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From: Jackson, Jimmy

Sent: Tuesday, October 09, 2007 4:47 PM

To: Markush.Comments

Subject: BIOCOM Markush comments

Please find attached BIOCOM's comment on the referenced proposed rule change

Jimmy Jackson

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October 9, 2007

Sent via E-mail to: markush.comments@uspto.gov

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

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

RE: Comments on Proposed Rules: “Examination of Patent Applications That Include Claims Containing Alternative Language”

Dear Sirs:

BIOCOM appreciates the opportunity to provide comments on the proposed changes to “Examination of Patent Applications That Include Claims Containing Alternative Language”, Notice of proposed rulemaking (the “Notice”), as published in 72 Fed. Reg. 154, 44992-45000 (August 10, 2007).

BIOCOM is a regional advocacy organization representing more than 570 dues paying life science companies and service providers in Southern California. Strong intellectual property protection is important to attract the substantial investment required to bring new life-saving therapeutics to the market. Toward that end, BIOCOM and its member companies have a keen interest in potential changes to the patent examination process which may increase the cost of obtaining patents, increase the risk of a challenge to the resulting patents, and consequently reduce the ability of small companies which do so much of the innovative research in this country to raise the capital necessary to pursue their goals.

BIOCOM supports the goal of improving patent examination by the United States Patent and Trademark Office (USPTO), especially the goals of enhancing patent quality, reducing pendency, and eliminating true abuses of Markush claim practice. However, the proposed changes contained in the Notice seem overly broad to deal only with true abuses and, therefore, need to be substantially revised.

BIOCOM’s primary objections to the proposed new rules relate to:

1. Two aspects that seem totally unrelated to Markush claims, but would place unreasonable burdens, and therefore extra expenses, on patent applicants.
2. An unduly restrictive view of Markush claims and restriction requirements, which

seems contrary to long established legal precedent, and the implementation of which would again place undue additional expenses on patent applicants.

1. Comments on Proposals Unrelated to Markush Claims

1.1. Comments Regarding Proposed 37 Rule § 1.75(d)(2)

This proposal seems unrelated to the examination of Markush claims, and should be rejected because it places an unnecessary and undue burden on Applicants.

The proposed rule would require Applicants to identify disclosure support for all claims in a prior-filed application for which Applicant claims benefit under any section of Title 35, United States Code. The effect of this proposed rule would be a requirement that Applicants describe and identify the supporting disclosure for all claims in any applications which claim priority to any prior filed application, including any prior filed provisional application, any prior filed utility application, any PCT International application, and any foreign priority application. While specific statistics on the issue are not readily available, it can readily be estimated that the majority of all applications that are substantively examined by the USPTO claim priority to some prior provisional, PCT or foreign application. This means that the majority of Applicants will be burdened with a requirement that previously did not exist.

It is presumed that the purpose of the rule is to aide Examiners in analyzing “intervening” prior art references, which are applicable to Applicant’s claims, when the application claims benefit of a prior application. But this issue has been easily dealt with for years by Examiners rejecting claims based on any intervening prior art, and then placing the burden on the Applicant in those cases to establish that the cited prior art is not appropriate because Applicant’s claims are supported in a prior benefit application.

This issue has already been addressed in the most important type of situation, namely continuation-in-part (CIP) applications. The rules that go into effect on November 1, 2007 already require CIP applicants to provide a claim by claim, element by element, identification of support in the priority benefit application(s).

The effect of the proposed new rule would be to place an unnecessary and significant burden on Applicants in the majority of cases, instead of placing that burden on Applicants in only the relatively small percentage of cases in which intervening prior art may be relevant. There seems to be no good reason, either substantively or procedurally, for the PTO to change a long standing practice which has worked effectively in patent prosecution, and instead change to a system that places a significant burden on Applicants when the reason for that burden is only relevant in a small percentage of cases.

1.2. Comments on Proposed Rule 1.75(e)

This proposed rule appears to require Applicants to draft claims in the so-called Jepson format. Although the proposed rule says that an independent claim “should” contain the Jepson-type language, the proposal seems likely to provide the basis for Examiners to reject or object to claims that are not in the Jepson format.

The USPTO has no statutory authority to require claims to be in any particular format, e.g., the Jepson format. The USPTO is authorized by statute to examine claims for compliance with the

statutory provisions of 35 U.S.C. §§ 100, 101, 102, 103 and 112. See *In re Harnisch* 206 USPQ 300, 304 (CCPA 1980). Those statutory provisions do not provide any basis for requiring Applicants to utilize any particular format, especially the Jepson format, nor do they provide any basis for Examiners to reject claims that are not in Jepson format.

2. Comments on Proposed Rules Relating to Markush Claims

2.1. *The proposals are contrary to established case law.*

The proposed rules relating to practice for Markush claims, including proposed rules 1.75(a), 1.75(j)(4), 1.140 and 1.142, are contrary to legal precedent binding on the USPTO which establishes that the USPTO does not have the statutory authority to limit claims in the manner proposed.

The fundamental basis of the proposed rules is the USPTO belief that “two or more independent and distinct inventions may not be claimed in a single claim” (see proposed 37 C.F.R. § 1.140(a)) and that the “propriety of the requirement for restriction shall be determined without regard to whether the plural inventions are recited in separate claims or as alternatives within a single claim” (see proposed 37 C.F.R. § 1.142(b)). But this reasoning was specifically rejected by the CCPA when that court last reviewed Markush claim practice.

The concurring opinion of Judge Rich in the CCPA decision of *In re Weber* is most instructive and most clear in directly rejecting the USPTO’s legal reasoning with respect to the new proposed rules. As Judge Rich explained, the USPTO’s 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 that no matter how many independently patentable inventions may fall within it.” *In re Weber*, 198 USPQ 328, 334 (CCPA 1978). As explained by Judge Rich in his concurring opinion, and in the majority opinion of *In re Weber*, 35 U.S.C. § 121 provides the USPTO with authority to “restrict an application to one of several claimed inventions” but it does not provide a basis to reject a claim or refuse to examine a claim that may encompass a plurality of “independent and distinct” inventions. *In re Weber*, 198 USPQ 331-332.

Following the decision of *In re Weber*, the CCPA again reviewed Markush claims practice in 1980 specifically in a case where the USPTO had rejected Markush claims under 35 U.S.C. § 121. There the court found that the Applicant’s Markush claim was not “improper” because all of the compounds encompassed by the claims were “coumarin” compounds, thereby having structural similarity, and because “the claim compounds all belong to a subgenus, as defined by Appellant, which is not repugnant to scientific classification.” *In re Harnisch*, 206 USPQ at 300, 305 (CCPA 1980).

The USPTO’s new proposed rules on Markush claim practice, therefore, are directly contrary to long established legal precedent which clearly establishes that the statutory authority provided by the USPTO under 35 U.S.C. § 121 does not provide the USPTO with authority to “reject a particular claim” for encompassing a plurality of claimed inventions. Indeed, the court has already told the USPTO that “it is elementary patent law that the number of “species” “covered” by a patent having a generic claim is virtually without limit...” *In re Weber*, 198 USPQ at 334 (J. Rich concurring).

The “elementary patent law” principle explained by Judge Rich and violated by the USPTO’s proposed rules is that, simply stated, 35 U.S.C. § 121 permits the USPTO to restrict groups of claims in an application so as to limit one application to one invention, but the USPTO has no

statutory authority to reject or otherwise refuse to examine a generic claim “no matter how many independently patentable inventions may fall within it”.

2.2. *The practical impact of the proposed rules will negatively impact patent protection available to innovative life science companies.*

(a) *Additional required divisional applications will increase the financial burden on applicants.*

The impact of these new proposed rules must be considered in the context of other newly enacted rules. If the proposed Markush claim rules are enacted, the issuance of complicated and lengthy restriction requirements will necessitate the filing of an increased number of divisional applications for applicants to fully cover their disclosed inventions. This obviously will place an increased financial burden on applicants. Budget considerations may cause applicants to delay in the filing of divisional applications, resulting in potential gaps in patent coverage to which applicants should be entitled. Newly implemented restrictions on the number of continuations and total claims will also make it more difficult for applicants to pursue generic claim coverage.

(b) *Presumptions implicit in the new restriction requirement will negatively impact on patentability.*

The Notice states that “... the claim is limited to a single invention when at least one of the following two conditions is met: (1) All share Or (2) all of the species are prima facie obvious over each other” (See, page 44996, col 1). This presumption seems to indicate that if an applicant tries to argue that a group of compounds created by a Markush group are not subject to restriction according to the single invention requirement, then the presumption of obviousness would negatively impact a subsequent showing of “unexpected results” for a selection invention application.

(c) *The proposals improperly restrict the scope of claims necessary to protect innovative technology.*

The explanation/justification of proposed rules concludes by stating, “Put differently, applicant should narrow the scope of protection sought via separate claims and not nested sets of overlapping alternatives.” This conclusion seems to reveal the real indifference of the USPTO to the needs of an inventor and ignores the well-founded needs of applicants to obtain appropriate protection for innovation. The patent statute already provides the USPTO with the appropriate legal standards for analyzing and rejecting improper claims (see 35 U.S.C. §§ 101, 102, 103 and 112). The USPTO should not, and indeed lacks the authority to, promulgate new rules that place additional barriers for applicants to properly and fully cover their inventions.

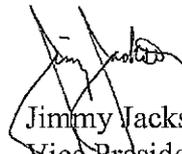
The new proposed rules further have the potential to leave huge economic gaps in US-based technology. It is not, nor should it be, the objective of an applicant for a patent to narrow the scope of his or her protection. One has the right, and patent practitioners have the absolute obligation, to seek the broadest possible protection under the law. The USPTO should not be enacting rules that only seek to minimize the work of examiners, without fully considering the impact on patent applicants.

The new proposed rules will make it far more expensive, and in some situations impossible, for applicants to fully protect their inventions. The combination of these new proposed rules and the already enacted limits on the number of claims which may be presented without invoking the

need to file a burdensome Examination Support Document, as well as limits of the number of continuation applications that can be filed, will have a potentially devastating impact on the ability of life science companies to capture innovative discoveries, such as biologically active compounds. Small biotech and startup companies with limited patent portfolios will be faced with greatly increased costs and will see their assets diminish or vanish as they lose the ability to protect all aspects of their intellectual property.

For these reasons, BIOCOM believes that the proposed rules in the Notice should be withdrawn, and more consideration should be given to rules that would aid the USPTO and not negatively impact patent applicants. BIOCOM would welcome the opportunity to discuss with the USPTO new proposals that could meet the objectives of both the USPTO and patent applicants to enhance patent quality.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jimmy Jackson", written over a circular stamp or seal.

Jimmy Jackson
Vice President, Public Policy and Communications
BIOCOM