 (C.C.P.A. 1978) ("in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.")

their investment capital; and they will not reinvest in innovation. Moreover, the burdens created by the proposed rules will unduly necessitate longer and more patent applications, a burden to both the Office and the applicant.

2. The changes to practice are not supported by findings that the changes are necessary or will have their intended effect, and the Office has not considered less drastic alternatives

The Office presents no data to justify the proposed rulemaking. There is no data indicating how many applications are affected by the rules; no data to indicate the scope of the perceived problem; no data to justify limiting "nested" Markush groups to one. There is also no data to indicate the amount of search and examination time that will be saved by the proposed rules; no data to indicate how many divisional applications will be necessitated by the increased restriction requirements that will likely result from implementation of the rules; and no data to indicate the increased burden upon applicants as they attempt to comply.

The Office is proposing to revise the rules of practice relating to claims using alternative language because the "search and examination of such claims often consumes a disproportionate amount of Office resources as compared to other types of claims." However, the Office does not discuss to what extent this burden is undue or justified, or why examination of certain types of inventions should not take longer than others. There is also no indication that consideration ws given to less onerous alternatives.

3. The Office should be moving toward harmonization with other major examining authorities rather than deviating from established practice.

Markush claiming is a well established and effective method for claiming chemical and biotechnological inventions. The format and handling of Markush claims is accepted as common practice in the European Patent Office[2] and the Japanese Patent Office,[3] and search and examination policy are geared to dealing with the current format of Markush claims. These major examining authorities have adopted the "unity of invention" standard for searching and examining applications. The Patent Cooperation Treaty (PCT) has established similar rules and examining guidelines to deal with the current format of Markush claims and unity of invention.[4] While the U.S. has adopted the unity of invention

---

[2] European Patent Convention, Art. 82 (2005); EPC Implementing Regulations to the Convention on the Grant of European Patents, Chap. II, Rule 30 (2004); Examination in the European Patent Office, Part C, Chap. III, 7.4a (2005); http://www.european-patent-office.org/legal/guiex/e/c_iii_7_4a.htm

[3] Examination Guidelines for Patent and Utility Models in Japan, Part I, Chap. 2, (2002); see http://www.jpo.go.jp/quick_e/index_tokkyo.htm

[4] See Regulations Under The Patent Cooperation Treaty, Part B, Rule 13 (April 1, 2007). See also, PCT International Search and Preliminary Examination Guidelines, Chapter 10, 10.17 (March 25, 2004); http://www.wipo.int/pct/en/texts/pdf/ispe.pdf

standard to comply with PCT guidelines for examining International applications, it still adheres to its proprietary "restriction practice" for domestic applications. Moving toward an International regime will facilitate greater sharing and cooperation among the major examining authorities and open up the possibility of efficiencies for both applicants and Patent Offices.

The proposed rules would change practice to create yet another system of rules and standards that would be unique to the U.S. and at variance with other major examining authorities. Claims would need to be written in a separate format for the USPTO, and yet another new standard for restriction practice would be adopted. GSK recommends that the Office adopt the unity of invention standard applied by the PCT to evaluate patent applications, and adhere to claiming practices that have found common application throughout the world's patent system.

## II. Concerns/Recommendations on Specific Changes to the Rules

1. Each claim must be limited to a single invention – § 1.75(a)

§ 1.75(a) is amended to require that "[a] claim must be limited to a single invention." New § 1.140(a) defines a "single invention" as:

> A claim that reads on multiple species using alternative language is limited to a single invention when all the species encompassed by the claim meet at least one of the following two conditions:
>
> (1) The species share a substantial feature essential for a common utility, or
>
> (2) The species are *prima facie* obvious over each other.

The Office has created a semantic fiction that a claim may be limited to a "single invention," even if it is drawn to independent and distinct inventions, if the species share a substantial structural feature essential to its utility. Alternatively, multiple species may be considered a single invention if the applicant is willing to admit they are patentably indistinct.

