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**COMMENTS IN RESPONSE TO THE REQUEST FOR
COMMENTS ON GREEN PAPER CONCERNING RESTRICTION PRACTICE**

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Sir:

This paper is in response to the Federal Register Notice: Vol. 70, No. 107, Monday, June 6, 2005; pp. 32761 – 32762, entitled “Notice of Availability of and Request for Comments on Green Paper Concerning Restriction Practice”. This paper is divided into two parts. The first part revisits this submitter’s previous issues raised regarding how Restriction practice must be applied relative to a Markush claimed invention. The second part comments on the assorted Restriction Practice options noted by the USPTO.

I. Restriction Of Markush Claimed Subject Matter

The Patent Office has been totally unresponsive to the submitters first comment dated July 23, 2003, discussing Markush Claim Restriction Practice for Issue 10 in response to the initial “Request for Comments on the Study of the Changes Needed To Implement a Unity of Invention Standard in the United States,” in Federal Register, Vol. 68, No. 97, Tuesday, May 20, 2003; pp. 27536 – 27539.

This lack of response to submitters eleven-page discourse on Markush Claim Restriction Practice, including an analysis of applicable case law, demonstrates: (a) a total failure by the USPTO to address how restriction practice should be applied relative to the fundamental claiming format for

organic materials, i.e., a Markush claim; and (b) the USPTO's lack of adherence to administrative law principles of fairness by not addressing the issues posed by submitters with sufficient specificity. Most significant is that a Markush claimed invention should involve its consideration "as a whole", and therein lies the issue. The USPTO does not address the "whole" requirement properly, particularly as dictated by case law.¹

Once again, the submitters provide comment as to how a Markush claim should be analyzed and whether it is properly subject to restriction under the principles of the judicially created doctrine of Markush practice.

Current restriction practice rules and procedures require alignment with current case law. This Comment details what modifications are required by suggesting rule changes and the interpretations thereof, i.e, MPEP, to specifically account for chemical structures expressed in a Markush-type format.

¹ Patent law case law employs the overarching standard of considering the "invention as a whole" on various numbers of issues. For example,

§ 101 issues, see MPEP § 2106, "Finally, when evaluating the scope of a claim, every limitation in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. See, e.g., *Diamond v. Diehr*, 450 U.S. at 188-89, 209 USPQ at 9 ("In determining the eligibility of respondents' claimed process for patent protection under 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.").

§ 103 issues, see *Texas Instruments Inc. v. U.S. Intern. Trade Com'n*, 854 F.2d 1327 (unpublished opinion) "It is not proper to **dissect** claims and reconstruct them in piecemeal fashion by picking and choosing from among the prior art references using the patent as a blueprint. In re Kamm, 452 F.2d 1052, 1056-57, 172 USPQ 298, 301-02 (CCPA 1972). In determining obviousness, therefore, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the **invention as a whole**. Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1832 (Fed.Cir.1987). Further, if prior art references require selective combination to conclude that an invention would have been obvious, there must be some teaching or suggestion in the references that would support their use in combination. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed.Cir.1985), *cert denied sub nom.*, 475 U.S. 1017 (1986). . .";

Information Disclosure Statement Issues, see *Abbot Labs v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 67 U.S.P.Q.2d 1191, Fed.Cir.(Ill.), Jul 03, 2003 " . . .Because these references refer only to narrow preferred embodiments and not the **invention as a whole**, the specification passages do not support the limitation imported into the claims by the district court. The specification simply does not indicate that Abbott restricted its claims to the preferred embodiments. Instead, the specification refers to the water content in these preferred embodiments as amounts that "can be used" or "is believed to be" an appropriate Lewis acid inhibitor. These *1280 descriptions in the specification are far from an express disavowal of other effective amounts. . ."; and

Unity of Invention Issues, see PCT Rule 13.2 or MPEP §1850.

In particular, this Comment proffers the following as proposed solutions: (a) 35 U.S.C. §121 does not require modification; (b) 37 C.F.R. §1.141, which is consistent with 35 U.S.C. §121 requires modification to add elements of case law, such as those from *In re Harnisch*, 206 U.S.P.Q. 300, 631 F.2d 716; and (c) the MPEP requires modification of §803 and §803.02.

Search procedure for Markush-type claims also requires modification to be in alignment with the case law of *In re Harnisch*, 35 U.S.C. §121, and the PCT Rule 13.2 Unity of Invention standards, as interpreted in MPEP §1850.

