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From: Evans, Dolores (NIH/OD) [E]
Sent: Tuesday, October 09, 2007 4:09 PM
To: Markush.Comments
Cc: Rohrbaugh, Mark (NIH/OD) [E]
Subject: NIH/OTT comments

Attention: Kathleen Kahler Fonda

On behalf of Mark L. Rohrbaugh, Director, Office of Technology Transfer, National Institutes of Health (NIH), attached please find NIH's comments (in PDF format) to the USPTO's Proposed Rules for Examination of Patent Applications That Include Claims Containing Alternative Language, as published at 72 Fed. Reg. 44992 (Aug. 10, 2007).

Should you have any difficulty viewing the attached document, please do not hesitate to contact me at evansdo@mail.nih.gov and/or 301-594-7700. Thank you for the opportunity to submit comments.

Sincerely,

Dolores Evans

Secretary

Office of Technology Transfer
6011 Executive Boulevard, Suite 325
National Institutes of Health
Rockville, Maryland 20852-38004
(301) 594-7700 Office
(301) 402- 3257 Fax
NIH Mail Stop Code: 7660
evansdo@od.nih.gov



October 9, 2007

VIA ELECTRONIC MAIL

John J. Doll
Commissioner for Patents
Mail Stop Comments-Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

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

Dear Commissioner Doll:

The written remarks presented herein are directed to the United States Patent and Trademark Office's (USPTO) Request for Comments to the Notice of Proposed Rulemaking for Examination of Patent Applications That Include Claims Containing Alternative Language, published at 72 Fed. Reg. 44992 (Aug. 10, 2007) (hereinafter, "the proposed Markush rules"). These comments represent the views of the National Institutes of Health (NIH).¹

I. General Comments to Proposed Markush Rules

NIH recognizes that the proposed Markush rules are part of the USPTO's ongoing initiatives to improve patent quality and reduce application pendency, including the recent Final Rule for Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, published at 72

¹ NIH is the lead agency within the Department of Health and Human Services (HHS) in matters of technology transfer. In addition to providing patent and licensing services to all Institutes and Centers within NIH and the U.S. Food and Drug Administration (FDA), it is the lead agency responsible for coordinating and facilitating technology transfer policy functions for NIH, FDA, and Centers for Disease Control and Prevention (CDC). The Bayh-Dole Act of 1980 (Pub. L. No. 96-517, 94 Stat. 3015, as amended) permits recipients of federal grants and contracts to retain title to their inventions developed under such federal funding. In October 1986, Congress also enacted the Federal Technology Transfer Act (FTTA, Pub. L. 99-502, 100 Stat. 1785), which amended the Stevenson-Wydler Innovation Act of 1980. The FTTA, as amended, stimulates transfer of Government-owned technology by offering incentives to both federal laboratories/scientists and collaborating partners in universities, foundations, and private industry.

Fed. Reg. 46716 (Aug. 21, 2007) (collectively, “the new continuation and claims examination rules”).

We believe that, while the USPTO’s goals are laudable, the proposed Markush rules, in conjunction with the new continuation and claims examination rules, will disproportionately and negatively impact the pharmaceutical, biotechnology and related arts, thereby adversely affecting the development of innovative biomedical technologies that benefit public health. Indeed, NIH believes that the proposed Markush rules may represent a “tipping point” beyond which biopharmaceutical research and therapeutic development may be significantly impacted in a manner that may have negative effects, particularly for products in small market niches, such as those for rare diseases.

More specifically, a pharmaceutical or biotechnology innovator often begins a chain of patent applications to a new family of promising drug therapies by filing an application disclosing a broad Markush group. As the innovation cycle progresses, a particular member of the group may become the focus of the investigation. For example, data may become available related to a member of the Markush group that is pharmaceutically superior to other representatives of the broad genus originally disclosed or to the specific members initially targeted for late-stage clinical trials. That is, while each independent invention may be patentable, the commercial viability of the inventions may not be apparent until after the prosecution process has begun.

