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From: Robert D Titus

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To: Markush.Comments

Subject: [Docket No: PTO-P-2006-0004];[FR Doc: E7-15591];[Page 44992-45001];

Patent cases: Examination of patent applications that include claims containing alternative language

Importance: High

The comments of Eli Lilly and Company on the proposed changes to the examination of patent applications that include claims containing alternative language are attached.

Respectfully Submitted:

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October 8, 2007

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

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

RE: Comments on "Examination of Patent Applications That Include Claims Containing Alternative Language" 72 Federal Register 44992 (August 10, 2007)

Dear Under Secretary Dudas:

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer comments regarding the above-captioned proposed rule changes. Lilly is a research-based pharmaceutical company focused on developing innovative therapies for unmet medical needs. Lilly employs over 40,000 employees worldwide, involved in the discovery, development, and marketing of innovative pharmaceutical and biotechnological medicines.

Lilly, both in its own right and through various non-governmental organizations, has long supported efforts to strengthen the effectiveness of the U.S. patent system. Part of that strengthening can come from greater harmonization of substantive patent laws—and their application to patent examining procedures—throughout the world. Because Lilly supports measures to improve the rigor and completeness of the patent procurement process, we fully support the goals of the proposed rules as they relate to examination quality and pendency times for patent applications. That said, we also have concerns with the proposed rules as detailed below. In light of our concerns, we offer below an alternative framework for addressing the issues raised in the proposed rulemaking.

Our response is guided by the recognition that there is an unprecedented—and unacceptable—backlog of applications in the United States Patent and Trademark Office (Office). We further understand the Office's position that the extensive use of Markush-type or alternative language can contribute to that backlog because of the inordinate amount of effort required by the Office to assure that the subject matter in some of these applications is subjected to a complete and rigorous examination. Lilly also understands the position that the Office has taken that alternate language claims are potential avenues for circumventing the requirements of 37 C.F.R. § 1.75(b)(1).

As a company, however, we do not believe that the Office should place arbitrary limits on the ability of inventors to adequately claim their inventions, either *de facto* or *de jure*, without some overarching public interest that could justify doing so. We agree that some alternative claiming practices by a tiny percentage of inventors are problematic for the Office. If the most complicated claims of this small number of applications were subjected to a complete and rigorous examination, the disproportionate workload demands placed on the Office would be unfair to the many other users of the patent system—forcing them to pay for the attention that would be needed to thoroughly examine a few claims of a few inventors. The unfairness rests in large measure on the Office's need to examine all patent applications under the fee schedule that title 35 of United State Code currently mandates, *i.e.*, one fee fits all claims, regardless of their relative size, complexity or scope.

Lilly is supportive of proposals that would use a fee-for-services-requested approach to fee setting for patent examination. Fee-based differentiation of this type is a preferable and fairer means for assuring that inventors whose inventions may be best protected through extensive use of alternative claiming practices can do so—*provided that they pay their own way through the patent examining process*. If alternative claiming practices mean that a single claim in a single patent application entails the equivalent workload for a patent examiner of examining 10, 100, or more typical patent applications, then the fees for examination should reflect the magnitude of the differential examination work being requested by the inventor.

Unfortunately, 37 C.F.R. § 1.75(b)(1) did not adopt—and it could not have adopted under the current patent statute—a fee-based approach for inventors where the numerosity of the claims is disproportionately burdensome to the patent examiner. In the case of Rule 75(b)(1), the Office dealt with inventors who determined that their inventions would be best protected by providing an extensive set of claims by creating a *de facto* bar to presenting such claims. Given the risks to the enforceability of a patent inherent based upon “inequitable conduct” concerns in providing an examination support document mandated by Rule 75(b)(1) if an extensive claim set is provided, the Office has left such inventors with an unfortunate choice. Thus, we disagree with the Office that concerns over the implementation of Rule 75(b)(1) should be a consideration in the current rulemaking effort.

Our views on these issues would be different if the inequitable-based unenforceability concerns could be addressed by the Office, the Congress or the courts. In that context, Lilly would support rulemaking by the Office that would broadly mandate preparation of Rule 75 examination support documents *by all inventors in all patent applications*. This step, together with workload-based fee-setting authority for the Office, would largely, if not fully, address concerns over applicant claiming practices and supersede the need for special rulemaking efforts directed to the number and nature of claims in a patent application being examined.

In light of these considerations, we find ourselves in agreement with the ends sought by the Office, but in strong disagreement with the means. Lilly believes that the rules proposed by the Office create a standard that will be difficult to apply and will result in the unreasonable and unpredictable restriction of Markush claims. Furthermore, Lilly believes that these proposed changes will have a disproportionate impact on the chemical and biotechnology arts.

As an alternative to the proposed rules (and in absence of congressional delegation of greater workload-based fee-setting authority to the Office and resolution of the “inequitable conduct” concerns inherent in mandating examination support documents), Lilly proposes interim action by the Office on the issue of claim scope based upon the uniform application of internationally recognized *unity of invention* principles, *i.e.*, abandoning the practice of applying the Office’s chemical compound classification system as a basis for restriction. Finally, the appropriate application of 35 U.S.C. §§ 101 and 112, first paragraph, represents a more reasonable approach for meeting the objectives of the Office and will better serve inventors.