A. Introduction

Currently, the application of restriction practice is not uniform throughout all patent practice disciplines. In particular, Markush practice possesses inherent inconsistencies, which ultimately necessitates adopting particular aspects of PCT Rule 13.2 Unity of Invention standard. One must be mindful, however, that adopting such aspects must concurrently promote the “. . . public interest that no [restriction] requirements be made which might result in the issuance of two patents for the same invention.”² Uniform application of the Restriction laws throughout patent practice will further that interest. To achieve this, the USPTO must implement changes in Markush restriction practice rules and procedures, to adopt certain aspects PCT Rule 13.2 Unity of Invention.

B. U.S. Restriction Practice Case Law and the PCT International Restriction Practice Standard are Consistent with One Other.

(i) There Are Two Sources for Current Restriction Practice Law in the United States.

“Restriction” is a generic term that includes the practice of electing between distinct inventions³, including those inventions that involve Markush-type claims.⁴ U.S. patent practitioners seek guidance from two independent restriction practice sources: (a) 35 U.S.C. §121; and (b) *In re Harnisch*, 206 U.S.P.Q. 300, 631 F.2d 716 (hereinafter “*Harnisch*”) and related cases (hereinafter collectively “*Harnisch cases*”⁵). Restriction practice, however, as applied by the USPTO in chemical patent prosecution for Markush-type claims is not aligned with 35 U.S.C. §121 or the *Harnisch cases*.

² See MPEP §803.01.

³ See MPEP §802.02.

⁴ See MPEP §803 “Guidelines”.

⁵ The *Harnisch cases* collectively include: *In re Harnisch*, 206 U.S.P.Q. 300; *Ex parte Holt and Randell*, 214 U.S.P.Q. 381; *In re Haas*, 198 U.S.P.Q. 334 (Haas II); *In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328; *Ex parte Brouard Leroy, and Stiot*, 201 U.S.P.Q. 538; *In re Jones*, 74 U.S.P.Q. 149; and *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208.

35 U.S.C. §121⁶, provides the legal standard for patent examiners, and practitioners, to determine the number of inventions within a patent application. The statute requires that there be more than one “*independent and distinct*” (emphasis added by submitter) invention claimed in a single application to allow proper issuance of a restriction requirement.⁷

While 35 U.S.C. §121 does not detail how Markush⁸ claimed subject matter should be handled in prosecution, case law has established those details in the judicially created doctrine of “Markush practice”.⁹ For chemical patent practice, this doctrine focuses primarily upon the principles of the *Harnish cases*, which provides the bases¹⁰ upon which an improper Markush group would require restriction. Specifically, the *Harnish cases* provide an approach to evaluate Markush groups. In part, in determining the propriety of a Markush grouping, the compounds must be considered as wholes and not broken down into elements or other components. The *Harnish cases* also provide the requisite elements that satisfy the PCT Rule 13.2 Unity of Invention standard, i.e., that individual compounds encompassed by a Markush structure must share a “*single structural similarity*” and a “*common utility*”. This case law must be recognized and procedurally practiced by the USPTO for compliance to the statutory mandate of 35 U.S.C. §121. Without accord between the statute and case law, the appropriate application of laws regarding Restriction practice in the United States is not correctly effectuated regarding Markush-type claims.

⁶ See 35 U.S.C. §121 states, “If two or more independent **and** distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application that complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.” Emphasis in bold.

⁷ “A Markush-type claim is directed to “independent and distinct inventions,” if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). *In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328 at 332. However, when a Markush grouping does not contain “independent and distinct” inventions, “the substances grouped have a ‘community of chemical or physical characteristics’ which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification, within the meaning of such decisions as *Ex parte Burke*, supra, and *In re Swenson et al.*, supra.”). *In re Jones*, 74 U.S.P.Q. 149 at 151.

⁸ “In summary, there is no ‘doctrine’ to be considered but only a body of case law, emanating from both ‘higher’ and ‘lower’ authority, not altogether consistent, the latest decisions tending to carry the most weight as precedent.” *In re Harnisch*, 206 U.S.P.Q. 300 at 302.

⁹ See *supra* text accompanying note 4.

¹⁰ See *In re Haas*, 198 U.S.P.Q. 334 (Haas II) (holding that 35 U.S.C. §121 does not provide a basis for rejection of a claim)(quoting *In re Harnisch* at 302).

