

From: JENJ (Jennifer Johnson)
Sent: Wednesday, April 09, 2008 8:42 PM
To: Markush.Comments
Cc: JENJ (Jennifer Johnson)
Subject: ZymoGenetics' Comments on Proposed Rules for Claims Containing Alternative Language

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

Dear Adviser Fonda,

Please post the attached .pdf on the Comments Regarding Proposed Rules for Examination of Patent Applications That Include Claims Containing Alternative Language, 73 Fed. Reg. 12679 (March 10, 2008).

Sincerely,

Jennifer K. Johnson

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ZYMOGENETICS

April 9, 2008

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

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

RE: Comments Regarding Proposed Rules for Examination of Patent Applications That Include Claims Containing Alternative Language, 73 Fed. Reg. 12679 (March 10, 2008).

Dear Under Secretary Dudas,

ZymoGenetics, Inc. appreciates the opportunity to comment on U.S.P.T.O. Proposed Rules for Examination of Patent Applications That Include Claims Containing Alternative Language, 73 Fed. Reg. 12679 (March 10, 2008); relating to the Proposed Rulemaking entitled the same, 72 Fed. Reg. 44992 (August 10, 2007). (collectively referred herein as "*Proposed Rules*.") We respectfully request consideration of the following comments.

A. Introductory Remarks

On August 21, 2007, during the public comment period for the initial Proposed Rules, the U.S.P.T.O. (the "*Office*") published the final rules for "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" (71 Fed. Reg. 48 (January 3, 2006)) and the Rules for "Changes to Practice for the Examination of Claims in Patent Applications" (71 Fed. Reg. 61 (January 3, 2006)). These rules are now permanently enjoined by the U.S. District Court for the Eastern District of Virginia. At the time of the initial Proposed Rules, in light of these events, ZymoGenetics chose not to provide comments under the "new" rules. However, since those rules are no longer in effect, we are providing our comments at this time.

B. Proposed Rules Would Adversely Financially Impact ZymoGenetics and Small- to Mid-size Biotechnology Companies

The Office has specifically requested information about the economic impact of the Proposed Rules on small entities. Although ZymoGenetics as a mid-sized company is not currently a small entity, we present a financial impact analysis that demonstrates the effect of the Proposed Rules which would similarly apply to small entity Biotechnology companies.

The Proposed Rules rely on an incorrect assumption that "an Applicant *would need to file at most approximately seven divisional applications following an Examiner's restriction requirement*, even if more were needed to seek patent protection for the full scope of the originally claimed inventions". 73 Fed. Reg. at 12683, emphasis added. For Biotechnology arts, this assumption clearly underestimates current Office restriction practice as applied to originally claimed inventions in the Biotechnological arts. As described below, a 7-way restriction is minimal under current 35 U.S.C. §121 practice, and excludes the further impact of an intra-claim restriction required by the Proposed Rules.

Under the Proposed Rules, the Office has not distinguished what it means by a proper *Markush* claim covering a "single invention" except to say that all species within a group must be among other things, interchangeable or admittedly obvious over each other. Therefore, it is assumed that under the Proposed Rules, for a typical *Markush* claim a single species within such claim will be further intra-claim restricted into separate restriction groups. Consequently, the Proposed Rules have effectively set limitations on the number of species of an invention that may be claimed in a single claim arbitrarily as one, without consideration of the entire scope of the invention(s) (both with respect to genus and species) for which the Applicant is entitled under law. Applicants will be required to either file excessive numbers of individual claims, and/or to split apart applications into many divisional applications which is time consuming and costly to the Biotechnology business. Pursuing such divisionals and independent claims would be financially devastating, and alternatively, not pursuing them would restrict the Applicant's ability to claim the entire invention as entitled by law.

We have surveyed a number of patent families across our typical biotechnology patent portfolio and have concluded that our business would be greatly and adversely affected if the Proposed Rules were enacted. Unfortunately, our data show that for ZymoGenetics, a mid-sized Biotechnology company in the business of developing human therapeutic protein drugs, the excessive costs and reduction in potential patent coverage on our products resulting from this Proposed Rules will potentially devastate our business. Because we cannot justify excessive patent application and prosecution costs that would be required to comply with this Proposed Rules, we and certainly other smaller Biotechnology companies, will be forced to (i) settle for weak patent protection for our products (i.e., the patents cover less than what we are entitled under law), (ii) keep our inventions as trade secrets (no public benefit), or (iii) simply go out of business because we cannot obtain adequate coverage for our products to attract investors, or to justify costs of development, clinical trials and FDA approval.