I. The New “Essential for Common Utility” Standard of Proposed Rule 1.140(a)(1) is Unworkable and Unnecessary

A. Proposed Rule 1.140(a)(1) is Not Consistent with *In re Harnisch*

The Office proposes amending 37 C.F.R. § 1.75(a) to specify that a claim must be limited to a single invention.¹ Claims using alternative language, specifically Markush claims, represent a “single invention”

¹ Examination of Patent Applications That Include Claims Containing Alternative Language, 72 Fed. Reg. 44992, 44995 (2007) (proposed Aug. 10, 2007) [hereinafter *Proposed Rules*].

pursuant to proposed rule 37 C.F.R. § 1.140(a) if all of the alternatives are *prima facie* obvious or the common structure shared by all of the compounds is essential for their common utility.²

A stated purpose of the proposed amendments is to provide official procedures for the examination of claims that lack unity of invention.³ Curiously, this proposed rule stands in stark contrast to the guidance provided by *In re Harnisch* (Harnisch), that unity of invention is satisfied if compounds within a Markush grouping share a common utility and a single structural similarity⁴ and therefore represent a single invention.⁵

Although the Office acknowledges the unity of invention conditions held in Harnisch,⁶ it doggedly asserts that the new “essential for their common utility” proposition in proposed rule 37 C.F.R. § 1.140(a)(1) (Rule 140(a)(1)) enjoys support in Harnisch.⁷ This necessary assertion is simply incorrect.

Alternate language claims, such as Markush claims, are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims, and have traditionally been accepted as a single invention.⁸ Restriction of any invention, including an invention described in Markush format, is only proper if the inventions “are able to support separate patents and they are either independent or distinct.”⁹

Inventions are “independent” if “there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect.”¹⁰ Inventions are “distinct” if “the inventions *as claimed* are not connected in at least one of design, operation, or effect . . .”¹¹ When presenting a Markush claim, it is understood that the applicant is asserting that all of the compounds encompassed by the claim share a common activity or utility.¹² Because all of the species within a Markush expression are taught to

² *Id.* at 45000 (“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 conditions: (1) The species share a substantial feature essential for a common utility, or (2) The species are *prima facie* obvious over each other.”)(to be codified at 37 C.F.R. § 1.140(a)).

³ *Id.* At 44995 (“However, to date, the Office has not established official procedures for examiners to follow when examining a claim that recites alternatives wherein the alternatives lack “unity of invention” or for restricting an application to one invention where multiple independent and distinct inventions are recited as alternatives in a single claim. The Office is proposing to revise the rules of practice to provide such procedures.”).

⁴ *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980).

⁵ *Id.* at 306.

⁶ *Proposed Rules*, *supra* note 1, at 44994 (“[T]he *Harnisch* court found that the claimed compounds, which were defined as members of a Markush group, had unity of invention because they shared a common function as dyes, and shared a substantial structural feature as coumarin compounds.”).

⁷ *Id.* at 44996; Manual of Patent Examining Procedure, 8th ed., Rev. 5 (Aug. 2006) [hereinafter M.P.E.P.] at § 803.02.

⁸ M.P.E.P. *supra* note 7, at § 2173.05(h); *In re Harnisch* at 305 (“Under these circumstances we consider the claimed compounds to be part of a single invention so that there is unity of invention . . .”); *In re Jones*, 74 USPQ 149, 151 (CCPA 1947) (“[U]nder all the circumstances of this case, the substances grouped have a ‘community of chemical or physical characteristics’ which justify their inclusion in a common group....”).

⁹ M.P.E.P. *supra* note 7, at § 803

¹⁰ *Id.* at § 802.01(I).

¹¹ *Id.* at § 802.01(II).

¹² *In re Driscoll*, 195 USPQ 434, 437 (CCPA 1977) (“It is generally understood that in thus describing a class of compounds an applicant is, in effect, asserting that the members of the Markush group do not fall within any recognized generic class, but are alternatively usable for the purposes of the invention, and therefore, regardless of which of the alternatives is substituted on the basic structure, the compound as a whole will exhibit the disclosed utility.”).

share a common activity or utility, it is not possible for them to be considered unrelated inventions that are independent and distinct.¹³

Motivation to redefine unity of invention in Rule 1.140(a)(1) is therefore clear; the Office cannot refuse to examine what applicants regard as their invention unless the subject matter in a claim lacks unity of invention.¹⁴ The Office has proposed a new theory of unity of invention such that all alternatives within a Markush expression failing to meet the new “essential for their common utility” requirement are independent and distinct, thereby rendering the claim susceptible to restriction before examination in contravention to the holding of *Harnisch*.¹⁵

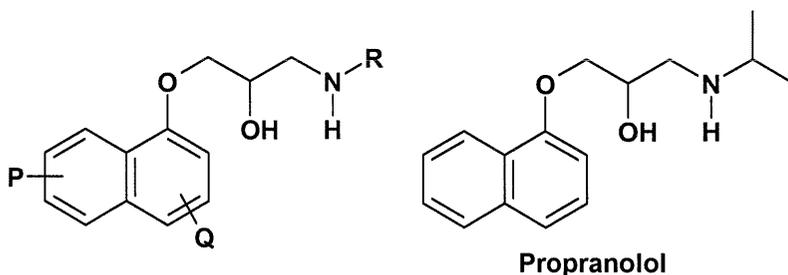
This proposed theory of unity of invention is scientifically untenable and inconsistent with case law guidance. Its adoption will create unnecessary confusion and inconsistency in restriction practice and should be abandoned.

B. Proposed Rule 37 C.F.R. § 1.140(a)(1) Will Be Difficult to Apply Because it is Scientifically Untenable

A compound's utility is the integration of contributions from all of its structural elements and, therefore, each of them are essential for its utility collectively, not individually as the application of 37 C.F.R. § 1.140(a)(1) implies. This scientific truism is inherent in the case law proposition “that in determining the propriety of a Markush grouping the compounds must be considered as a whole, and not broken down into elements or other components.”¹⁶

In spite of these prohibitions in the case law, the Office now invites applicants to explain that the substantial feature shared by all members of the grouping is essential for the utility of each species embraced within the Markush expression to avoid restriction.¹⁷ Demonstrating that a portion of a molecule is essential for the utility attributed to the compound as a whole is a nonsensical and scientifically meaningless task. The difficulty in applying this standard is illustrated by the following example.

U.S. Patent #3,337,628 encompasses propranolol, a β -adrenergic blocking agent, in the following Markush expression:



¹³ *Daniels and McCombie v. Daum and Clarke*, 214 USPQ 911, 915 (BPAI 1982).

¹⁴ *Proposed Rules*, *supra* note 1, at 44994 (“Consistent with the *Harnisch* decision, the Office cannot refuse to examine what applicants regard as their invention unless the subject matter in a claim lacks unity of invention.”).

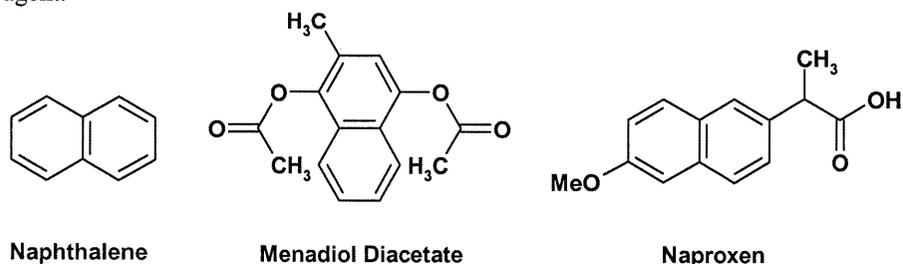
¹⁵ *Id.* at 44995 (“Thus, the Office proposes that if a claim defines multiple independent and distinct inventions, the examiner may apply a restriction requirement before examination.”).

¹⁶ *Harnisch* at 305; M.P.E.P. *supra* note 8; **See also**, *In re Jones*, 74 USPQ 149, 151 (CCPA 1947) (“In determining the propriety of a Markush grouping, moreover, the compounds which are grouped must each be considered as a whole and should not be broken down into elements or other compounds.”); and *Ex parte Brouard, Leroy and Stiot*, 201 U.S.P.Q. 538, 540 (BPAI 1976) (“We agree with appellants that the compounds as a whole must be considered rather than the “B” substituent alone.”).

¹⁷ *Proposed Rules*, *supra* note 1, at 44996.

The naphthalene ring clearly is a structural feature common to all of the compounds embraced by this Markush expression. Because the alternatives for variables R, P, and Q are such that molecules comprising these alternatives are not *prima facie* obvious in view of each other across the entire scope of alternatives, this modest Markush expression does **not** satisfy the requirements of a single invention under 37 C.F.R. § 1.140(a) unless it can be demonstrated that the common naphthalene core itself is essential to the β -adrenergic blocking activity of each species taken as a whole.¹⁸

Looking to the art it is found that naphthalene itself is an insecticide, but that other compounds comprising a naphthalene core have disparate utilities: menadiol diacetate is a vitamin, and naproxen an anti-inflammatory agent.¹⁹



Because the prior art establishes that naphthalene itself is not “essential” for any utility other than insecticidal activity, it can only be that the alternatives for variables R, P, and Q must be essential for the β -adrenergic blocking activity of the compounds as a whole. The application of proposed rule 1.140(a)(1) would therefore permit restriction of this Markush expression based on the alternatives for variables R, P, and Q based solely on the vagaries of the individual examiner.

As the example above illustrates, application of proposed Rule 1.140(a)(1) is difficult given the tension between its literal requirements and established technical principles. This example illustrates the need for comprehensive guidance to practitioners and extensive training of Examiners to implement the proposed rule in a meaningful way. It is proposed that this rule simply not be adopted in view of the difficulties illustrated above. If the rule is adopted, however, it is proposed that its implementation be delayed until sufficient guidance and training is developed by the Office to assure uniform application.

C. **The Proposed Rule 37 C.F.R. § 1.140(a)(1) Definition of Unity of Invention Should be Abandoned in Favor of the PCT Definition to Promote International Harmonization of Claim Scope**

Adoption of proposed Rule 1.140(a)(1) will result in the allowance of claims of disparate claim scope from the Office compared to patents issuing on the same disclosure from other PCT signatory countries, particularly the European Patent Office. The burden on the Office would be lightened if the well-understood PCT unity of invention standards were applied to restriction practice rather than the newly-minted version of Rule 1.140(a)(1).