In fact, in most pharmaceutical cases, a Markush claim contains a group of independent and distinct inventions resulting from the results of many tests and experiments. It is a group of inventions – and the genus is a hindsight generalization of what was learned from the trial and error experimentation. A more apt description than the Office's single invention construct is that given by the PCT in Rule 13.1 – the genus is "a group of inventions so linked as to form a single general inventive concept."

The Office characterizes the test in § 1.140(a) as consistent with *Harnisch*, although it goes beyond the case. The proposed rule adds that the structural feature be

"essential" to the utility. *Harnisch* spoke only to the compounds sharing a common function, and a substantial structural feature, and alluded to the "concept of unity of invention." Likewise, the international standard, formulated in the PCT Guidelines, requires only that:

> (a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:
> (A) all alternatives have a common property or activity, and
> (B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or
> (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.[5]

The "essential to common utility" standard required by § 1.140(a)) involves speculation, since the contributions that many structural features make to the properties of a compound are normally not precisely known. Such a fragmentary analysis would be improper under *Harnisch*, which suggests that compounds must be considered as a whole.[6] Moreover, it really adds nothing to the analysis if a common structural feature and a common utility are present.

GSK recommends that the Office adopt a unity of invention standard and acknowledge that a group of independent and distinct inventions, so linked as to form a single general inventive concept, should be joined in a single claim. Additionally, the Office should base unity upon a common structural feature and a common utility shared among the members of the group (i.e., without any "essential" link between structural feature and utility).

2. Format requirements for claims - § 1.75(j)

Proposed § 1.75(j), which set down criteria that a claim that reads upon multiple species using alternative language must meet, is probably the most problematic portion of the rules. Although styled as procedural, these requirements are quitesubstantive in nature. The requirements constrain the right of an inventor to claim "the subject matter which [he] regards as his invention,"[7] and they relate to issues that are properly accounted for by rejections under 112. (The fact that these are petitionable, rather than appealable, is discussed elsewhere.) Taking the various subsections in turn:

---

[5] PCT International Search and Preliminary Examination Guidelines, Chap. 10, ¶10.17 (March 25, 2004)
[6] In re Harnisch, 671 F.2d 716, (C.C.P.A. 1980) ("in any Markush group the compounds 'will differ from each other in certain respects.' … in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components)
[7] 35 U.S.C. 112, ¶2.

175.(j)(1) requires that the number and presentation of alternatives not make the claim "difficult to construe." This creates a new and subjective standard for objecting to a claim. Different examiners are bound to perceive claims with differing degrees of difficulty. If a claim particularly points out and distinctly claims the subject matter in accordance with § 112, ¶2, that is sufficient under the law for clarity. If it does not, then it should be rejected under § 112. No new criteria are needed.

§ 1.75(j)(2) prohibits any member of a Markush group from being described itself by a Markush group (e.g., nesting of Markush groups). Otherwise put, it permits only one variable substituent in a structure to be described by a Markush group. It is unclear why the Office drew the line at only one group, rather than permit nesting 2 or 3 groups deep. Clearly, nesting 2 or 3 groups deep does not render claims unclear, so the limitation (and indeed the choice of one) would seem to be arbitrary, if not capricious. The vast majority of granted patents and pending patent applications would not comport with the rule enunciated here.

The use of nested Markush groups is a short handed way of describing a genus of chemical compounds. It is also often the clearest and most concise way to communicate a genus. One could write out the permutations encompassed by any claim that uses nested Markush groups; however, the time required would be prohibitive for a moderately sized genus, and in any case, it would be a burdensome exercise. In fact, if one did expand nested groups in conventional Markush-type claims, the amount of paper that an examiner would need to review would become burdensome for the Office. This burden upon the applicant creates a roadblock to effectively claim his invention.

The proposed limitation on claiming would appear to render many common terms, such as halogen and alkyl, as inappropriate terms within a Markush group – because each is itself a group of alternatives. Of course, to comply with the rule, such terms could be enumerated to recite specifically the members of the group. A simple illustration of a claim to a substituted phenyl using the nested Markush terms alkyl and halogen makes the point. Although simple and clear, figure 1 is not in compliance with the rule.

A compound having the structure:

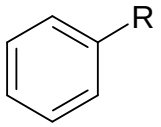


figure 1

wherein R is OH, $OCH_3$, $C_{1-6}$alkyl, or halogen.

However, the claim would comply if R is expanded to recite all the members encompassed by the terms $C_{1-6}$alkyl and halogen, e.g.:

R = OH, $OCH_3$, methyl; ethyl, n-propyl, i-propyl; n-butyl, s-butyl, i-butyl, t-butyl; 1-pentyl, 2-pentyl, 3-pentyl, 1-butyl-2-methyl, 1-butyl-3-methyl, 2-butyl-2-methyl, 1-propyl-3,3-dimethyl; 1-hexyl, 2-hexyl, 3-hexyl, 1-pentyl-2-methyl, 1-pentyl-3-methyl, 1-pentyl-4-methyl, 2-pentyl-2-methyl, 2-pentyl-3-methyl, 2-pentyl-4-methyl, 3-pentyl-2-methyl, 3-pentyl-3-methyl, 1-butyl-1,1-dimethyl, 1-butyl-2,2-dimethyl, 1-butyl-3,3-dimethyl, 1-butyl-2,3-dimethyl, 1-butyl-2-ethyl, fluoro, chloro, bromo, and iodo.

The specific recitation aids neither clarity nor efficiency; rather, it has quite the opposite effect. Compound claims resulting from actual research are many-fold more complex than this simple example, and the advantages of using nested Markush groups is greatly multiplied when used to describe them.

Restricting a claim to one Markush grouping per chemical moiety is also at odds with the manner in which research is conducted. Pharmaceutical research proceeds by experimenting to improve the various substituents on a lead compound. Accordingly, research occurs by preparing a series of compounds with varying substituent moieties to test and refine the desired properties of the molecule. The process will produce results that accord with a trail of experiments. Substituents will be added, removed or modified; negative, positive, and enhanced results will be noted. Positive and enhanced results will drive the next round of experiments – the next round of Markush modifications. Accordingly, as research progresses new nested Markush groups are identified that maintain or enhance activity, and further define the invention.

Finally, nested Markush groups may be used to identify minor modifications to molecules, but would not affect the overall function of the molecule. Without the ability to conveniently claim insignificant variations of the general inventive concept, it becomes a trivial exercise to obviate a claim and the value of the invention is considerably diminished.

The proposed rules will make it extraordinarily difficult, if not impossible, to obtain claims for new classes of compounds that are routinely examined and granted under existing practice. GSK would recommend that the Office use rejections under § 112 to remedy problems that it would attribute to undue breadth or unclear claim structure, and not impose arbitrary rules as to the manner in which an applicant may claim his invention.[8]

§1.75(j)(3) prohibits an alternative from being encompassed by any other alternative within a Markush group (e.g., reciting chloro and halogen within the same Markush group). This rule would seem to be a consequence of the fact that, under (j)(2),

---

[8] As recognized by the *Harnisch* court, issues of scope may present the greater problem today: "In the early years of the development of Markush practice, many of the cases involved the problem of clarity -- avoiding the uncertainties of alternatives and the like. More recently, the cases have centered on problems of scope, which are related to enablement." In re Harnisch, 671 F.2d 716, (C.C.P.A. 1980) In any event, rejections under § 112 are the appropriate tool to remedy these problems

no alternative may be described by another alternative (i.e., by necessity any Markush group that contains both a member and a group generic to it must violate (j)(2)). As mentioned, GSK sees no need for 1.75(j)(2).

Under current practice this is permitted, as long as it does not render the claim indefinite under § 112. There would seem to be no reason to change current practice, since there would be no additional search burden for the alternative that was encompassed (e.g., searching halogen would inevitably require that chloro be searched).