(ii) **35 U.S.C. §121 and the Harnisch Cases are in Accord with One Another.**

The legal provisions of 35 U.S.C. §121 and the *Harnisch Cases* are in accord with one another. 35 U.S.C. §121 requires examination of a claim to determine not only whether the inventions are separately “*independent*”, or separately “*distinct*”, but also whether the inventions are both “*independent and distinct*”. This standard requires analyzing the invention as a whole to determine if a restriction requirement is necessary. The standard is consistent with *Harnisch* explicitly stating that the “. . . compounds must be considered as wholes. . .” to determine the propriety of a Markush group and whether a restriction requirement is necessary.

For example, one of the *Harnisch* cases prohibits the Examiner from dissecting “the molecule into core and pendant substituents and then concludes that variable cores inherently constitute an improper Markush group.” *Ex parte Holt and Randell*, 214 U.S.P.Q. 381, 386. That is, an Examiner cannot dissect an Applicants’ compounds and then conclude that the variations in that core constitute an improper Markush group, thereby permitting a restriction requirement of the group so defined. An examiner must consider the compounds of the Markush grouping as a “*whole*”. This noted phrase taken from the *Harnisch cases* is consistent with the approach to viewing compounds as *wholes*,¹¹ i.e., “independent and distinct”, pursuant to 35 U.S.C. §121.

(iii) **Adoption of Certain Aspects of PCT Rule 13.2 Would Not Contravene Current U.S. Restriction Laws.**

PCT Rule 13.2 Unity of Invention, which defines the international Restriction practice standard, does not contravene 35 U.S.C. §121 and the *Harnisch cases*.¹² PCT Rule 13.2 must be understood clearly for what it does, and does not, statutorily mandate. PCT Rule 13.2 requires the claims of an invention to be examined and dissected for “*special technical features*” within the claims of the invention “*as a whole*.” Those “special technical features” are the elements of the invention, put together in combination with one another, to arrive at to what is already known in the art, i.e., something useful, novel and non-obvious per U.S. practice.

More specifically, under each PCT Rule 13.2, the claimed invention must be considered “*as a whole*” when assessing the propriety in the application of restriction standards. This language is

¹¹ With a particular focus upon Markush-type claims, support for the concept that restriction principles require an analysis of the claim as a “*whole*” can be found in *In re Harnisch*, 206 U.S.P.Q. 300; *Ex parte Holt and Randell*, 214 U.S.P.Q. 381; *Ex parte Brouard, Leroy, and Stiot*, 201 U.S.P.Q. 538; and *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208.

¹² PCT Rule 13.2, *Circumstances in Which the Requirement of Unity of Invention is to be Considered Fulfilled*, states: “Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only 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.” Emphasis added in bold.

consistent with both, the analysis of the claimed invention as a “*whole*”, i.e., “independent and distinct”, per 35 U.S.C. §121; and with the analysis of a Markush grouping, i.e., considered “*as a whole*,” under the mandate of the *Harnisch cases*.

Thus, if the USPTO adopts aspects of PCT Rule 13.2, particularly the Unity of Invention standard for Restriction practice, such would not contravene the “*independent and distinct*” language, of 35 U.S.C. §121, and the language, “*considering the compounds as wholes*”, in the *Harnisch cases*. Additionally, each directly supports the language utilized in PCT Rule 13.2, “*as a whole*”.

C. Evaluating United States Restriction Law Interpretations

A dissection of Restriction practice laws, rules, and interpretations thereof will now follow to assess what changes would the benefit current USPTO rules and procedures. As an overview, (a) 35 U.S.C. §121 does not require modification; (b) 37 C.F.R. §1.141, although generally consistent with 35 U.S.C. §121, requires modification to specifically add the *Harnisch* elements; and (c) MPEP §803 and §803.02 require modification.

(i) Although Rule 37 C.F.R. §1.141 is Consistent with 35 U.S.C. §121; 37 C.F.R. Still Requires Modification.

Although Rule 37 C.F.R. §1.141 is consistent with 35 U.S.C. §121, 37 C.F.R., in particular 37 C.F.R. would still benefit from being modified to incorporate the elements of the Unity of Invention standard therein. Implementing the elements from PCT Rule 13.2 into 37 C.F.R. will achieve this modification.

The USPTO’s interpretation of 35 U.S.C. §121, in Rule 37 C.F.R. §1.141¹³, is consistent with, and exactly tracks language found in 35 U.S.C. §121. That is, 37 C.F.R. §1.141 directly tracks the language from 35 U.S.C. §121 to view the claim as a “*whole*” by casting the legal standard as “*independent and distinct*”¹⁴. As discussed above, both approaches, though worded differently, do not attempt to divide an invention, or in a case with Markush-type claims, divide the Markush claim groups, when considering the propriety of a restriction requirement. Rather, the Examiner is directed to examine and analyze the invention for what it represents in its entirety, i.e., viewing more than the individual elements of the invention as a basis for restriction.