Under the proposed Markush rules, in view of the new continuation and claims examination rules, innovators will now face a dilemma: (a) attempt to comply with the proposed Markush rules, which may result in requiring more claims to capture the claimed inventions, thereby adding to cost and burden (e.g., through the filing of examination support documents); or (b) risk rejection of claims based on improper Markush grouping, thereby receiving an office action that cuts into the applicant’s examination process, now more limited by the new continuation rules.

Furthermore, under the new continuation rules, innovators seeking to preserve priority to ensure patentability of species over a genus may be required to file multiple applications for each sub-genus in a Markush group. But publicly-funded institutions, small research incubators, and biotechnology entities, from which many significant and highly innovative drugs and therapies have originated, may have only limited resources to devote to patent prosecution expenses. The combination of the proposed rules and the new continuation and claims examination rules may divert resources to prosecution costs that would be better spent on continued experimentation.²

II. Specific Comments to Proposed Markush Rules

NIH appreciates the difficulties presented to examiners by broad Markush claims that fail to adequately define claim scope. More specifically, NIH understands that the provisions of the proposed rules, including Section 1.75(j)(1) and 1.75(k), are directed to these issues. Such difficulties, however, may be better addressed by the requirement that claims in Markush format

² See also NIH Office of Technology Transfer’s Comments to the proposed “Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims” (71 Fed. Reg. 48), as submitted May 3, 2006.

set forth a core molecule or part thereof upon which the applicant relies for patentability, as further described below.

A. Proposed Section 1.75(j)(1)

Proposed Section 1.75(j)(1) provides, in relevant part, that “[a] claim that reads on multiple species by using alternative language” must meet certain conditions, including that “[t]he number and presentation of alternatives in the claim does not make the claim difficult to construe.” We believe that §1.75(j)(1) may invite subjective interpretation that will vary by examiner.

In addition, the bare requirement that Markush claims must not be “difficult to construe” runs counter to the nature of biopharmaceutical innovation. In the biopharmaceutical and related arts, overlapping compounds or compositions may be known for alternative uses and the inventive process provides new indications for use or new formulations with superior properties.

Indeed, it is suggested that this undermines the very core of the inventive process, i.e., that inventions are often complex. NIH suggests that, rather than recognizing this reality, the proposed rules urge that the language of claims be simplified without regard for the nature of the invention claimed.

NIH strongly recommends that, under proposed §1.75(j)(1), where claims in the alternative format recite a core molecule or part thereof upon which the applicant relies for patentability, such claims should not be deemed “difficult to construe.” Under this format, the presence of a core molecule (or part thereof) sets forth an objective standard that enables examination of species without undue burden upon the examiner.

NIH further suggests that there are procedural mechanisms that may be beneficial in the examination of Markush claims. For example, examiners may initiate interviews (in person or by teleconference) directed solely to clarifying their understanding of that which is claimed or request information under 37 C.F.R. §1.105. Through these measures, examiners and applicants may work in cooperation to improve the examination process of Markush claims.

B. Proposed Section 1.75(k)

Proposed Section 1.75(k) provides, in relevant part, that “[a] claim may not incorporate another part of the specification or drawings by reference, unless there is no other practical way to define the invention.” NIH appreciates that there may be some applications where the incorporation by reference of other parts of the specification may result in lack of clarity during the examination process. However, many biopharmaceutical applications are directed to complex molecules, including sequence identifications, for which the requirement of §1.75(k), in connection with the claims examination rules, would effectively remove any benefit to Markush practice, even where it properly defines an invention.

NIH suggests that, where Markush claims set forth a core molecule or part thereof upon which the applicant relies for patentability, such claims shall be permitted to incorporate another part of

the specification or drawings under proposed §1.75(k). We believe that, in this manner, the goal of adding clarity during examination while also ensuring proper claim scope is more appropriately achieved.

In conclusion, NIH appreciates the opportunity to present our views to the USPTO. Please do not hesitate to contact us if we can be of further assistance.

Sincerely,



Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer