

**From:** Lila Feisee

**Sent:** Wednesday, April 09, 2008 6:53 PM

**To:** Markush.Comments

**Cc:** Lila Feisee

**Subject:** BIO Comments to Notice of Proposed Rulemaking: Examination of Patent Applications That Include Claims Containing Alternative Language

Dear Ms. Fonda:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide the attached comments on the United States Patent and Trademark's (PTO) *Examination of Patent Applications That Include Claims Containing Alternative Language* as published in the Federal Register, 73 FR 12680 on March 10, 2008.

BIO provided comments previously in response to the Office's initial request for comments on *Examination of Patent Applications That Include Claims Containing Alternative Language 72 FR 44992*. BIO's full comments are available at <http://bio.org/ip/domestic/20071009.pdf>.

Regards,

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April 9, 2008

Mail Stop Comments - Patents

Commissioner for Patents

Attention: Kathleen Kahler Fonda, Legal Advisor, Office of Patent Legal Administration

P.O. Box 1450

Alexandria, VA 22313-1450

**Comments to Notice of Proposed Rulemaking Entitled: *Examination of Patent Applications That Include Claims Containing Alternative Language***

Dear Ms. Fonda:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide further comments on the United States Patent and Trademark's (PTO) *Examination of Patent Applications That Include Claims Containing Alternative Language* as published in the Federal Register, 73 FR 12680 on March 10, 2008. BIO provided comments previously in response to the Office's initial request for comments on *Examination of Patent Applications That Include Claims Containing Alternative Language* 72 FR 44992. BIO's full comments are available at <http://bio.org/ip/domestic/20071009.pdf> and the arguments presented therein remain valid.

In its current request for comments, the PTO continues to maintain the need for the proposed rule changes because many patent claims as currently drafted are confusing, difficult to search, and consume a disproportionate amount of the PTO's resources. The PTO also argues that the cost of the rules will impact a small portion of patent applicants, and for those whom the rules would impact, the cost would be manageable. The PTO argues that 82% of small entity biotechnology and chemical applicants would not incur any notable incremental costs associated with the rule as they already contain language which would be acceptable under the proposed rule. Moreover, by the PTO's own admission, a large portion of the applications that would be subject to these proposed rules is concentrated in the biotechnology and chemical arts.

The PTO maintains that that the costs incurred by patent applicants as a result of these rules would arise from three possible corrective options: 1) the filing of a divisional (estimated by the PTO as \$10,258), 2) filing an amendment to correct claim format (estimated by the PTO at \$4,029) and 3) filing a divisional and filing one amendment (estimated by the PTO at \$14,287). According to the PTO, an applicant would need to



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file at most 7 divisional applications to address an examiner's restriction requirement at a total increase in cost of about \$40,000.

The PTO's reliance on AIPLA's cost increments is in error. The AIPLA explained in its 2007 Economic Analysis that the cost increments are only for typical cases "without any unusual complications." The new rules would force applicants to unwind nested variables. While there is no precedent for this type of amendment, the PTO's estimate of \$4,000 to amend claims into their proper format is considerably below what would be required from an outside counsel to "unwind" nested Markush claims into non-Markush claims. Therefore, this type of amendment cannot be considered a typical amendment without complications as contemplated by the AIPLA. The AIPLA cost increments are too low for this fact and the PTO should not rely on them.

Assuming *arguendo* that the PTO's cost estimate of \$10,258 is appropriate, the estimated cost is still erroneous. The cost of 7 divisionals would total to approximately \$72,000, not \$40,000 as indicated by the PTO. BIO believes that an estimated total cost for filing 7 divisional applications would be higher due to the prosecution and filing strategies associated with multiple applications. The proposed rules would require hundreds of species to be listed in order. This would complicate the drafting process and would decrease the readability of the claims. The associated preparation and prosecution costs would increase and the PTO's cost analysis should appropriately reflect this fact.

Furthermore, these proposed rules should not be viewed in isolation, rather the cost and impact of these rules must be viewed in conjunction with a whole array of additional rules e.g. the IDS rule package, the claims and continuations rule packages, as well as legislative changes, e.g. post grant, derivation proceedings, applicant quality submissions, etc. which would dramatically increase the cost to applicants in the coming years. Such dramatic changes to patent rules and the increased prosecution charges related to these changes will necessitate the prosecution of narrow claims essentially preventing patent applicants from obtaining full patent coverage. Biotechnology companies will be placed in the untenable situation of deciding whether to fund the next research project, or to seek protection on one of the many PTO restricted inventions. Given enough time, companies' patent assets will dwindle, and potentially critical innovations will be left unprotected as the quid pro quo of patent rights is effectively eliminated by cost and process constraints. Such diminished patent protection for biotechnology innovation renders any investment with almost speculative risk and inevitably will turn venture investment to other less risky industry sectors.

In addition to the general U.S. filing and prosecution costs, biotechnology companies are likely to incur additional costs for filing for patent coverage for the same inventions in other jurisdictions. As an example, the EPO has no restrictions on the use of nested Markush language. It is our position that nested Markush language makes claims more readable, not less so, and foreign patent offices may take the same position. If so, the result of the proposed rules would be that applicants would prepare two sets of claims. One application would have all the species listed in serial fashion, in order to comply

with U.S. regulations. However, a second application would be drafted that includes nested Markush language for foreign jurisdictions. This would further increase the costs

of protecting biotech inventions. Additionally, the proposed rules would work against harmonization efforts. If two applications are required, one for the U.S. and a second for ex-U.S., then programs such as the Patent Prosecution Highway would suffer. Such uncertainty in claiming/patenting strategy between jurisdictions is likely to increase both cost and uncertainty and should be avoided.

BIO also continues to maintain, as stated in its October 9 comments, that the PTO's rulemaking ability in this area is questionable at best. The courts have consistently maintained the ability to claim and define his or her invention and that the applicant is entitled to have each claimed examined on its merits (*In re Weber*<sup>1</sup> and *In re Haas*<sup>2</sup>). Moreover, the proposed rules expressly contradict *In re Harnisch*<sup>3</sup> because the contested Markush claims in *Harnisch* were deemed to be proper.<sup>4</sup> The *Harnisch* court emphasized that, when faced with the issue of a single claim that may or may not contain patentably distinct inventions, the facts of the individual case must be taken into account.<sup>5</sup> Indeed, the court cited several cases where factual analyses of compounds falling within disputed Markush claims resulted in reversal of initial rejections of those claims.<sup>6</sup> In essence, the court held that **if** a rejection based on "improper Markush language" is viable, such a rejection **must** be based on factual determinations.<sup>7</sup> The per se rule now offered by the PTO appears to directly contravene established law regarding Markush claims.

While BIO appreciates the great challenge the PTO faces in addressing its workload, BIO urges caution in implementation of processes that would diminish patent protections and make obtaining patents costly and difficult. BIO and its members are open to discussions with the PTO in order to develop constructive measures to address the PTO's challenges.

Sincerely,



Lila Feisee  
Managing Director, Intellectual Property  
The Biotechnology Industry Organization

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<sup>1</sup> *In re Weber*, 580 F.2d 455 (CCPA 1978).

<sup>2</sup> *In re Haas*, 486 F.2d 1053, 1055 (CCPA 1973)

<sup>3</sup> 631 F.2d 716 (CCPA 1980).

<sup>4</sup> *Harnisch*, 631 F.2d at 721

<sup>5</sup> *Harnisch*, 631 F.2d at 722.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* (analyzing prior case law and the pending case and concluding that "we decide this and like cases **on their facts** on a case-by-case basis" (emphasis added)).