Under PCT Rule 13.2, unity of invention is considered to be fulfilled “when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”²⁰

¹⁸ *Id.* at 44997.

¹⁹ *The Merck Index*, Eleventh Edition, Merck and Co., Inc., Rahway, NJ (1989).

²⁰ PCT Rule 13.2; M.P.E.P. *supra* note 7, at § 1850.

With respect to a Markush claim, the “requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2 shall be considered to be met when the alternatives are of a similar nature.”²¹ When the Markush claim is for alternatives of chemical compounds, “they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (B)(2) In cases where the common structure cannot be a unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.”²²

The plain meaning of these rules and guidelines makes it clear that the PCT Rule 13.2 requirement for “a technical interrelationship and the same or corresponding special technical features” is met in a Markush claim for alternative chemical compounds when: a) all of the alternatives have a common property or activity and b) a significant structural element is shared by all of the alternatives. The concept that the shared structure must be essential to the common property or activity is introduced only in those circumstances where “the compounds have in common only a small portion of their structures.”²³

The following example illustrates the potential disparate treatment of a claim under the proposed standard as compared to the PCT unity of invention standard.

A prior art protein of around 200 amino acids is known in the art and is generally considered to be potentially useful in treating a particular medical condition Y, but is not efficacious at pharmaceutically acceptable dosages. A research effort identifies 12 novel species that exhibit significantly improved activity in a relevant disease model relative to the prior art protein. Alignment of those protein sequences shows the new molecules have changes randomly dispersed along the primary structure and, therefore, the applicant is unable to describe the structural limitations of the improved molecules in generic terms. Instead, the following claim is presented:

An isolated protein comprising an amino acid sequence selected from the group consisting of the amino acid sequences of SEQ ID NOs: 1-12.

When considered by the International Search Authority, the International Preliminary Examining Authority, and/or the EPO this claim will likely be found to possess unity of invention because the alternatives are of a similar nature in accordance with Rule 13.2 and/or Rule 30(1) of the EPC.²⁴ Application of the proposed rules by the Office, however, will likely result in the restriction of the claim into 12 groups, because the applicant will be unable to demonstrate that the 12 proteins share a substantial feature (i.e., structure) essential for a common utility given that each protein claimed possesses a unique primary sequence.

²¹ PCT Search and Examination Guidelines § 10.17; M.P.E.P. *supra* note 7, at § 1850(III)(B).

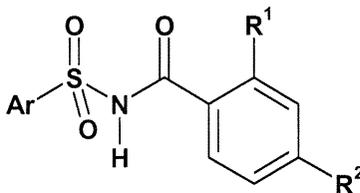
²² *Id.*

²³ WIPO’s International Search Preliminary Examination Guidelines, paragraph 10.17(b) ; M.P.E.P. *supra* note 7, at § 1850(III)(B).

²⁴ EP Patent Application No. 94901584.6 (In a Communication pursuant to Article 96(2) EPC dated April 5, 2002, the Examining Division of the EPO found unity of invention in an analogous situation stating “that the combination of the technical feature, i.e., the introduction of multiple specific mutations with the directed functional alteration i.e. a reasonable augmentation of the biological activity, may form the basis for a unifying concept of the presently claimed proteins. Therefore, the requirements of Article 82 EPC . . . are fulfilled.”).

The Office must apply unity of invention standards to applications filed under 35 U.S.C. § 371²⁵ and so the effect of Rule 1.140(a)(1) should be easily avoided by PCT practice. Recent experience suggests that the Office is well-aware of this strategy and is already experimenting with the application of the new unity of invention standard under proposed rule 140(a)(1) in the examination of cases filed under 35 U.S.C. § 371. It is understood that the Office may cause unity of invention to be re-examined,²⁶ but that does not justify the re-definition of unity of invention as proposed by the Office. The strained reasoning necessary to support restriction under the Office's new understanding of unity of invention is well-documented in the file history of the following case.²⁷

Although unity of invention was previously established by the EPO as the PCT searching authority, a requirement for restriction was made final in a U.S. application of the following Markush expression:



On petition, the Director held that for a core to be the basis of unity of invention that the activity must be provided by the core and the activity (of the core) must be known in the art, an obvious application of proposed rule 1.140(a)(1) given that there is no such requirement under PCT Rule 13.2. The Director reasoned as follows:

“It devolves that that activity must be associated with the common core or structure which is extremely well known and used in many different pharmaceutical applications. However, there appears to be no indication that benzoylsulfonamides possess the antitumor activity claimed herein in the prior art which leads to the presumption that the activity is provided by the Ar substituents. In view of this conclusion Lack of Unity does exist between the different Ar groups attached to the benzoylsulfonamide structure.”

“The benzoylsulfonamide structure is a structure common to all members of the Markush group and possesses pharmaceutical activity (as it is the basis for many sulfa drugs). However, antitumor activity is not a known utility for benzoylsulfonamides. Therefore the benzoylsulfonamide structure does not provide Unity of Invention to the compounds of the Markush group because it does not possess the utility claimed.”

In the first paragraph, the Director clearly required the benzoylsulfonamide core itself to possess antitumor activity before it could be the basis for unity of invention, but determined that it was not associated with antitumor activity because no prior art benzoylsulfonamides were known to possess antitumor activity. In the second paragraph, the Director stated that the benzoylsulfonamide core was found to possess some pharmacological activity, given that it is an element of many sulfa drugs.

Having failed on petition to the Director, petition was made to the Office of PCT Legal Administration. The Legal Examiner acknowledged that all compounds possessed a common property or activity and that all of the compounds shared a common chemical core that occupied a large portion of their structure. This acknowledgment is sufficient to establish unity of invention under PCT Rule 13.2. Instead of concluding that

²⁵ 37 C.F.R. § 1.475; M.P.E.P. *supra* note 7 at § 1893.03(d). “Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage applications submitted under 35 U.S.C. § 371.”

²⁶ 35 U.S.C. § 372(b)(2) “[T]he Director may cause unity of invention to be re-examined under section 121 of this title.”

²⁷ U.S. Patent Application No. 10/535,002.

unity of invention was indeed established, however, the Legal Examiner sustained the requirement for restriction for the following reasons:

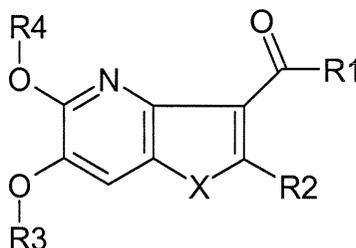
- a) In the case of independent claims to A + X and A + Y, unity of invention is present *a priori* as A is common to both claims. However, if it can be established that A is known, there is a lack of unity *a posteriori*, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.
- b) In the case where only a small portion of the structures is common to the compounds, the common portion must not only define a contribution over the art, but must also be essential to the common property or activity.

The lengths that the Office went to support restriction of the claim under the guise of unity of invention is both remarkable and confusing. The reasoning in paragraph a) is irrelevant given that restriction was required of a single claim. The statement in paragraph b) is inconsistent with the acknowledgment that all of the compounds embraced a common chemical core that occupied a large portion of their structure.

Requiring examiners to apply the principles of the proposed rules to unity of invention issues will result in multiple further examples of this type of legalistic acrobatics. A much better alternative would be to further align restriction practice with well-established principles of unity of invention, as such are outlined in Annex B of the Administrative Instructions Under the Patent Cooperative Treaty.

C. The Office's Classification System Is Not A Suitable Basis for Restriction or Establishing the Undue Burden of Searching a Markush Claim

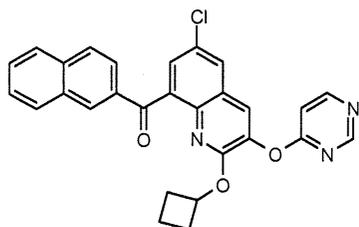
The over-application of the Office's archaic system of classes and subclasses when assessing the idea of "a substantial feature essential for common utility" is a significant problem. This is best typified by a recent presentation regarding these proposed Markush rules given by John LeGuyader, Director TC1600. In that presentation the following is given as an example of a compound claim listing plural inventions (Example 3 on slides 29-30):



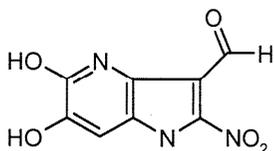
Wherein:

- X is O, N, S, CH₂, CH₂CH₂, or CH=CH;
- R1 is hydrogen, alkyl, cycloalkyl, hydroxyl, amino, substituted amino, aryl, or heteroaryl;
- R2 is halo, cyano, or nitro;
- R3 is aryl or heteroaryl; and
- R4 is hydrogen, lower alkyl, lower cycloalkyl, acyl, aroyl, or heteroaryl.

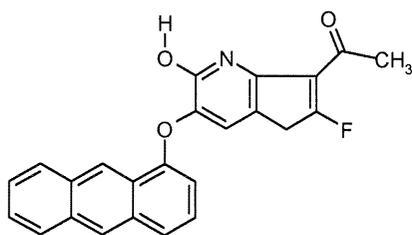
The presentation goes on to state that this results in "structurally and functionally diverse species", giving the following examples



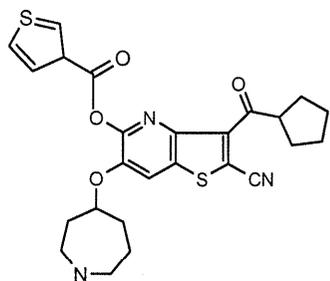
1,3-diazine derivative
Class 544, subclass 242



Pyridyl-pyrrolo derivative
Class 546, subclass 113

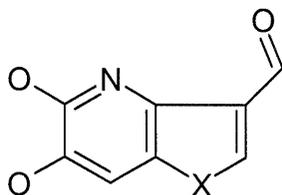


Anthracene Derivative
Class 546, subclass 183



Azepine derivative
Class 540, subclass 484

Each example shares the following core structure:



X = O, N, S, CH₂, CH₂CH₂, or CH=CH

The fact that variables appended to the core are in different classes should be irrelevant to an analysis of whether the Markush expression should be restricted.²⁸ The core is readily recognizable and a search of the core structure itself is easily performed, presenting no undue burden on the examiner. Furthermore, searching the core structure would identify any prior art compounds or generic disclosures comprising the core and any of the appended rings that led to different classifications above. The above approach creates a problem where one need not exist. The substantial shared feature was clear to see from the Markush group as it was presented.

