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From: mike.m.strickland@gsk.com [mailto:mike.m.strickland@gsk.com]
Sent: Tuesday, May 02, 2006 4:23 PM
To: AB94Comments
Subject: GSK Comments on Examination of Claims Practice

Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Clarke,

Attached are the comments of the GlaxoSmithKline on the proposed rules changes to “Practice for the Examination of Claims in Patent Applications.”

We appreciate the opportunity to offer our comments and would greatly appreciate confirmation that our comments have been received by the U.S Patent and Trademark Office.

Thank you.

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline

Comments on Proposed Changes to Practice for the Examination of Claims in Patent Applications

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

Mail Stop Comments - Patents
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Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

Comments on Proposed Rules: "Changes to Practice for the Examination of Claims in Patent Applications" 71 Fed. Reg. 61 (January 3, 2006)

Dear Under Secretary Dudas:

In response to the Proposed Rulemaking published January 3, 2006, at Federal Register, Vol. 71, No. 1, p. 61-69, GlaxoSmithKline ("GSK") submits the following comments. Separate comments are submitted concurrently herewith directed to the related continuing application proposed rulemaking.

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. Through attendance at one of the many town hall meetings recently held by the Patent Office to further inform the public of the crisis facing the Patent Office and the need for patent reform, GSK has gained insights into the difficulties facing the Patent Office as it tries to cope with an ever increasing backlog of newly filed applications in the midst of a very tight job market for skilled workers to fill the growing ranks of the corps of examiners.

While GSK appreciates the position in which the Patent Office currently finds itself, GSK must oppose the proposed rulemaking because: (1) the Patent Office lacks authority to implement the proposed rulemaking; and (2) even if the Patent Office were to have authority, the proposed rulemaking will not work to meet the stated goals of the Patent Office of reducing workload and improving quality of examination. If the Patent Office decides to enact the proposed rules despite the lack of authority to do so, GSK requests consideration of alternatives, such as those discussed below. The proposal of alternatives by GSK should not be viewed as an admission by GSK that the Patent Office has the authority to enact any of the proposed alternatives or even that GSK

views the alternatives as rendering the proposed rules acceptable. GSK reserves the right to challenge any final rules through the appropriate legal channels.

At a minimum, GSK submits that the proposed rulemaking should be revised to: (1) specify that each proper Markush claim will be treated as a single claim for the purposes of § 1.75(b)(1); (2) ensure that the Patent Office issues a notification in each case pending at the time the proposed rules are adopted for which the rules will apply; (3) allow additional claims to be examined upon payment of a per claim surcharge without submission of an examination support document; (4) consider changes to Rule 1.56 practice to allow for more open communication between applicants and examiners; and (5) drop the proposed classification of a dependent claim of a different subject matter category than the claim from which it depends as an independent claim.

As the Patent Office has been most solicitous of comments regarding ways to improve the proposed rules rather than comments attacking the rules as unworkable, the body of these comments is organized to focus first on proposed alternatives, followed by an explanation of the reasons that the Patent Office lacks authority to enact the proposed rules as well as reasons that the proposed rules will not be effective to meet the stated goals of the Patent Office.

Proposed Alternatives or Revisions to the Proposed Rulemaking:

GSK provides the following comments for consideration by the Patent Office in light of the Office's current concerns.

1. Markush Practice

Section 1.75(b)(1) is proposed to provide that an applicant must submit an examination support document in compliance with §1.261 that covers each representative claim if either: (1) The application contains, or is amended to contain, more than ten independent claims; or (2) the number of representative claims (*i.e.*, the independent claims plus the number of dependent claims designated for initial examination) is greater than ten. The Office has suggested counting *each alternative* in the Markush claim as a separate claim for purposes of §1.75(b)(1), with the possibility of allowing the applicant to group alternatives in the claim with a showing "that each alternative in the claim includes a common core structure and common core property or activity, in which the common core structure constitutes a structurally distinctive portion in view of existing prior art *and* is essential to the common property or activity." The Office has requested comments on how claims written in an alternative form, such as claims in a Markush format, should be counted for purposes of § 1.75(b)(1).