3. Election and restriction to species - § 1.146

Under this proposal, the PTO could require an election of species for the purpose of initiating a search for a generic claim, as in current practice. However, the Office proposes to add § 1.146(b), authorizing the examiner to require restriction of any claim to the elected species (or the species searched and examined) if any species encompassed by the generic claim is not patentable. Current practice requires restriction to the elected species only if "no claim to the genus is found allowable."

Application of the proposed rule would appear to encourage examiners to dispose of cases merely by finding a relevant prior art reference to a species or an inoperable species within the genus -- limiting claims to the examined species in the process. This would foreseeably result in patents with limited scope – necessitating the filing of a divisional or continuation application to obtain protection for non-elected, unexamined subject matter. Accordingly, it would have the effect of increasing the rate of patent filing, and creating an attendant burden on the Office and the applicant to proceed with examination in another application.

When an examiner limits the claims via restriction into subgenera based upon species, there is also the likelihood that the resulting patent protection will be fragmentary and even further prosecution in other applications will not allow the applicant to recoup the full scope of the generic claim. Inevitably, subgenera will occur for which the specification contains inadequate written description to support a claim. Generally, there is no way that the grant of a fragmented genus through restriction practice will equal the protection granted by the original genus.

GSK recommends that current practice not be disturbed. It is in the interest of both the examiner and the applicant to work together to find a generic claim of sufficient scope that further patent filings would not be needed. This promotes administrative efficiency, and more reliable cooperation.

4. Designation of claims in continuation-in-part applications - § 1.75(d)(2)

The PTO proposes to amend rules related to applications that add new subject matter, yet seek the benefit of the priority date of the parent application, i.e., continuation-in-part (CIP) applications. The proposed rule would require that the applicant identify which claim or claims in the CIP are supported in the parent application in conformity with § 112.

This provision would seem to have applicability in the case in which a prior art reference against the claimed invention was publicly available after the priority date, but before the filing of the CIP, i.e., an intervening art reference. In this instance, the reference would be effective only against claims that were not supported in the parent case.

While there is reason to provide such a document where an intervening reference is identified and applied to the claims, the proposed rule appears to require such a document to be filed with all CIPs. Clearly, where no intervening reference has been identified, such a document would add no value to the patent examination, and the burden upon the applicant would not be justified. GSK would recommend that the proposed rule be amended so that such a document need be submitted only if an intervening art reference was identified and applied to pending claims.

5. Appeal of examiner objections

The proposed rules are styled as procedural in nature and an applicant's remedy against an unfavorable ruling by an examiner is by way of petition. As described above, the rules affect substantial rights of applicants. The rules curtail an applicant's right to claim what he regards as his invention – a right as fundamental as patentability itself. Accordingly, the refusal to examine a claim that is clear and distinct should be appealable to the Board of Patent Appeals. The very due process that was accorded to Weber, Haas, and Harnisch, has now been obviated by rulemaking.

As a result of the effect on claim scope of both the ability of examiners to restrict claims to piecemeal subgenera and the limitations imposed upon claims by 1.75(j), GSK recommends that the Office make the refusal to examine a claim an appealable rejection. As distinguished from restriction among claims, where the full scope of what the applicant regards as his invention can be pursued in separate applications, the limitations on claims impinge on a substantive right.

**Conclusion**

The Office should reconsider the current rules relating to the "Examination of Patent Applications That Include Claims Containing Alternative Language," and consider whether there are less drastic methods to achieve its policy goals. Many of the Office's

objectives may be achieved merely by an appropriate application of § 112. If implemented as proposed, the rules will reduce the effectiveness of the the patent system for applicants and create burdens for both the applicant and the Office.

GlaxoSmithKline appreciates this opportunity to comment and looks forward to your thoughtful consideration.

Respectfully submitted,

Charles Kinzig
V.P., Corp. Intel. Prop.
GlaxoSmithKline