²⁸ *Ex parte Brouard, Leroy, and Stiot*, 201 USPQ 538 (BPAI 1977) (“[T]he fact that different fields of search are involved does not establish that the Markush group is improper.”).

Although Lilly has no position on whether the proposed Markush group was proper (many of the substituents seem indefinite or overly broad) there is nothing gained by dismissing the clearly identified “core feature” and focusing on the side chains for determining unity of invention. Strict adherence to the Office’s classification system cannot be the basis for determining unity of invention.

II. 35 U.S.C. §§ 101 and 112 Are Adequate to Ensure Proportionality Between the Claims and the Disclosure

The Office should not promulgate new rules to restrict Markush claims according to a new, ambiguous standard, but instead should apply existing patent laws to assure adequate enablement of an operable invention. Lawful application of 35 U.S.C. §§ 101 and 112, first paragraph, require reasonable proportionality between an applicant’s contribution (*i.e.*, what’s actually invented) and reward (*i.e.*, claim scope) by barring overreaching by applicants.²⁹

A disclosure that does not adequately enable an invention claimed with respect to its asserted utility may be rejected under 35 U.S.C. § 101.³⁰ This utility requirement mandates that the invention be operable to achieve useful results.³¹ A rejection under 35 U.S.C. § 101 would be warranted where there is a good reason to doubt that a useful activity has been determined or demonstrated in fact for the plurality of possible compounds encompassed by a Markush claim. In the most egregious examples, such as the genus A-B-C-D-E³², where there is no indication that the species share a common utility, a § 101 inoperability rejection would be warranted.

The first paragraph of 35 U.S.C. § 112 specifically requires that a patent application contain the manner and process of making and using the invention “in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.”³³ The written description requirement is the area of U.S. law that should ensure reasonable scope commensurate with the patentee’s contribution related to a specific invention.³⁴

As Judge Lourie so succinctly reminded us in Enzo I, the written description requirement of Section 112 “reflects the *quid pro quo* of our patent system.”³⁵ The Office and its corps of examiners are the gatekeepers controlling what the public gets in return for its grant of a time limited monopoly on an invention. Accordingly, among the statutory high-hurdles an inventor should expect to face when requesting a patent is a written description requirement that is properly applied by the Office.

The Office’s relaxed application of the law of written description under the auspices of the Office’s Written Description Guidelines would be a better point of focus for resolving some of the pendency problems now plaguing the Office.³⁶ Further, enablement requires the specification to teach those skilled in the art how to

²⁹ M.P.E.P. *supra* note 7 at §§ 608.01(p) and 2164.03

³⁰ *Ex parte Stevens*, 16 USPQ2d 1379, 1380 (BPAI 1990).

³¹ *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992), *reh’g denied, en banc suggestion declined* (1993).

³² *Proposed Rules, supra* note 1, at 44994.

³³ 35 U.S.C. § 112, para. 1 (2000); **See also:** *Application of Boon*, 169 U.S.P.Q. 231, 235 (1971).

³⁴ For a comprehensive review of the history and current status of written description jurisprudence, see, for instance, Paula K. Davis, *Questioning the Requirement for Written Description: Enzo Biochem v. Gen-Probe and Overly Broad Patent Cases*, 37 Ind. L. Rev. 467 (2004); and Wenrong Huang, *Enzo’s Written Description Requirement: Can It Be An Effective Check Against Overly Broad Biotechnology Claims?*, 16 Alb. L.J. Sci. & Tech. 1 (2006).

³⁵ *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, (Fed. Cir. 2002).

³⁶ Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001).

make and use the full scope of the claimed invention without undue experimentation.³⁷ Upon presentation of a Markush claim, an Examiner must review the entire specification to find support or may now require the applicant to point out support for the invention as claimed.³⁸

Comparing the breadth of Markush alternatives with the disclosure is an effective means to draw a close relationship between the claim and the description, thereby constraining claim scope.

The Written Description Guidelines define a “representative number of species” as a sufficient number of species to be representative of the entire genus.³⁹ Where there is substantial variation within a genus, a sufficient variety of the species must be described to reflect the variation within the genus.

A “representative number” depends on whether one skilled in the art would recognize that the applicant was in possession of the necessary common features of the genus in view of the species disclosed. There is no magic number for a “representative number” of species. However, “[a] patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.”⁴⁰

Furthermore, as the CAFC duly noted in *In re Wands*⁴¹ a key factor in determining enablement is the predictability or unpredictability in the art.⁴² In the pharmaceutical arts, where small alternations in structure can result in significantly different pharmacological properties⁴³, the Office can properly insist that the scope of the claims be commensurate with the scope of exemplification.

Lilly believes that adherence to the general principles governing compliance with the enablement and written description requirements of 35 U.S.C. § 112, first paragraph, would go a long way to reducing the burden on the Office. Doing so will eventually act as a deterrent to the filing of overly broad claims devoid of sufficient structural limitations.

III. Proposed Rule 75(d)(2) Should be Modified in View of New Rule 105(a)(1)(ix)

Lilly appreciates the need for the Examiner to be able to determine the effective priority date for each claim in the event the Examiner finds intervening art (that is, art having an effective publication date between the

³⁷ *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988); *Enzo Biochem, Inc. v. Calgene, Inc.*, 52 U.S.P.Q.2d 1129, 1136 (Fed. Cir. 1999), *reh'g and reh'g en banc denied*.

³⁸ 72 Fed. Reg. 46737 (August 21, 2007) (“Section 1.105(a)(1) is amended to provide that an applicant may be required to set forth where (by page and line number) in the specification of the application, or any application the benefit of whose filing date is sought under title 35, United States Code, there is written description support for the invention as defined in the claims (whether in independent or dependent form), and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, under 35 U.S.C. 112, ¶ 1. Therefore, in situations in which it is not readily apparent where the specification of the application, or an application for which a benefit is claimed, provides written description support and enablement under 35 U.S.C. 112, ¶ 1, for a claim or a limitation of a claim, the examiner may require the applicant to provide such information.”).

³⁹ *Regents of the University of California v. El Lilly and Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

⁴⁰ *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004); *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), *reh'g denied, reh'g, en banc, denied* 375 F.3d 1303 (Fed. Cir. 2004).

⁴¹ *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

⁴² *Id.* at 737, citing *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

⁴³ *See, e.g., Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

earliest priority date and the filing date of the application in question). We believe, however, that this proposed rule change goes too far in introducing unnecessary litigation risk to applicants in order to meet this need.

In accordance with the early disclosure purposes of filing patent applications, provisional patent applications are usually filed when an important invention is substantially complete. It is usual in the pharmaceutical industry for additional work to be conducted on the subject matter of the application after the filing of the priority application. Such work is often added at the time of filing the international application. As such, many, if not most, pharmaceutical patent applications will be subject to Rule 75(a)(2).

This rule, as proposed, would call for the applicants to designate which claims in the application at issue were fully compliant with 35 U.S.C. §112, first paragraph. Such designation would only benefit the examination of the application in the event of intervening art, a substantial minority of patent applications. Such designations, however, will be fodder for charges of inequitable conduct in litigation concerning the patent that grants from the application. In most cases, therefore, compliance with this proposed rule would expose applicants to unnecessary litigation risk, with no benefit to the examining corps.

Instead, we propose an alternative that balances the risks to applicants with the needs of the examiner:

1. The Examiner conducts a search as today, using the latest of the possible priority dates as the endpoint of the search; and
2. In the event of finding intervening art, the Examiner requires Applicants to identify the appropriate priority date, in a Rule 105 communication with a shortened response period.

Lilly believes this modification to the proposed rules is more consistent with the recently promulgated Rule 105(a)(1)(ix) in that it gives the Examiner the option of seeking the priority information, but does not require it *a priori* from the applicants.

Under our proposal, for any continuation-in-part filed after the Examiner has first conducted a search on the application from which priority is claimed, the Examiner should request a claim-by-claim priority analysis before supplemental searching on the CIP application.

We encourage the Office to seriously consider this proposed alternative to Rule 75(a)(2).

IV. Clarification is Requested for Sections of Proposed Rule 75(j)

A. Proposed Rule 75(j)(1)

The proposed Rule 75(j)(1) states that a condition of using alternative language is that, “[t]he number and presentation of alternatives in the claim does not make the claim difficult to construe.” Lilly strongly believes that patent claims should be understandable on their face to a person of ordinary skill in the art and, therefore, concur with the aim of this rule.

The only concern, however, is with the broad and subjective nature of the language of the rule. “Difficult to construe” appears to be a very minimal standard. At the least, Lilly would propose this rule be modified to “unnecessarily difficult to construe”. Even with such a modification, it is hoped the comments accompanying any final rule and subsequent guidance materials provide a more objective standard.

It is clearly in the interest of both the Office and applicants that practitioners have guidance on what constitutes proper claim structure. Excessive examiner-to-examiner variability in what constitutes “difficult to construe.” will lead to highly inefficient prosecution, defeating the overarching aims of this proposed rule.

B. Proposed Rule 75(j)(2)-(3)

The proposed Rule 75(j), paragraphs (2) and (3) state that a condition of using alternative language is that, “(2) [N]o alternative is defined as a set of further alternatives within the claim; and (3) [N]o alternative is encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the invention.” Lilly’s greatest concern with these paragraphs is the ambiguity inherent within them.

Lilly’s reading of paragraph two is that the following part of a claim would be considered non-compliant:

[Structure having R¹ as a substituent]...

Wherein:

R¹ is fluoro, chloro, -N(R²)(R³), or -O-R⁴, where R² and R³ are independently hydrogen, methyl, or ethyl, and R⁴ is C₁-C₃ alkyl or -CF₃...

In this example R², R³, and R⁴ are alternatives furthering defining R¹. If Lilly’s interpretation of the intent of this rule is correct, we strongly suggest that this rule would be counterproductive.

As noted before, Lilly concurs with the Office’s goal of ensuring that claims are understandable to a person of ordinary skill in the art, and thus concur with the idea, if not the exact language of proposed Rule 75(j)(1). Paragraphs (2) and (3), if we understand them correctly, will probably have the unexpected consequences of making claims more difficult to understand.

In the above example, it would certainly be practical, yet inefficient, to expand “-N(R²)(R³)...where R² and R³ are independently hydrogen, methyl, or ethyl” into the following:

-NH₂
-NH(CH₃)
-NH(CH₂CH₃)
-N(CH₃)₂
-N(CH₃)(CH₂CH₃)
-N(CH₂CH₃)₂.