Applicants are entitled to claim their inventions as they choose, so long as they comport with the requirements of 35 USC §112. ("An applicant is given, by statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112." (*In re Weber, Soder, and Boksay*, 198 USPQ 328, 331 (CCPA 1978))) Alternative expressions, such as Markush claims, are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. Markush-type generic claims recite a plurality of alternatively usable substances or members because, in most cases, there is no appropriate or true generic language that allows the inventor to adequately describe the invention. As the Patent Office is well

aware, Markush claims are examined as if they are limited to one of the recited alternatives within each group. Accordingly, it would not be reasonable to assume that such claims require all the recited alternatives, and thus that each alternative should be treated as a "separate claim." Individual alternatives within Markush groupings have never been treated as separate claims, and there is no logic to assuming that they carry the examination burden of separate claims. They simply do not carry such a burden.

As commonly employed in chemical patent practice, even a Markush claim of modest scope will result in many more than ten independent claims for purposes of §1.75(b)(1). The proposals offered by the Office would effectively require applicants using Markush claims to file an examination support document. The Office is clearly attempting to avoid examining a Markush claim solely because it is viewed by the Office as broad, something it has been unable to accomplish by reliance on US restriction practice. ("So the discretionary power to limit one application to one invention is no excuse at all for refusing to examine a broad generic claim - - no matter how broad, which means no matter how many independently patentable inventions may fall within it." (*Id.* at 334)). The problem of searching and examining broad Markush claims in the chemical arts has been acknowledged by the court. *See, e.g., In re Harnisch*, 206 U.S.P.Q. 300 (CCPA 1980). The Office should address perceived problems associated with searching and examining Markush claims by consistent and rigorous application of the requirements under 35 USC §112 and by promulgating and consistently applying unity of invention principles. *Id.* at 305.

GSK proposes that, once a Markush claim is determined to possess unity of invention, each proper Markush claim should be treated as a single claim for purposes of §1.75(b)(1).

2. Retroactive Application of Proposed Rules

In the proposed rulemaking, the Patent Office states that "[t]he proposed changes to §§ 1.75 and 1.104 (if adopted) would be applicable to any application filed on or after the effective date of the final rule, as well as to any application in which a first Office action on the merits (§ 1.104) was not mailed before the effective date of the final rule. The Office will provide applicants who filed their applications before the effective date of the final rule and who would be affected by the changes to the final rule with an opportunity to designate dependent claims for initial examination, and to submit either an examination support document under § 1.261 (proposed) or a new set of claims to avoid the need for an examination support document (if necessary). The Office appreciates that making the changes in the final rule also applicable to certain applications filed before its effective date will cause inconvenience to some applicants. The Office is also requesting suggestions for ways in which the Office can make the changes in the final rule also applicable to these pending applications with a minimum of inconvenience to such applicants."

GSK agrees with the Patent Office that making the changes in the final rule applicable to currently pending applications will create a large burden for applicants, such as GSK, who likely have a large number of currently pending applications that will meet the criteria requiring a designation of claims. GSK believes that the onus should not be placed on the applicant to determine the applications to which the newly adopted rules apply.

GSK proposes that, upon adoption of the proposed rules, the Patent Office be required to send out a notice in each currently pending application to which the newly adopted rules apply, and that applicants be given 3 months (extendable to 6 months upon payment of extension of time fees) within which to designate claims and, if necessary, file an examination support document. A time period of 3 months to respond to such a Notice may, at first blush, seem excessive. However, the Patent Office must consider: (1) that customers with a large number of qualifying applications will be inundated with such Notices; and (2) that applicants must be given an adequate amount of time to prepare and submit an examination support document if they so choose.

3. Offer Alternative to Submission of Examination Support Document

Given the limited number of cases affected, GSK submits that providing for excess claim fees on some appropriate scale may obtain many of the objectives advanced by the Patent Office without exceeding its authority.

4. Consider Major Changes to Current Rule 1.56 Practice

As explained below, the primary reason why the proposed rulemaking will not work, and why the Patent Office lacks authority to make the proposed change, is the barrier provided by the examination support document. The Patent Office seems to be reaching out to applicants and asking for applicants help in examining the application, in effect expanding the capacity of the examining corps without expanding its size by outsourcing part of the examination of the application to the applicant. The Patent Office must realize that applicants want to help improve the system and provide for more efficient examination, but even efforts undertaken in prosecution with the best of intentions and good faith can, when exposed to the glaring light and viewed through the often misshapen lens of litigation, be mischaracterized as deceitful omissions and willful manipulations.

Without changes first to Rule 1.56 practice, and accompanying changes in the law of inequitable conduct, the practical affect of the proposed examination support document is an absolute limit on the number of claims allowed. However, should Rule 1.56 practice, and with it the law of inequitable conduct, be changed, this may not always be the case.