In our experience, our biotechnology applications often require *Markush* claims to encompass the entire scope of an invention. Prior to a restriction requirement, our biotechnology applications routinely provide numerous independent embodiments of an invention in a single application: e.g., polynucleotides, polypeptides, active fragments thereof, fusion proteins, antibodies, antibody derivatives, methods of making, methods of using, diagnostics, research tools, as well as method of treatment, and pharmaceutical formulations of each of the foregoing molecules. Patent coverage of these numerous embodiments necessitates an application with numerous independent claims (often in *Markush* format) to adequately cover the full scope of the described invention. These numerous independent embodiments are currently typically restricted by the Office into separate restriction groups on the basis that they are drawn to separate inventions; thus, a single original application usually leads to a multiplicity of divisional applications. However, the Proposed Rules will take this restriction practice even further, by counting each species within a *Markush* claim as a separately examined intra-claim restriction group thereby increasing the number of divisional applications from 30- to over 100-fold depending on the type of invention claimed.

To emphasize the magnitude of the economic impact of the Proposed Rules we have outlined two types of inventions for which we typically file: (1) a novel therapeutic protein and (2) a novel therapeutic antibody. First, in our experience it is not uncommon in a Restriction Requirement for an application on a novel therapeutic protein to be restricted an average of 6- to 20-ways, and we have encountered 50- to 60-way restriction requirements in many of our cases. In such applications, there are typically 5-10 species within each restriction group (these may encompass active fragments of a protein, mature forms, certain fusion embodiments, different therapeutic uses, disease indications, etc.). Consequently, under the Proposed Rules, to cover a reasonable scope of a therapeutic protein invention

typically claimed, it would take 30-200¹ independent divisionals per novel therapeutic protein invention. If ZymoGenetics were to file on only 10 such novel therapeutic protein inventions per year at a conservative filing fee of \$4000 each, those 10 inventions would cost ZymoGenetics \$1.2M – \$8M per year in filing fees alone. The Office's estimate for each new divisional is over \$10K (see Table 2, 73 Fed. Reg. at 12682), which would raise these estimates to \$3M – \$20M per year in filing fees alone.

Second, for a typical application on a novel therapeutic antibody, there are typically 50-100 species within each restriction group (these may encompass various neutralizing CDR sequences, combinations thereof, various antibody structures, antibody fragments, certain fusion embodiments, different therapeutic uses, disease indications, etc.). Consequently, to cover a reasonable scope of an invention typically claimed, it would take 300-2000² independent divisionals per novel therapeutic protein invention. If ZymoGenetics were to file on only 3 such new antibody inventions per year at a conservative filing fee of \$4000 each, those 3 inventions would cost us \$3.6M – \$24M per year in filing fees alone. The Office's estimate for each new divisional is over \$10K (see Table 2, 73 Fed. Reg. at 12682), which would raise these estimates to \$9M – \$60M per year in filing fees alone.

The combined cost for 10 novel therapeutic proteins and 3 novel therapeutic antibodies would be \$4.8M – \$32M per year in filing fees alone. Again, the Office's estimate for each new divisional is over US\$10K (see Table 2, 73 Fed. Reg. at 12682), which would raise these estimates to \$12M – \$80M per year in filing fees alone.

In a typical year ZymoGenetics will file and prosecute *over 250* patent applications for inventions that comprise both novel proteins and antibody-based inventions. To obtain a reasonable scope of our inventions (not the entire scope as entitled by law), under the new Proposed Rules, it would cost ZymoGenetics, as an extremely conservative estimate, over US \$35 million per year in filing fees alone. This cost does not include the cost of personnel resources at ZymoGenetics needed for their preparation, or the costs of prosecution, issuance and maintenance of these patents. This added cost in U.S. patent filing fees alone would increase our entire worldwide patent budget over 15-fold, and would be unduly burdensome and not economically feasible for ZymoGenetics.

Due to the excessive costs resulting from the Proposed Rules, for practical reasons it would be cost-prohibitive to protect a reasonable scope of our inventions, and in many cases impossible to protect the entire scope of the inventions to which an Applicant is entitled under law. Moreover, as discussed further below, the effect of this rule is particularly detrimental in the Biotechnology arts where inventions are complicated and are already encumbered by extensive restriction practice.

ZymoGenetics' patent portfolio is comparable to similarly situated and smaller Biotechnology companies. Moreover, we have just over 500 employees, and have only recently become a large entity. It is reasonable to use our company as a model in considering the negative financial impact of these Proposed Rules, and extrapolate this adverse impact to the Biotechnology industry as a whole, and particularly smaller businesses within the industry. The disparate impact on a single industry and small- to mid-sized businesses is simply unfair. While the Office may believe that these rules are non-substantive, they will in practice be substantive - the changes *will* have a *significant economic impact* on *every* small or mid-sized Biotechnology entity who desires to claim the full scope of its invention(s). Applicants will be faced with paying exorbitant costs, keeping their inventions as trade secrets rather than filing patent applications, or more likely being forced to give up the full scope of their inventions to which they are entitled by law. Thus, we *oppose* the promulgation of these Proposed Rules.

¹ The lower end being 30 divisionals (6-Way Restriction X 5 species = 30); the higher end being 200 divisionals (20-way restriction X 10 species). The average would be somewhere in that range, with a conservative estimate at 50 divisionals.

² The lower end being 300 divisionals (6-Way Restriction X 50 species = 300); the higher end being 2000 divisionals (20-way restriction X 100 species). The average would be somewhere in that range, with a conservative estimate at 500 divisionals.

C. The Proposed Rules Financially Adversely Impact the Entire Biotechnology Industry.

The Proposed Rules are particularly harmful with respect to the Biotechnological arts where the inventions necessitate *Markush* claiming, are complex, and there are practical considerations in bringing a product to market. Product development times for therapeutic biotechnology products are long; the average time to advance a new drug from discovery to FDA approval is 10 to 15 years. See, Tufts Center for the Study of Drug Development reported in November 2001. During this long product development cycle, complex experiments are often required to determine the commercial embodiment of an invention. The final commercial product may be a single embodiment among several embodiments disclosed in a patent application, and that embodiment may not be known for years after the filing date.

The Proposed Rules will have a detrimental effect on U.S. Biotechnology businesses. Biotechnology companies like ZymoGenetics use *Markush* genus claims to obtain a meaningful scope of drug patents that both narrowly cover a drug itself and that more broadly cover an area of protection surrounding the drug. Biotechnology companies often need to obtain certain patents quickly, e.g., on narrow embodiments of an invention, in order to raise essential investor capital. And, broader and follow-on claims are often pursued as the product becomes more perfected as a therapeutic candidate. Broader claim scope allows the opportunity to provide specific data and information to the Office as we advance a drug from discovery into clinical trials and eventually to patients. If we are denied this opportunity, we could be caught in a predicament where we cannot obtain needed scope of patent protection for drugs because the full scope of the applications have been denied or cannot be pursued due to the enormous financial burden; and we are forced to accept very narrow patents prior to knowing the precise form of the therapeutic drug. Resulting patents might not cover the actual form of the therapeutic drug used in patients nor provide adequate protection against potential infringers making minor modifications to the drug.

If enacted, the Proposed Rules would create uncertainty in the Biotechnology industry as to whether the full scope of the invention could be protected at all. As a small business and now as a larger entity, our patents have enabled us to attract investors who believe in the pursuit of therapeutic drugs, and this investment has enabled us to advance drugs into the clinic. Moreover, without patents protecting biotechnology products, the enormous costs of research and development may not be recouped. Without meaningful drug patents, investors may no longer support Biotechnology industry efforts needed to make drugs, which could seriously damage the business. Without a robust Biotechnology industry, fewer new drugs would be developed to help patients fight their diseases.

Applicants in the Biotechnological arts submit applications to obtain the full scope of the invention(s) described and claimed in an application; i.e., the entire scope of the invention as entitled under law. One accepted way of doing so is through *Markush* claiming, where a patentee defines the genus of the invention where one cannot be reasonably described using other terms. The claiming of a genus would be virtually impossible under the Proposed Rules, because the genus claims (*Markush* claim) would be restricted into several species groups, and never be examined as a whole. The Applicant would be forced to accept narrow (species-only) coverage of their life-saving inventions.

The Proposed Rules would make claiming a Biotechnology invention so cost-prohibitive as to effectively limit biotechnology applications to a single or very few species. In so doing, the Office would be denying an Applicant's right to obtain claims to the full scope of their invention, to which an Applicant is entitled by law.

We *oppose* the promulgation of these Proposed Rules. The financial burden resulting from these application practices under these rules would negatively impact the Biotechnology industry and ultimately reduce the availability of therapeutic molecules that may benefit the public. These outcomes would be against the public interest.

D. The Office Lacks Authority to Enact the Proposed Rules

(1) Requirements pursuant to Proposed Section 1.140 are Counter to Law

The Office has proposed to add new section 37 C.F.R. §1.140 requiring that a *Markush* claim be limited to a “single invention” in applications filed under 35 USC §111(a). (72 Fed. Reg. at 45000). The Proposed Rule considers such claims to be properly limited to a single invention when one of the following two conditions are met: (i) all of the species encompassed by the claim share a substantial feature essential for common utility; or (ii) all of the species encompassed by the claim are *prima facie* obvious over each other. However, the two conditions required are either counter to case law, vague, or contain and impermissible standard that exceeds the Offices authority to enact.

The Office purports to claim that the first requirement is based upon the guidance provided in *In re Harnisch*, 631 F.2d 716 (CCPA 1980). 72 Fed. Reg. 44996. *In re Harnisch* held “that the claimed compounds all belong to a subgenus, as defined by appellant, which is not repugnant to scientific classification.” *In re Harnisch*, 631 F.2d at 718. However, the Proposed Rule goes beyond the ruling in *In re Harnisch*, and in fact is inconsistent with the case law. *In re Harnisch* clearly states that the grouped compounds in a claim need only share a “community of properties justifying their grouping” (such properties not specifically functional, chemical or structural, but loosely determined *by the Applicant* in a subgenus) that is “not repugnant to principles of scientific classification”; further adding that such subgenus “compounds *must* be considered as wholes and not broken down into elements or other components.” *In re Harnisch* at 718 and 722, emphasis added. Likewise, *In re Weber* provides solid reasoning why an Applicant should not be forced to break their genus claims into individual species: “[i]f, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim.” *In re Weber*, 580 F.2d. 455, 458 (CCPA 1978). This Proposed Rule requires the Applicant to split apart their genus claims into individual species, by mandating exactly what both *In re Harnisch* and *In re Weber* hold as illegal.

The first requirement under this Proposed Rule, the “essential to utility” component, is counter to law - the Office has overstepped their authority by changing the standard for determination of a subgenus as held *In re Harnisch*. *In re Harnisch* does *not* suggest, as the Office suggests, that for a proper claimed group of members to stand, that “all of the species encompassed by the claim share a *substantial* feature *essential for common utility*.” 72 Fed. Reg. at 44996, emphasis added. All *In re Harnisch* requires is a “*community of properties*” that is “*not repugnant to principles of scientific classification*.” *In re Harnisch*, 631 F.2d at 718, emphasis added. The Office has gone beyond their authority in increasing the standards required under law in several ways: The Office has taken (1) a *community of properties*, and is now requiring an elevated *substantial feature*, (2) a standard where such feature is *not repugnant* to principles of scientific classification, and is now requiring an elevated standard of *essential* for common utility, and (3) a standard where such features as not repugnant to *principles of scientific classification*, and is now requiring an elevated standard of essential for *common utility*. Moreover, the Proposed Rules ablate the legal right of the Applicant to define the subgenus (e.g., such “subgenus, *as defined by appellant*.”) *In re Harnisch*, 631 F.2d at 718, emphasis added. These Proposed Rules on their face overrule case law by drastically changing the standards under which *Markush* claims are proper; consequently, they clearly overstep the Office’s rulemaking authority.

Ironically, under the standards of this Proposed Rule, the claimed *In re Harnisch* compounds themselves would be deemed improper, because while all members of the claimed group of dyes have a *community of properties* (coumarin nuclei), there is no evidence that such feature is *substantial*, or that it is *essential* to the *utility* of the compounds as a dye. Clearly, it is not required under the law of *In re Harnisch* that grouped members meet such a standard. Moreover, like *In re Harnisch*, there are many instances where inventions share a common structural feature that is not known or

characterized well-enough to show it is a substantial feature, nor that such feature is essential to utility. Therefore, many inventions subject to the Proposed Rule could not meet the standard and hence will be denied the opportunity to receive full patent protection as a group. This is particularly troublesome to the unpredictable arts of Biotechnology.

The Office provides an alternative to the first “essential to utility” requirement, wherein Applicants assert that the grouped compounds are *prima facie* obvious over each other – in effect requiring that an Applicant place on the record that the multiple members of the group are patentably indistinct (whether they in fact are or not). This is exceptionally problematic for several reasons. First, the Court recognized in *Ex Parte Dahlen* that there are instances wherein one member of a group may need to be dropped because of problems with a reference showing such a member (or compound). *Ex Parte Dahlen*, 1934 CD 9. *Ex Parte Dahlen* clearly allows that in such an instance the group can properly be reduced to a group of smaller scope. Under the Proposed Rule, such prior art would render all other species within the claim *prima facie* obvious by Applicant’s own admission, and hence unpatentable. An Applicant in such a situation may be faced with either filing all species in separate applications prior to examination, which will not equal the entire scope of the claimed members as a whole, thus losing the full breadth of their entitled invention (discussed below), or grouping the species along with a statement that the members are all obvious over each other, thus jeopardizing the claims over a single reference (in direct opposition to *Ex parte Dahlen*).

The problem with this Proposed Rule becomes clear for an invention claiming grouped members wherein a substantial feature that is essential for utility cannot be identified, and the grouped members are not *prima facie* obvious over each other. Here the applicant’s only option under this Proposed Rule is to claim a single species, thereby losing the full scope of their invention (in direct opposition to *In re Weber*). For all intents and purposes, any reasonable Applicant will not risk making admissions of obviousness on the record to keep claim members together; therefore, this second aspect of the “test” under the Proposed Rules is for all practical purposes unavailable to the Applicant. Only the first part of the test is relevant, and in many instances the heightened standards under the first condition cannot be met. This Proposed Rule clearly denies Applicants the full scope what they regard as their invention, (35 U.S.C. §112). The Office lacks the authority to enact rules contrary to Applicants’ statutory rights.

In addition, this Proposed Rule is beyond the Office’s rulemaking authority because the standard is based on identifying a “*substantial feature*” and that such feature is “*essential for common utility*”, which is arbitrary and capricious, and therefore unconstitutionally vague. The Proposed Rule runs counter to the law in *In re Harnisch*, and will change standard for which a *Markush* claim is proper. There is no guidance in the Proposed Rule or elsewhere in patent law as to what a “substantial feature” comprises, or as to what is “essential for common utility.” Patent Applicants are at a complete loss as to what the rule means, and what types of *Markush* claims would be proper. Hence the Proposed Rule not only exceeds the Office’s rulemaking authority as described above, but it is unconstitutionally vague.

(2) The Proposed Rules are an Improper Administrative Attempt to Circumvent Practices Repeatedly Prohibited by the District Court

In its introduction to the Proposed Rules, the Office notes that all attempts to narrow the use of *Markush* claims have been rejected multiple times by the District Courts in cases such as *In re Wolfrum*, 486 F.2d 588, *In re Weber*, 580 F.2d 455, and *In re Haas*, 486 F.2d 1053 (CCPA 1973). 72 Fed. Reg. at 44993. The courts prohibited the approaches taken by the Office, characterizing the rejection of the *Markush* claim as an improper use of the various statutes upon which those rejections were based. There is a very good reason for the District Court’s position in these cases. These rejections result in a violation of the Applicant’s right to claim their invention as they see fit within the scope of 35 U.S.C. §112, and this right should not be violated. See, e.g., *Weber*, 486 F.2d at 458.

Unfortunately, the Proposed Rules are just one more attempt at the administrative rule promulgation level to craft a means to narrow permissible claims and constrain Applicant's rights to fully claim their invention. Contrary to the Office's assertions, 72 Fed. Reg. at 44993, it is immaterial that violation of the Proposed Rules is not a "rejection" of the claim (as had occurred in the cited cases) as the Proposed Rules will effectively result in an identical inability to present the full scope of an invention in one application. Therefore, this difference is not sufficient to distinguish the effect of the Proposed Rules from the detrimental effect on Applicant's rights the courts sought to avoid in the *In re Wolfrum*, *In re Weber*, and *In re Haas* decisions. Consequently, these Proposed Rules are effectively substantive, and beyond the Office's rulemaking authority.

For example, the present rules necessarily bring about a result rejected by the *In re Weber* court – requiring a single claim to be divided up and presented in several applications. This would result in "fragmentary claims" that "would not necessarily be the equivalent of the original claim." *In re Weber*, 486 F.2d. at 458. The court also noted that putting the Examiner in charge of determining the subgenera would have significant description issues. *Id.* Under the Proposed Rules, many *Markush* claims would become these disapproved "fragmentary" claims if the claim does not meet the arbitrary "substantial feature essential for a common utility" or the highly damaging "*prima facie* obvious" standards of proposed Section 1.140 (discussed above). Thus, the Proposed Rules directly violate the previous guidance of the District Court in how to properly handle inventions best claimed in the alternative and thus cannot be instituted without improperly disregarding the court's statements and reasoning.

The primary justification provided by the Office for putting these rules in place now and upending years of case law is an increase in the administrative burden currently upon the agency. 72 Fed. Reg. at 44994. However, heavily relying on this type of justification conveniently ignores the relationship between Applicant's statutory rights and administrative concerns set forth by the District Court in these series of cases. In particular, the *In re Weber* court stated: "[I]n drawing priorities between the Commissioner as administrator and the Applicant as beneficiary of his statutory rights, we conclude that **the statutory rights are paramount.**" *In re Weber*, 486 F.2d at 458, emphasis added. The Proposed Rules flip this hierarchy and impinge on Applicant's rights in an asserted attempt to correct administrative problems. This is contrary to the way the District Court interpreted the application of the statutes which underlie the agency rules. Thus, the case law in this area fatally contradicts the Proposed Rules and argues strongly against their adoption.

(3) Requirements pursuant to Proposed Section 1.75(j) Exceed the Office's Rulemaking Authority

The Office has proposed to add paragraph 1.75(j)(1) to specify that the number and presentation of alternatives in a claim must not make the claim "difficult to construe." And, the Office has proposed to add paragraphs (j)(2) and (j)(3) to specify that "no alternative can itself be defined as a set of further alternatives within a claim" and that "no alternative can be encompassed by any other alternative within a list of alternatives." This Proposed Rule exceeds the Office's rulemaking authority because a standard based on a showing "difficult to construe" is arbitrary and capricious, and therefore unconstitutionally vague. Moreover, the rule exceeds the Office's rulemaking authority under statute.

35 U.S.C. §112, second paragraph, already sets forth the requirement 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, e.g., that the claims must be clear. The Office lacks the authority to promulgate substantive rules imposing restrictions that go beyond the statute.

Therefore, so long as a claim remains clear under 35 U.S.C. §112, the Office has no statutory authority to add an additional substantive requirement that use of alternative claim language may not make a claim "difficult to construe." Likewise, so long as a claim remains clear under 35 U.S.C. §112, the Office has no statutory authority for addition of an additional substantive requirement that "no alternative can itself be defined as a set of further alternatives within a claim or that no alternative can be encompassed by any other alternative within a list of alternatives". 71 Fed. Reg. at 44997.

Moreover, the addition of proposed section 1.75(j) will place determining the scope of claimed subject matter under the Examiner's control, and the United States Court of Customs and Patent Appeals has repeatedly held that, under 35 U.S.C. §112, second paragraph, the determination of the scope of the claimed subject matter is governed **not by the Examiner's conception of the "invention" but by that "which the Applicant regards as his invention"**. (emphasis added) See e.g., *In re Weber*, 580 F.2d at 458 and *In re Wolfrum*, 486 F.2d 588, 591 (CCPA 1973).

(4) The Proposed Rules are merely Supplementary to Rules Previously Prohibited as Substantive Rules

The ability of the Office to promulgate what it considers "procedural" rule changes was recently deemed to "exceed the scope of the USPTO's rulemaking authority under 35 USC §2(b)2." *Tafas v. Dudas*, No. 07-cv-0846 (E.D. Va. 2008). The present Proposed Rules were presented as a means to block Applicants from circumventing the previously proposed claims rule, Changes to Practice for the Examination of Claims in Patent Applications 71 Fed. Reg. 61 (Jan. 3, 2006), which are now permanently enjoined and were found to be "void as 'otherwise not in accordance with law' and 'in excess of statutory jurisdiction [and] authority.'" *Tafas*, No. 07-cv-0846. Because the Proposed Rules are supplemental to now permanently enjoined and void rules, the present Proposed Rules must be abandoned as well.

Moreover, the Proposed Rules are substantive because § 1.146(b) changes the requirement for restriction in a species election in such a way that the separate patents to each species limits scope and will never equal the original genus. This Proposed Rule authorizes an Examiner to require restriction of any claim to the elected species if any species encompassed by the genus claim is patentable. This differs from the current practice where restriction is only required if no claim to the genus is found to be allowable. The Proposed Rules are substantive because it alters the rights of the Applicants and changes existing law.

E. The Proposed Rules Do Not Support the Office's Stated Goals

(1) The Office already Examines Species without further Restriction, and Admits that the Problem with Alternative or Markush Claiming Impacts only a Few Applicants.

One must question whether applications with *Markush* claims language actually pose a problem that justifies the promulgation of these rules. The Office admits that the impact is skewed against the Biotechnology and Chemical Arts (73 Fed. Reg. at 12681), but that really only a small percentage of such Applicants would be affected by the Proposed Rule: 8% of applications in Biotechnology arts and 2% in Chemical Arts. (73 Fed. Reg. at 12682). Moreover, the Office has presented no evidence that current restriction practice and species election does not work. The evidence of the "problem" as presented by the Office is so small, that it begs the question as to whether such a draconian rule is needed; especially where evidence shows that the Proposed Rules would severely impact select industries both financially, as well as weaken and deny patents within those industries.

(2) The Proposed Rules do not Accomplish the Office's Stated Objective

The Office's stated objective of the Proposed Rules is "to improve practices pertaining to claims that recite alternatives in a manner that will **enhance the Office's ability to grant quality patents**³ that effectively promote innovation in a **timely manner**." (73 Fed. Reg. at 12680, emphasis added).

³ It is unclear what the Office means by patent quality. The Office has said that a reduction in patent issuances is an indication that patent quality has increased. However, the Office has shown no data that statistically correlates reduction in issuance with patent quality. In instances where overall patents are reduced (such as under these Proposed Rules where it is impossible for a company like ours to support all the patents needed to reasonably protect our products), how is the quality of patents enhanced? Resulting patents will be easier to design around (hence weaker) and likely less enforceable (due to errors in Examination, and piecemeal prosecution amongst several Examiners for a single invention). Such an outcome could hardly be considered an increase in patent quality.

However, these Proposed Rules will negatively impact the Office's ability to accomplish this objective: it will create more pending cases for examination, thus adding to the backlog of unexamined applications; it will increase the time needed for an Examiner to fully understand the claimed subject matter and relationship between co-pending applications; and it will increase the likelihood for confusion by the Examiner who must review and comprehend the relationship between an application and the related applications cited in the IDS. The result is an opposite effect from what the Office intends to solve. The Proposed Rules will increase the Office's burden while *reducing* the Office's ability to grant quality patents that effectively promote innovation in a timely manner.

(3) The Proposed Rules will Increase Examiner Confusion and Reduce Patent Quality

The Proposed Rules will also increase the number of related applications and patents that the Examiner will need to consider when reviewing any one application because the additional co-pending divisional applications will also need to be disclosed in the Information Disclosure Statements (IDS) for each application. Likewise, if continuation applications are filed off of the divisional applications, the number of applications and patents that the Examiner will need to consider in the IDS will be far greater than under the current rules. The Examiner will need to understand the interplay between the claimed subject matter of a large number of divisional applications and their respective continuation applications, as well as the priority relationship amongst these applications, resulting in more Examiner time required to review each application; creating a conundrum that can only create inefficiency, increase the likelihood of confusion related to the art before the Examiner, increase the likelihood of mistakes in examination, and hence *decrease* the quality of resulting patents.

(4) If the Proposed Rules are Imposed Retroactively, it would be Inefficient and against Public Interest

We note that the Proposed Rules will be particularly burdensome and detrimental to efficiency if they are applied retroactively, as many applications will have been drafted without the suggested Proposed Rules in mind. A retroactive application will force the filing of many divisional applications which many small- to mid-sized businesses had not anticipated or cannot afford. An Applicant may choose either to file several continuing and divisional applications prior to enactment of the Proposed Rules, or appeal existing applications, rather than fronting the large financial burden of complying with the rules. This would cause a general decrease in patents (including quality patents) from smaller businesses. The only businesses that could afford to prosecute existing portfolios under these rules are large companies with very high patent budgets. This outcome surely is against public policy.

(5) The Rules Do Not Serve the Public Interest under the Constitution

The Proposed Rules do not serve the public in at least two ways. First, the publication of applications already provides notice to the public of the entire scope of the inventions that may arise therefrom. All patentable claims resulting from those applications must be supported by the published disclosures. The proposed limitations on *Markush* claiming practice will not decrease public confusion where Applicants must split their single application into tens if not hundreds of divisional applications. Such practices increase confusion amongst the public rather than reduce the public's confusion or establish more certainty.

Second, where companies and inventors cannot afford to pursue the entire scope of their inventions, would necessarily forfeit pursuit of alternatives or full coverage of inventions to which the public could receive benefit. This does not serve the interest of promoting science and the useful arts, but rather drives it into hiding, since the most affordable outcome would be to maintain inventions as trade secrets rather than obtain patents on such narrow embodiments as to be financially untenable.

(6) The Proposed Rules Will Harm the Public Because It will be Difficult to Determine the Scope of Patent Coverage and Expiration Dates Due to Piecemeal Prosecution

The rules will have the effect of creating more uncertainty for the public. The number of divisional applications (and their corresponding continuation applications) that will need to be filed for a claim containing alternate language will dramatically increase the number of applications, patents, their corresponding expiration dates, terminal disclaimers, and patent term adjustments that the public will have to look at to fully understand the metes and bounds of the patentee's rights. As discussed above, all these divisional applications and their continuation applications could be prosecuted concurrently or sequentially, resulting in piecemeal prosecution and less certainty for the public. This practice will also reduce patent quality.

F. Alternative Solutions That Could Solve the Office's Problem

The Office states that the Proposed Rules are "part of its ongoing efforts to enhance patent quality and reduce pendency" 72 Fed. Reg. at 44992. Alternative solutions could be implemented that would not only alleviate the perceived burden on Office resources with respect to alternative claim language, but would also reduce application pendency and enhance patent quality. Such solutions would not be detrimental to select industries, such as Biotechnology, Chemistry, and Pharmaceutical industries.

(1) Request Examination. The Office could adopt a request for examination system whereby Applicants must request examination within a certain time frame and pay an examination fee in order for the Office to initially examine an application. Those who wish to expedite examination could pay a fee to do so, if immediate issuance is needed for their industry. Such examination request systems are common outside of the United States. This practice will reduce the number of applications to be examined, while still preserving an Applicant's rights - the burden is on Applicants to decide what applications are of sufficient interest to warrant examination. Applications of questionable value could be deferred; many of them may be abandoned. The most valuable, rather than all, applications would be pursued. By reducing application pendency, such a requirement would also reduce the burden on Office resources and help facilitate proper examination of pending applications, including those containing claims with alternative language.

(2) Pre-Examination Interview. The Office could adopt a procedure whereby Examiners grant Applicants a pre-examination interview for applications containing claims with alternative claim language. Such a procedure would alleviate the burden on Office resources, since it would allow Applicants to facilitate an Examiner's familiarity and understanding of the application subject matter, allowing the Examiner to fully understand the invention earlier which would expedite examination. In particular, this procedure would provide Examiners the opportunity to further understand the general inventive concept as it relates to the scope of claims with alternative language. Examination of claims containing alternative language based on a general inventive concept is consistent with the "unity of invention" test acknowledged by the court's ruling in *In re Harnisch*, harmonizes with the PCT unity of invention standard, and, moreover, obviates the Office's proposed tests based on "*prima facie* obviousness" and "substantial feature essential for common utility," both of which are inconsistent with *In re Harnisch*.

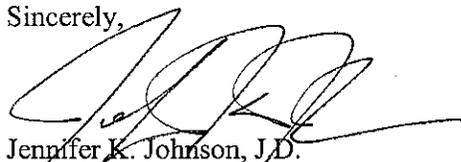
(3) Reform Restriction Practice. The controversy surrounding alternative claiming could be reduced by reforming restriction practice and adopting the PCT unity of invention standard based on a single general inventive concept. This would allow Examiners to examine the entire scope of an application at once and would reduce the number of applications that must be processed and examined.

(4) *Fee Increases for Alternative Claims*. The Office could discourage use of alternative language in claims by increasing fees for applications that contain such claims. For example, the Office could devise a schedule that imposes additional fees based on the number of claims containing alternative claim language. Such a fee structure, although costly to Applicants, would discourage “excessive” use of alternative language in claims. It is noted that the Office has successfully used an increased fee schedule to discourage the use of multiply dependent claims in applications.

(5) *Revamp the “point system” for Examiners and Increase Training*. The Office could encourage the issuance of **quality patents** by maintaining a productive highly trained workforce who is competitively compensated for the time they spend on examination rather than the disposition of applications. The point system encourages rapidity of examination, and hence increases the likelihood of mistakes in examination, thereby **decreasing** the quality of resulting patents. Examiners need to be competitively compensated and given more time to examine complicated inventions, so that the Office retains experienced Examiners⁴ – this should be appreciated by the Office. Revising the point system and devising means of Examiner retention could go a long way in increasing the quality of patents as well as reducing pendency. The fact that Applicants are filing complex inventions (such as biotechnology inventions) is a good problem for a nation (and the Office) to have. If the Office is finding they do not have the time or resources to support examining the inventions of this country, then maybe the Office itself should look into revising its own practices in order to support such innovation, rather than spending resources on crafting Proposed Rules that are intended to deny patents. Protection of those patentable inventions is not only constitutionally mandated but all patentable inventions should be supported by the agency responsible for the granting of such rights.

Again, we appreciate the opportunity to provide comments on the Proposed Rules.

Sincerely,



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⁴ Moreover such revision of Office compensation and time schedules would likely enhance Examiner satisfaction and help the Office retain experienced examiners. Regional offices around the United States would also have a positive impact in this regard and have the potential to compete with in-house and law firm positions around the country.