In this very simple example, the difficult of reading the claim would be much greater than that originally written. In a complex genus, eliminating the ability to define an alternative through the use of further alternatives would add considerable length to the claim, bringing it into conflict with Rule 75(j)(1).

Lilly appreciates that many claims are written with multiple levels of alternatives within alternatives, making such claims difficult to understand. Lilly encourages the Office to eliminate paragraphs (2) and (3) from Rule 75(j) and permit examiners to cite Rule 75(j)(1) as needed to eliminate these confusing claims.

There is additionally some concern about what is meant by an “alternative” in these paragraphs. Lilly reads the term to be a variable, such as the labeled R groups above. Lilly does not read this term to include terms such as “C₁-C₃ alkyl” as such terms are well known to practitioners in the art. Such a reading would fly in the face of over 100 years of chemical patent practice and must, therefore, be avoided. Additional guidance around this would be greatly appreciated.

C. Proposed Rule 75(k)

Proposed Rule 75(k) provides, in part, that, “A claim may not incorporate another part of the specification or drawings by reference, unless there is no other practical way to define the invention.” While Lilly agrees that the examples given are egregious and should not be encouraged, there is some concern about the proposed rule as written.

We believe this paragraph offers an opportunity to further align United States patent law with that of other countries, most notably, the European Patent Convention (EPC). It appears the intent of this rule was to align with Rule 29(6) of the EPC which states, "Claims shall not, except where absolutely necessary, rely, in respect of the technical features of the invention, on references to the description or drawings."

If that is indeed the intent, it would be better if the rule more closely paralleled the rule from the EPC. The US term "incorporation by reference" has specific meanings more commonly used, e.g., reliance on information found in another issued patent or priority patent (*see, e.g.*, Rule 57, MPEP §§ 201.06C, 608.01(p)). As such, its use in this rule leads to unnecessary confusion.

As noted earlier, Lilly strongly supports the notion that a person of ordinary skill should be able to read the claims of a patent and understand the invented subject matter. While it is recognized that an applicant can be their own lexicographer, the claims should, when practical, be readily understandable. Increased harmonization with European standards of clarity (EPC Article 84, EPC Rules 29 and 35) would enhance patent quality and would also ease the burden on the examiners.

V. Conclusion

Lilly believes the proposed rules can, with modification, achieve the Office's stated goals of increasing patent quality and reducing pendency. Lilly proposes, however, that any perceived gain in efficiency by restricting a proper Markush claim is illusory, as applicants will simply pursue the full scope of their invention in subsequent divisional applications, requiring the entire scope to be ultimately be searched and examined regardless of the proposed rule.

Alternatively, applicants in the unpredictable arts will invoke their "lexicographic privilege", resulting in the fabrication of unrecognizable terminology, making it even more difficult for both the Office and the public to identify and interpret relevant patents and patent applications.⁴⁴ When coupled with the already challenging aspects of claim construction, the additional hit to the notice function resulting from the "forced" usage of generic terminology in place of traditional alternative language will create unintended inefficiencies within the patent system and greatly detract from the stated goal of enhanced patent quality.⁴⁵

Furthermore, because the inevitable piecemeal examination of a Markush claim is unlikely to result in claims to the full breadth of the original claim, application of the proposed rule is inconsistent with the public interest in securing a full and complete examination of the claimed subject matter in an application. It is evident that examination costs and burdens to the public are high for patents that contain Markush claims encompassing subject matter nowhere described or enabled in the patent specification. Therefore, the Office and public policy would be better served by making reasonable and fairly based rejections for lack of enablement or written description whenever possible.

⁴⁴ John R. Thomas, *Claim Re-Construction: The Doctrine of Equivalents in the Post-Markman Era*, 9 Lewis & Clark L. Rev. 153 (Spring, 2005), "Patent attorneys often write in fields that lack consistent technical terminology. In contrast to patents arising in biotechnology and chemistry, for example, business method and software patents are more prone to describing the identical technical feature using different words. Exacerbating these difficulties is the ability of the drafter to coin his own terms to include in claims. This "lexicographic privilege" has been justified on the inability of existing language to characterize innovative products and processes. Unfortunately, it also results in idiosyncratic claim limitations that can require a great deal of effort to decipher."

⁴⁵ *See*, Jay P. Kesan, Carrots and Sticks to Create a Better Patent System, 17 Berkeley Tech. L.J. 763, 784 (2002) ("Patentees used different terminologies (based on their individual organizations) to refer to the same underlying technique. This makes the problem of locating relevant prior art even more difficult. The English language is a blunt instrument to describe computer software.").

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October 8, 2007
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These rules provide a golden opportunity for enhanced harmonization with other major patent offices, most notably the European Patent Office. By harmonizing the Office's views of clarity, unity of invention, and new matter with those of the EPO, applicants will be able to more efficiently prosecute their patents globally.

Enhanced proper use of rejections under currently existing laws (most notably the first paragraph of 35 USC § 112) will free examiners to focus on those claims that are clearly supported by the specification, easing their searching burden.

Sincerely,

A handwritten signature in black ink, appearing to be "RDT", with a long horizontal flourish extending to the right.

Robert D. Titus, Reg. No. 40,206

Paul J. Gaylo, Reg. No. 36,808

Robert L. Sharp, Reg. No. 45,609

on behalf of Eli Lilly and Company