5. Avoid Arbitrary Statutory Class Designations

If examination is limited to a certain number of claims, the Patent Office should not be allowed to restrict claiming strategies in a manner not linked to the burden of searching. Where different statutory classes or independent claims within a class do not, in reality, impose additional burden, they should not be counted against the examination limit.

GSK offers the foregoing comments to aid the Patent Office in the event the Office decides to adopt the proposed rules. Notwithstanding these comments, GSK submits that the Patent Office lacks the authority to adopt the proposed rules, and that, even if the Patent Office did have the authority to adopt the proposed rules, these rules would not aid the Patent Office in achieving its stated goals.

The Patent Office Lacks Statutory Authority:

The Patent Office derives its rulemaking authority from 35 U.S.C. § 2, which states, in pertinent part, that "The Office . . . may establish regulations, not inconsistent with law . . . ." (Emphasis added). Under U.S. patent law, it is clear that there are no statutory limits as to the number of claims that a patentee can use to claim his invention. 35 U.S.C. §112, second paragraph states: "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." Accordingly, the Patent Office does not have the authority to adopt a rule that sets an absolute limit as to the number of claims that will be examined in an application.

The Patent Office appears to acknowledge that its rulemaking authority is so limited. In the proposed rulemaking, the Patent Office states:

> The Office is now proposing changes to its practice for examination of claims in patent applications that avoids placing limits on the number of total or independent claims that may be presented for examination in an application, but does share with an applicant who presents more than a sufficiently limited number of claims for simultaneous examination the burden so imposed.

71 Fed. Reg. 61, 62 (Jan. 3, 2006) (emphasis added). Additionally, at various town hall meetings held by the Patent Office, officials from the Office were quick to point out that there will be no absolute limit on the number of claims that will be examined because applicants wishing to have more than ten claims examined are always free to submit an examination support document.

At first blush, the proposed rules may, thus, seem to be within the Patent Office's rulemaking authority. However, in view of applicant's duty of candor, as set forth in 37 C.F.R. § 1.56, and the current state of the law regarding inequitable conduct, the proposed requirement of submitting an examination support document in order to obtain examination of more than ten claims in an application sets a *de facto* absolute limit as to the number of claims that will be examined in an application, as no reasonable or responsible applicant will file the onerous examination support document. In fact, in public comments at The Fifth Annual Hot Topics in Intellectual Property Law Symposium, held at Duke Law School on February 17, 2006, John Whealan, Deputy General Counsel, Intellectual Property Law and Solicitor, United States Patent and Trademark Office, commented that, given the current state of the law of inequitable conduct, no one would want to submit an examination support document during prosecution.

Accordingly, adoption of the proposed rule limiting the initially examined claims to ten without the submission of an examination support document is inconsistent with law and, thus, adoption of this proposed rule would exceed the Patent Office's rulemaking authority.

The Patent Office Goals Will Not Be Met:

Even were the Patent Office to have authority to limit claiming as proposed, such a change would not address the Patent Office workload or quality of examination goals. As an initial matter, based on data presented by the Patent Office at various town hall meetings, only a limited number of cases would be affected by the proposed rulemaking. While this data may have been presented in anticipation of the outcry of objections from affected parties, it also follows that the potential benefit to the Patent Office is likewise, at best, very limited.

Furthermore, as also recognized by the Patent Office at various town hall meetings, it is unlikely that any applicants will avail themselves of the examination support document as a means to obtain examination of additional claims. In fact, under current Rule 1.56 practice and inequitable conduct law, applicants will clearly view the examination support document as an unusable alternative. Accordingly, it is likely that this proposed rulemaking will merely result in an increased total number of applications being filed. As such, the burden on the Patent Office will likely increase, not decrease, as the Patent Office will lose the opportunity for control over restriction practice and the ability to maintain claims in a single case where it provides for improved efficiency of search and examination.

Finally, the proposed rulemaking may trigger increased usage of the PCT and national stage entry into the United States as an alternative. It is our understanding that, while excess claim fees could be applied to such applications, examination would have to be provided absent entry of a restriction requirement under the PCT unity of invention standard. Again, if this results, the proposed rulemaking will have failed to meet the goals stated by the Patent Office for the proposed rulemaking.

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 attempt to improve the patent system. However, for at least the foregoing reasons, GSK submits that this proposed rulemaking will not result in the desired improvements.

GSK appreciates the opportunity to provide comments on the proposed rules.

Sincerely,

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline