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From: David Korn

Sent: Tuesday, October 09, 2007 10:41 PM

To: Markush.Comments

Subject: Attached Comments from PhRMA

Attached are comments on the proposed rules on "Examination of Patent Applications That Include Claims Containing Alternative Language." Please do not hesitate to contact me if you have any questions.

Sincerely,

David E. Korn

Assistant General Counsel

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David E. Korn
Assistant General Counsel



October 9, 2007

VIA EMAIL – Markush.Comments@uspto.gov

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

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

Dear Ms. Fonda,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) to convey the views of PhRMA’s members on the proposed rulemaking on “Examination of Patent Applications That Include Claims Containing Alternative Language,” 72 Fed. Reg. 44992 [Docket No.: PTO-P-2006-0004]. PhRMA’s members are leading pharmaceutical research and biotechnology companies, devoted to inventing and making available medicines that allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding new cures, as well as in developing critically important improvements in existing therapies. Strong patent protection is required in order to promote innovative research by PhRMA members and make available to society the benefits of such research.

The enclosed comments express the concern of PhRMA’s members that the proposed rules would not achieve the laudable goals of improving Office efficiency and patent quality, but instead would harm the legitimate interests of patent stakeholders. As set forth in the enclosed comments, PhRMA is concerned that the Office may create rules that would be difficult to administer, could lead to the need for additional applications, could impose unnecessary limitations on applicants, and could be contrary to direction from the courts. As such, it could make it more difficult to obtain patent rights that are critical to recoup and justify the extraordinary costs of research and development of life saving medicines. For these and other reasons that are further elaborated in the enclosed comments, PhRMA urges you to reconsider the proposed rule changes.

Pharmaceutical Research and Manufacturers of America

PhRMA's members understand that the PTO's goals in proposing these rules are to improve Office efficiency and the quality of issued patents. PhRMA's members support these underlying goals, and would welcome further dialog with the PTO with these goals in mind.

Please feel free to contact me with any questions or concerns you may have.

Sincerely,

A handwritten signature in black ink that reads "David E. Korn". The signature is written in a cursive style with a large, stylized "D" and "K".

David E. Korn
Assistant General Counsel

Enclosure

**Comments of the Pharmaceutical Research and Manufacturers of America
in response to**

U.S. Patent and Trademark Office – Notice of Proposed Rulemaking

“Examination of Patent Applications That Include Claims Containing Alternative Language,”
72 Fed. Reg. 44992 (August 10, 2007)

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies. The member companies of PhRMA are devoted to inventing and commercializing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members alone invested an estimated \$43 billion in 2006 to discover and develop new medicines – fully 19.4 percent of their domestic sales on U.S. R&D. *See* PhRMA, *Pharmaceutical Industry Profile 2007* at pages 2-3, 43; available at www.phrma.org/files/Profile%202007.pdf. The benefits to society from these investments are undeniable. It is estimated, for example, that new medicines were responsible for 40 percent of the two-year increase in average life expectancy from 1986 to 2003 in the United States and 51 other countries. *See id.* at page 26.

The process of developing a single new drug from a new class of pharmaceutically active compounds typically extends over 10-15 years. It begins with drug discovery research that involves screening thousands of test compounds; continues with preclinical research involving perhaps 250 compounds; and is followed by clinical trials of a small number of candidate compounds that emerge from preclinical screening. Finally, if the clinical trials are successful, the result of these activities is that an application for authorization to market a single drug may be submitted to FDA for regulatory review. *See id.* at pages 6-8. Even for this level of effort and expense, there is no guarantee that a drug product will in fact be found safe and effective, and that the FDA will approve it. And all of the basic research, screening, clinical testing, and regulatory compliance is enormously expensive – the *average* cost for developing one new drug molecule now exceeds \$800 million. *Id.* at page 5.

Strong and predictable patent protection is essential to the business of developing new medicines. Plainly, there is considerable risk in committing significant capital and limited business resources to a development program that – if successful – will consume the better part of a billion dollars and *may* lead to a commercial product. The counterbalance to such

extraordinary business risk is a reasonable assurance that the prospective market for a future product can be protected through patent rights. Without the legal protection provided by patent coverage, there could be little incentive for a pharmaceutical company to take a product candidate through clinical trials and regulatory review.

The nature of pharmaceutical research demonstrates why it is so important for innovators to be able to secure patent claims that cover classes of molecules, and not only single “preferred” compounds. The intense competition in the research-based pharmaceutical sector makes the ability to secure basic product patents covering a comprehensive class of related candidate molecules important. However, to secure patentable claims, inventors must file their applications as soon as a new class of compounds is characterized with respect to a potential pharmaceutical activity (*i.e.*, as soon as a patentable utility has been identified). At that stage, it is difficult to determine which molecules in a class of molecules might emerge as the best candidates for clinical testing, and impossible to predict which of those, if any, might gain regulatory approval. If there is to be any product eventually brought to market, it will require patent coverage – and coverage for an as-yet unidentified product can only be assured if patent claims that reasonably cover a genus of new compounds are available.

The member companies of PhRMA are profoundly concerned that the rule changes that the Patent and Trademark Office (PTO) proposes will effectively preclude applicants from securing the breadth of patent protection that is essential to the mission of the research pharmaceutical and biotechnology industries. Although labeled procedural, the proposed rules would impose all-but-impossible standards to meet for constructing “proper” claims to protect classes of compounds. Under the rules as proposed, patent applicants could be forced to seek and procure claims covering only a few species within an inventive group of compounds. The effect of the rules would thus be significant and substantive, not procedural in nature. Moreover, when the rules are considered in conjunction with other rules being promulgated by the PTO, these procedural restrictions could operate to deny patent applicants the ability to effectively protect the full scope of their inventive contributions.

For the reasons we detail below, we do not believe that the PTO has a proper basis in law to promulgate the rules it proposes. Even setting that consideration aside, the PTO has not set

forth any adequate justification for implementing these significant changes to settled examination practices, which have been in place and followed consistently for several decades. PhRMA believes extensive changes to practice for Markush-type claims are unnecessary and could prove harmful to the pharmaceutical and biotechnology industries. In short, the proposed rules do not reflect sound policy, will impose significant, unnecessary and inappropriate burdens on patent applicants, and should be reconsidered.

The law allows applicants to claim their inventions as they view them

The second paragraph of section 112 of title 35, United States Code, provides discretion to applicants in how they may claim their inventions:

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*. [emphasis added]

It is left to the inventor to determine what he “regards as his invention.” The courts have recognized that this latitude may place burdens on the PTO to thoroughly and efficiently examine the full extent of claims that may be presented by an applicant. Such burdens are a legitimate policy concern, not only for the PTO, but for all patent applicants and the public at large who rely on the PTO to accurately and fairly examine applications and grant patents in a timely manner. Thus, the PTO is entitled to regulate its workflow, and the statute provides tools, such as the discretion to require restriction, that allow it to do so.

Inevitably, there is a tension between the PTO’s need for administrative efficiency and applicants’ right to claim their inventions as they see fit. The courts have determined how Congress intended to balance these competing priorities.

An applicant is given, by the 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. We have decided in the past that § 112, second paragraph, * * * allows the inventor to claim the invention as he contemplates it.

* * *

Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in 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, 580 F.2d 455, 458-459, 198 USPQ 328, 331-332 (C.C.P.A. 1978) (internal citations omitted).

The PTO may not restrict a Markush claim merely because it is broad

Under 35 U.S.C. § 121, the Director may require an applicant to pursue separate claims to independent and distinct inventions in divisional applications. That authority does not extend to breaking apart and requiring separate claiming of the subject matter encompassed and defined by a properly drawn Markush genus claim.

A simple Markush group (for example, “a widget selected from the group consisting of A, B, and C”) provides a form of expression that is fully equivalent to a straightforward recitation of alternatives (“wherein the widget is A, B, or C”). But a large Markush group, such as a typical claim to a class of chemical compounds that recites alternatives for several different substituents, is not simply a shorthand equivalent for an express recitation of every member covered by the group. This is so, even though it would be possible in theory to name every individual species covered by the generic language. It is settled law that a Markush group does not necessarily describe every species or subgenus it includes. *See generally, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996); MPEP § 2163.05, subsection II. The *Weber* court particularly understood the problematic implications of allowing the PTO to require restriction as to the subject matter of Markush-style claims:

If * * * 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. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In re Weber, 580 F.2d at 458, 198 USPQ at 331.

The standard the PTO proposes for determining whether a Markush group is properly drawn is more restrictive than what the case law authorizes. As the PTO notes in the discussion accompanying the present rule package, the courts have not provided any formula for satisfying what the *Harnisch* court termed “unity of invention.” One expression of the essential aspect of “unity” of a chemical genus is that the compounds have “a community of properties justifying their grouping which [is] not repugnant to the principles of scientific classification.” *In re Harnisch*, 631 F.2d 716, 722, 206 USPQ 300, 305 (C.C.P.A. 1980).

In the *Harnisch* case, the requirement for “unity of invention” was found to be satisfied because the members of the Markush group belonged to a single structural class, and they shared a common functional property. The standard of proposed 37 C.F.R. § 1.140(a)(1), on the other hand, would require that “the species [recited in the claim] share a substantial feature essential for a *common utility*” (emphasis added). It is difficult to see how the PTO can equate the possession of a “common utility” to the possession of a molecule of a “common functional property.” These two concepts are distinct. The *Harnisch* court did not find that the structural relationship shared by the compounds of the appealed claims was “essential” to their common functional properties, and it did not hold that a correspondence between structure and function was necessary for establishing “unity.” Moreover, as discussed below, it is impractical (and often impossible) for applicants to characterize “essential” features of a chemical structure.

The courts have repeatedly emphasized that the propriety of a Markush group must be assessed on a case-by-case basis. *See, e.g., Harnisch, id.* (“each case of this type must be considered on its own facts”). It is improper for the PTO to promulgate a rule of general application that would impose a uniform standard that is more stringent than any standard that the jurisprudence can support.

Applicants in the research pharmaceutical and biotechnology industries have a stake in supporting the PTO’s efforts to examine patents expeditiously and to issue valid claims. To achieve this goal, the PTO should use the aspects of current law, such as the standards actually applied in the *Harnisch* case, together with existing rules that give it reasonable procedural discretion to regulate examination, and develop more efficient and productive ways of examining this class of applications.

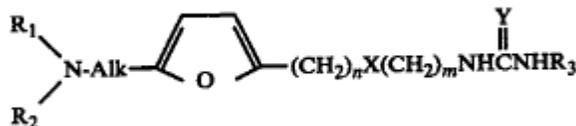
The PTO should modernize its practices instead of imposing limitations on applicants

To support its case for drastically restructuring the requirements that govern chemical patent practice, the PTO points to increases in the number and complexity of patent applications submitted for review. *See* 72 Fed. Reg. at 44994. The increases reported by the PTO in the number of filings it receives do not represent a development that is new or unforeseen by the PTO. Instead, the increases are consistent with the multi-year forecasts that the PTO has made and updated over the past twenty years. The increase in filings is consistent with the steady increases in R&D expenditures reported by companies in the research pharmaceutical and biotechnology industries over the past two decades. The PTO's suggestion that the increased number of applications filed in recent years justifies a drastic shift in the approach to examination of these applications is unwarranted.

As to the complexity of applications, we believe it is appropriate to remove examples of "extreme" Markush claims from the analysis. While we are aware from the public record that such claims have been filed, we believe they appear in only a small minority of cases. (We note that the PTO has not supported its proposed rulemaking with any analysis of the frequency with which claims it considers to be "burdensome" are presented.) Moreover, if claims are indeed overbroad, they will present very few practical challenges for examiners, in part because such claims may more readily be found to be anticipated (*i.e.*, because they encompass far more species of compounds than narrowly defined Markush groups). Existing rules and practice, particularly the substantive requirements for patentability (*e.g.*, the requirements of § 112 that address overbreadth and the consequences under §§ 102 and 103 for overbroad claims), are adequate to deal with truly egregious Markush claims.

The practice of drafting claims that the PTO now believes to be overly complex is not new. The PTO has competently and effectively examined claims to extensive Markush groups for decades. For example, claim 1 of U.S. Patent No. 4,128,658, filed in July 1977 and granted in December 1978, recites:

A compound of the general formula I:



or a physiologically acceptable salt, N-oxide or hydrate thereof in which R₁ and R₂ which may be the same or different represent hydrogen, lower alkyl, cycloalkyl, lower alkenyl, aralkyl in which the aryl portion is phenyl or phenyl substituted by alkyl, alkoxy or halo or lower alkyl interrupted by an oxygen atom or a group



in which R₄ represents hydrogen or lower alkyl; R₃ is hydrogen, lower alkyl, lower alkenyl or alkoxyalkyl;

X is $-\text{CH}_2-$, O or S;

Y represents =S, =O, =NR₅ or =CHR₆;

Alk denotes a straight or branched alkylene chain of 1 to 6 carbon atoms;

R₅ is H, nitro, cyano, lower alkyl, phenyl, phenyl substituted by alkyl, alkoxy or halo, alkylsulphonyl, or arylsulphonyl in which the aryl portion is phenyl or phenyl substituted by alkyl, alkoxy or halo;

R₆ represents nitro, arylsulphonyl in which the aryl portion is phenyl or phenyl substituted by alkyl, alkoxy or halo or alkylsulphonyl;

m is an integer from 2 to 4; and

n is 1 or 2; or when X = S, or $-\text{CH}_2-$, n is zero, 1 or 2.

This claim includes within its scope ranitidine, the active ingredient of the remarkably successful drug product ZANTAC®, used successfully by millions of patients to treat peptic ulcer disease and gastroesophageal reflux disease.

The claim above presents a typical chemical genus described with reference to its structure. It is clear and straightforward, and it corresponds to the subject matter that the inventors of the '658 patent describe as their invention. Yet this claim would be considered "improper" under proposed § 1.75.

The use by applicants of claims of this nature does not represent a crisis that compels the PTO to restructure the way pharmaceutical patent applicants claim their inventions and secure patent protection. Indeed, the kinds of problems that the PTO cites in the present rule package are of the same sort considered by the courts more than 25 years ago. *See, e.g., Harnisch, supra.* In fact, the *Harnisch* court in 1980 expressly invited the PTO to promulgate regulations “to anticipate and forestall procedural problems” related to the examination of Markush-format claims. The fact that the PTO has not done so in the more than two decades since indicates that the existing rules and examination practices have been sufficient to address any perceived problems in examining these types of claims.

Separate classifications do not reflect areas of innovation in modern science

The PTO cites the increased burdens associated with searching greater numbers of claims. The discussion in the Notice of proposed rulemaking implies that examiners routinely search Markush genus claims one species at a time, and that it is unreasonable to put the PTO to searching several subclasses in any single application.

Notwithstanding portions of the MPEP that retain language from the 1960s, patent examiners in the chemical arts – not only in the PTO, but also in the EPO and other major patent offices – no longer routinely conduct manual searches in “subclasses” of patents defined by a classification system. A properly maintained classification system is useful for tracking patent trends in different areas of technology. However, in fields such as chemistry or biotechnology, where essentially all of the relevant information is now available in indexed computer databases, a classified search is all but irrelevant.

The PTO’s classification system reflects, more than anything else, the historical development of chemical search areas. Modern pharmaceutical research often has little regard for history. Instead, tools such as combinatorial libraries and crystal structure-based drug design lead to new classes of compounds that define their own commonalities. This is simply the nature of innovation in contemporary chemical sciences. Fortunately, modern databases – which are regularly and effectively used by PTO examiners, as well as by researchers – provide powerful and efficient tools for searching structurally defined classes of molecules. Simply put, the suggestion that a search might be “burdensome” on the PTO simply because it implicates

different subclasses in the PTO's classification system does not take account of how searches can be performed by scientists working in this field, including scientists in the PTO.

Instead of attempting to impose limits by rule on patent claims, the PTO could better train examiners how to fully leverage the power of chemical and biotechnology computer database searches. The PTO could promote these objectives by providing more detailed guidance to examiners in the portions of the MPEP that concern searching. It could also make greater use of its in-house professional database searchers to instruct examiners in the design and interpretation of search results. Making the best use of database searches would provide greater value to patent applicants, conserve PTO resources, and support higher quality patents.

The proposed rules are unreasonably limiting and are impractical

The PTO's proposed rules presents real and serious problems for patent applicants in the pharmaceutical and biotechnology industries. It is not clear that under a literal application of the rules, one would *ever* be able to present any claim to a "proper" genus. As one example, the requirement of proposed § 1.75(j)(4) that alternatives be "substitutable one for another" does not square with case law providing that every limitation is material to construing a claim, and that a claim that recites different limitations defines a different invention. *See Forest Labs., Inc. v. Abbott Labs.*, 239 F.3d 1305, 1310, 57 USPQ2d 1794, 1797 (Fed. Cir. 2001) ("Where claims use different terms, those differences are presumed to reflect a difference in the scope of the claims"). The draft rules, even when taken in light of the supporting discussion in the rule package, do not make clear what the PTO proposes to require.

Specific points of concern include the following:

1. Each claim must be limited to a "single invention"

The PTO proposes to amend § 1.75 to allow for restriction within a single claim. In particular, § 1.75(a) is proposed to be amended to require that a claim must be limited to a single invention. What constitutes a single invention is defined in proposed § 1.140(a):

A claim that reads on multiple species using alternative language is limited to a single invention when all the species encompassed by the claim meet at least one of the following two conditions:

- (1) The species share a substantial feature essential for a common utility, or
- (2) The species are *prima facie* obvious over each other.

The Notice of proposed rulemaking indicates that a “feature” can be a common structure, material, or act necessary for at least one shared specific, substantial, and credible utility.

The Notice characterizes this proposal as being consistent with *In re Harnisch, supra*. That case, however, does not link the “function” requirement to the “common feature” requirement. Instead, *Harnisch* identifies two distinct criteria by which the claims on appeal were determined to recite a proper Markush group: (i) the compounds in the group shared a common utility (the compounds were all dyes), and (ii) they all had a “single structural similarity” (all of the compounds were coumarins). Thus, proposed § 1.140(a)(1) is contrary to case law.

The requirement of § 1.140(a)(1) may prove problematic because the feature(s) that are *essential* for utility are often not known at the time a patent application is filed. For a claim directed to a group of chemical compounds, for example, there is often an imperfect understanding of which features are essential for an initially identified utility. Particularly in the pharmaceutical and biotechnology arts, it may not be possible to ever characterize any particular feature of an invention as “essential.” Generally, the molecule as a whole is responsible for the utility of a compound. The concept that one could always assert that a certain part of a molecule as “essential” for any utility is repugnant to fundamental concepts in chemistry and biology. From a purely practical perspective, it is often not known what structural features are essential for utility, and indeed it is scientifically unrealistic to assign utility to a portion of a claimed molecule.

Utility under 35 U.S.C. § 101 is determined based on the claimed invention as a whole, *e.g.*, the molecule as a whole as claimed, not a portion of the molecule. *Diamond v. Diehr*, 450 U.S. 175, 188 209 USPQ 1, 9 (1981) (“In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole”). Requiring an applicant to identify a portion of a claimed invention that provides “utility” is

inconsistent with jurisprudence concerning the utility requirement of § 101. Indeed, an approach that attempts to correlate utility with a fragment of a molecule is inconsistent with the cases that specifically concern Markush practice. *See, e.g., In re Harnisch*, 631 F.2d at 722, 206 USPQ at 305 (“in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components”).

Requiring an applicant to identify an “essential” feature of any claim could lead to unwarranted difficulties enforcing the patent. An indication by the applicant that a feature is essential – by amendment, argument, or even simply through acquiescence in a determination by the PTO – might be interpreted to give rise to prosecution history estoppel, and could also be scrutinized for potential claims of inequitable conduct in litigation.

Implementing a new “essential” feature inquiry may also lead to inconsistent practices within the PTO. Labeling features of a unitary invention, such as a chemical compound, as “essential” may invite examiners to focus exclusively on those features during examination, reject claims over any art having those features, and argue that any other “non-essential” aspects of the claimed inventions are obvious. This would not be a proper approach to applying patentability criteria, and could lead to unfair results for patent applicants.

A more appropriate practice would involve decoupling the utility element of the “unity of invention” test from the shared substantial feature element. Thus, for a claim to be limited to a single invention, it would be necessary that (i) the species share a common utility, and (ii) the species share a substantial common feature. In chemical and biotechnology practice, the shared substantial feature may be structural, but other substantial features, such as function, an evolutionary relationship of genes or gene products, *etc.*, may provide a “community of properties justifying their grouping” in a single Markush-type claim. Such reasoning, in fact, would be consistent with both the *Harnisch* decision and the straightforward and familiar unity of invention standard used in PCT and international practice. Applicants and the PTO may benefit from adopting practices and standards aligned with those of other major patent offices.

Proposed § 1.75(b) would permit an applicant to include a preemptive explanation of why a claim that reads on multiple species is limited to a single invention at the time the claim is presented. The PTO believes this provision will be used often, reduce the number of restrictions,

and shorten the time to a first office action on the merits. The possibility that such explanations may create prosecution history estoppel, as discussed above, could make the proposed practice less attractive to and more burdensome for applicants than the PTO states.

2. Election of species

The PTO proposes to revise § 1.146, relating to election of species. Proposed § 1.146(a) appears to be largely consistent with current practice. Proposed § 1.146(b), however, would authorize the examiner to require restriction of any claim to the elected species if “any species encompassed by the [generic] claim is not patentable.” It thus appears to be the PTO’s intention to authorize a practice whereby, if the examiner finds any species within the genus claim in the prior art or determines that any species within the scope of the genus does not satisfy a requirement of § 112, *e.g.*, for lack of enablement, the applicant would be forced to limit the claim to the originally elected species.

We note that the standards of proposed § 1.146(a) and (b) import a number of substantive determinations, such as whether species are “patentably distinct” or “unpatentable.” The Notice of proposed rulemaking provides no guidance as to the proper evidentiary standards required to support such determinations, or how (or even whether) the applicant may rebut an adverse determination. The structure of the rule foreshadows arguments directed to substantive patentability standards as integral to procedural petitions, rather than presented through appeals according to current practice. The rule, as currently proposed, is likely to create significant problems in practice.

As to matters of substance, an analysis of a patentability requirement based only on a single species within the scope of a generic claim would be inconsistent with current law. For example, a claim to a genus can comply with the requirements of § 112, even if a separate claim to a particular species would not. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ2d 404, 414, (Fed. Cir. 1984) (“Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid”).

It would serve the interests of inventors and the public to continue to provide applicants the opportunity to amend the claims after a first office action to overcome the rejection of a non-

elected species, instead of requiring applicants to limit claims to elected species. Often a genus encompasses species that were in the prior art, but unknown to the applicant. Under the proposed rule, a simple amendment that would overcome such a rejection could be refused entry, and the applicant could be required to limit the claim.

Proposed § 1.146(b) could instead be modified to retain the essential aspects of current practice. The PTO may now require an applicant to elect a species within a generic claim. If the species is patentable, the PTO will then examine the genus claim, and may reject it if the claim as a whole is not patentable. The applicant may then make arguments for patentability or amend the claims as appropriate to render them patentable.

Compact prosecution is achieved under the current election of species practice. Under the proposed rules, if any species within an original genus claim were found to be unpatentable, applicants would be forced to file many divisional applications to pursue desired subgenus or species claims. Additional applications that might result from implementing the proposed rule would have the potential to exacerbate, not alleviate, the burdens on the PTO and applicants.

3. Priority practice

The PTO proposes to amend rules related to priority practice for continuation-in-part (CIP) applications. Proposed § 1.75(d)(2) would require:

If an application seeks the benefit under title 35, U.S.C., of a prior-filed application and discloses subject matter that was not disclosed in the prior-filed application, the applicant must identify which claims or claims in the application are disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior filed application.

It is not clear what the PTO intends by “seeks the benefit.” This provision could place undue burdens on both applicants and the PTO. The interests of all parties may be better balanced by triggering the provision relating to CIPs only if priority date of the claims becomes relevant during prosecution, for example, when intervening art is applied against specific claims. Such a rule is already PTO practice.

When a new claim is added, the applicant is in a position to identify textual support for the claim. A requirement to provide such information would be less problematic for applicants than the proposed rule. Additionally, the PTO may reasonably require applicants to point out “new” text added in CIP applications.

4. Clarity of claims

We are particularly concerned with the “format” provisions of proposed § 1.75. The PTO portrays these as procedural simplifications. In reality, these proposals could undermine much of contemporary chemical patent practice, to the detriment of applicants and the public. We also believe that these rules could ultimately work to the disadvantage of the PTO. In particular, because applicants would have to present claims in different jurisdictions to comply with different practices and policies, the proposed rules could cause U.S. claim practice to deviate further from standards followed for examination of these types of claims in other patent offices.

Proposed § 1.75(j) sets out requirements for the form of claims that read on multiple species. This proposal appears to add an additional layer of rules to examination, increasing the workload for both the PTO and applicants. Although framed in terms of formal requirements, the proposed rule appears to be directed to matters that may be addressed through rejections under 35 U.S.C. § 112, second paragraph.

Proposed § 1.75(j)(1) states that a claim must not be “difficult to construe.” The standard that would determine whether a claim satisfies this standard is not readily discerned from the Notice of proposed rulemaking. Moreover, it is difficult to determine how the requirement would differ from that of § 112, second paragraph. This subjective standard may be interpreted differently from examiner to examiner, adding additional uncertainty, costs, and time to patent prosecution. As such, it is improper and inaccurate to characterize this subjective, substantive proposal as a procedural rule.

Proposed § 1.75(j)(2) would prohibit defining alternatives as a set of further alternatives, *e.g.*, nesting of Markush groups. But often the nesting of alternatives is the clearest way to claim particular subject matter. Consider a claim including a Markush group “where R is selected from the group consisting of C1-C5 alkyl, C1-C5 alkenyl, and C1-C5 alkanol.” This claim appears to

be clear, but it would not comply with this proposed rule. Applicants may be forced to recite dense lists of individual species in “simplified” Markush claims. The proposed requirement has the potential to make claims in the pharmaceutical arts less concise, frustrating efforts to harmonize patent practice and share work product with other patent offices. Rejections under § 112, second paragraph, may be better suited than the proposed rule to addressing complicated or unclear claims.

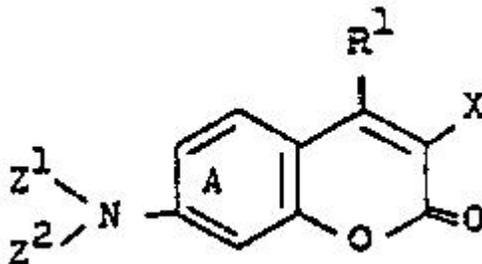
Proposed § 1.75(j)(3) would prohibit an alternative from being encompassed by any other alternative “unless there is no other practical way to define the invention.” This proposal would introduce a subjective issue into the standard. Current practice allows for the double-inclusion of an element in a Markush group so long as the claim is definite. MPEP § 2173.05(h)(I) states that “the mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear.” It may be preferable to maintain the current practice as set forth in the MPEP. Rejections under § 112, second paragraph, may be better suited than the proposed rule to addressing unclear claims.

Proposed § 1.75(j)(4) would require that each alternative within a list must be “substitutable one for another.” The entire inquiry would be unnecessary for any claim that, as a whole, is clear. It is not evident from the Notice of proposed rulemaking what is intended by the term “substitutable.” For example, structurally comparable alternatives often impart different functions or qualities to a claimed invention. Conversely, structurally distinct alternatives can impart comparable functions or qualities to a claimed invention. Consider an example of a very common type of Markush group reciting oxygen, nitrogen, and sulfur as options at one position in a chemical structure. Each element may impart different qualities to the molecule as a whole. It is not clear whether in this context, the recited alternatives would be considered “substitutable.” In addition, the proposed requirement may be unnecessary in view of the existing requirements of the second paragraph of 35 U.S.C. § 112.

We note that the “format” requirements of the proposed § 1.75 would declare Markush claims that have been *specifically* found in the past to be acceptable by the courts to have an “improper” form under the proposed rules. Such claims include those appealed in the following cases.

- *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (C.C.P.A. 1980)

1. Coumarin compounds which in one of their mesomeric limiting structures correspond to the general formula



wherein

X represents aldehyde, azomethine, or hydrazone,

R¹ represents hydrogen or alkyl,

Z¹ represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring and

Z² represents hydrogen, alkyl, cycloalkyl, aralkyl or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring

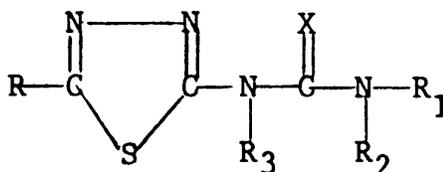
and wherein

Z¹ and Z² conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dyestuff chemistry.

- *Harnisch* claim 1 may not comply with proposed § 1.75(j)(2) because Z¹ and Z² are defined by individual Markush groups and are then further defined by additional alternatives (“can carry further radicals”).

- *In re Driscoll*, 562 F.2d 1245, 195 USPQ 434 (C.C.P.A. 1977)

13. A compound of the formula



wherein R is alkylsulfonyl (C1-C6);

R₁ is selected from the group consisting of H, alkyl (C1-C4), and cycloalkyl (C3-C6);

R₂ is from the group consisting of H, alkyl (C1-C4), haloalkyl (C1-C4), alkoxy (C1-C4), alkenyl (C2-C4), alkynyl (C2-C4), aryl, and haloaryl, and wherein R₁ and R₂ are alkylene which, together with N, form a ring of at least 3, but not more than 6 members;

R₃ is H or alkyl (C1-6); and X is selected from the group consisting of oxygen and sulfur.

- Driscoll claim 13 may not comply with proposed § 1.75(j)(2) because R₁ and R₂ are defined as alternatives reciting further alternatives (*i.e.* the number of carbon atoms in the radicals).
- Driscoll claim 13 also may not comply with proposed rule 75(j)(3) because aryl encompasses haloaryl.

We do not believe that the PTO has authority to promulgate rules that would run counter to the specific holdings of precedential decisions such as these.

5. General observations and suggestions

Viewed as a whole, the proposed rules appear to be calculated to significantly increase the number of restriction requirements and divisional application filings. Neither development appears likely to offer benefits to either applicants or the PTO. Implementing a new intra-claim restriction practice could complicate the preliminaries to examination on the merits, involving one or more additional written exchanges in each application. An increase in the number of restriction issues that the PTO raises could lead to an increase in the number of petitions from applicants traversing restriction requirements. All of these developments have the potential to increase the PTO's workload and prolong the average pendency of patent applications.

It may be preferable for the PTO to directly engage issues that ultimately relate to the clarity of the claims through rejections under 35 U.S.C. § 112, second paragraph, instead of attempting to fashion new standards. The case law provides adequate authority for the examiners to reasonably object to claims as reciting improper Markush groups, as discussed in such cases as *In re Weber, supra*, and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (C.C.P.A. 1978).

The PTO may wish to promulgate a simple procedural rule to provide guidance to examiners as to when such objections would be in order. Indeed, it may be preferable for the PTO to develop more experience and guidance with “improper Markush” objections to address the most egregious claims that it believes unduly complicate examination, before promulgating detailed rules imposing overbroad and burdensome standards applicable to every patent application. Practical experience, supported if necessary by guidance from the courts, may provide a more appropriate basis for effective and transparent rulemaking in the future.

Finally, the current practice relating to elections of species may be flexible enough to address many of the issues that now concern the PTO. A straightforward extension of current practice based upon proposed § 1.146(a) would obviate the need to analyze whether any given claim is directed to a “single invention,” and it would render moot any new variant of intra-claim restriction practice. Such an approach would have the advantage of relying on standards that are familiar to both applicants and PTO personnel, and it could provide the basis for a practical and efficient alternative to the proposed changes.

The proposed rules would improperly limit applicants’ substantive rights

The proposed rules, which the PTO characterizes as procedural in nature, in fact would tangibly limit applicants’ statutory rights to claim and patent their inventions. Under current practice, if an applicant presents a Markush claim that is found unpatentable – for example, because it peripherally includes compounds that were known – the applicant can amend the broad claim and obtain a patent on a suitably narrowed genus. Under the practice that the PTO proposes, if any species other than the one elected for examination is found to be unpatentable, the applicant will be limited to claiming the elected species. In the scenario described, the applicant would be forced to file divisional applications – potentially numbering in the hundreds or thousands – to secure patents to individual species. The very real effect is that applicants would never be able to secure claims that fully correspond to what they invented.

The burdens imposed by the proposed “Markush” rules would be compounded by the recently finalized “continuations” rule package, 72 Fed. Reg. 46716 (August 21, 2007), to place applicants at a substantial disadvantage. Revised 37 C.F.R. § 1.78 (2007) permits applicants to file divisional applications following a restriction requirement. However, a restriction

requirement imposed with respect to a generic invention can be effective as the basis for filing divisional applications only so long as no generic claim is pursued in any later application. Thus, the PTO advises applicants to fully prosecute a generic claim through to appeal in the first application in a series. *See* 72 Fed. Reg. at 46727. Under the proposed restriction practice, however, the PTO would simply withdraw the generic subject matter from consideration on making a determination that any species other than the elected species is “unpatentable.” Thus, the applicant would not have the option of appealing a rejection of the generic claim until the restriction issue had been resolved by petition.

Even if issues regarding the interplay of restriction practice and examination of a generic claim are resolved, the new regulatory regime may act to ensure that applicants would not be able to obtain comprehensive claim coverage for their generic inventions in anything resembling a timely fashion, unless perfectly patentable claims are presented for examination in the first instance. The apparent desire on the part of the PTO for applicants to “pre-examine” their own claims, and to avoid presenting claims that read on potentially unpatentable species, is not realistic. The statute and nearly 200 years of U.S. patent practice reflect the assumption that patent claims are not necessarily presented in grantable form – that is why patent offices conduct examination.

The net effect of the proposed rules is that it may become extraordinarily difficult and costly – if not impossible – to obtain claims for new classes of compounds that are routinely examined and granted under existing practice. The proposed change in practice is not a development that properly balances legitimate policy objectives.