¹³ See 37 C.F.R. §1.141, *Different Inventions in One National Application*, (a) states in part: “(a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§1.75) or otherwise include all the limitations of the generic claim. . .”

¹⁴ Note that the standard “*independent or distinct*” creates an entirely different standard, as discussed in Section C. (ii)(a) of this comment.

However, it is important to note that 37 C.F.R., and in particular 37 C.F.R. § 1.141, does not explicitly recite the *Harnisch* elements that should be considered. Therefore, 37 C.F.R. §1.141 should be amended to “fill the gap” between the rule and case law, by reciting the two primary requirements (“*single structural similarity*” and a “*common utility*”). Adopting aspects of the Unity of Invention standard, i.e., the elements noted in MPEP §1850¹⁵ from PCT Rule 13.2 will achieve this. Indeed, two elements emanating from the *Harnisch* language “*considering the compounds as wholes*” and the standard of “independent and distinct” set forth in 35 U.S.C. §121, are in accord with the Unity of Invention elements as discussed below.¹⁶

Thus, 37 C.F.R. §1.141 and the corresponding interpretations thereof, described in the MPEP should be aligned with current laws on Restriction practice. Codifying the requisite *Harnisch* criteria, and PCT Rule 13.2 elements, into 37 C.F.R. would clarify 35 U.S.C. §121 and would remain consistent with current MPEP §1850.¹⁷

(ii) The MPEP Contains Misinterpretations of Rule 37 C.F.R. §1.141 that the USPTO should Remove by the Adoption of Aspects of Unity of Invention from PCT Rule 13.2.

Adoption of aspects of PCT Rule 13.2, i.e., considering claimed inventions as a “*whole*” and utilizing the Unity of Invention elements presented in MPEP §1850, to current USPTO rules and procedures will rectify incorrect interpretations and applications of Markush Practice principles as presently recited in the MPEP. In particular, both interpretations of MPEP §803 and MPEP §803.02 directly contravene 35 U.S.C. §121 and the *Harnisch cases*. Both MPEP interpretations also directly contravene the USPTO’s own interpretation of the underlying approach to PCT Markush Restriction Practice, as interpreted and explained in MPEP §1850. Thus, adoption of the Unity of Invention aspects of PCT Rule 13.2 should be incorporated into MPEP §803 and §803.02. Such would correctly recite the appropriate approach to Markush-type claims in Restriction practice in the interpretive MPEP, assisting both patent practitioners and examiners in the ultimate application of 35 U.S.C. §121.

¹⁵ The Unity of Invention criteria as fleshed out, from PCT Rule 13.2, in MPEP §1850 are: “. . . (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 (C)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. . . .”

¹⁶ In Section C. (iii) below.

¹⁷ As discussed in detail in Section C. (iii) below.

(a) MPEP 803 Contravenes Current U.S. Statutory and Case Law

The standard of MPEP §803 is different from the standard in 35 U.S.C. §121 and 37 C.F.R. §1.141. MPEP §803 language permits restriction only if the claimed inventions are able to support separate patents and they are either “*independent or distinct*”.¹⁸ Not only does this interpretation: (a) create confusion because it directly contravenes the language of both 35 U.S.C. §121 and 37 C.F.R. §1.141, each reading “independent and distinct”; but the interpretation also, (b) adds an additional requirement, i.e., there must be a serious burden on the Examiner if restriction is required, over that required by both 35 U.S.C. §121 and 37 C.F.R. §1.141. The additional requirement of “serious burden” is discussed in detail below in Section II, entitled *A New Strategy for Searching Markush-type Claims should be adopted by the USPTO*.

The change from “and” to “or” creates an entirely different standard within which the patent practitioner should operate for restriction purposes. The connector “and” dictates that one should consider all of the features of the invention together, or variables together, when examining a Markush-type claim; whereas, the connector “or” dictates that a patent examiner can dissect a molecule, e.g., for which himself or herself defines, only to conclude that the variations on that contrived core constitute an improper Markush group. Such action taken by an Examiner is contrary to *Ex parte Holt and Randell*, 214 U.S.P.Q. 381, wherein the PTO Board of Appeals stated that there is no known basis for an Improper Markush Rejection where “[t]he Examiner dissects the molecule into core and pendant substituents and then concludes that variable cores inherently constitute an improper Markush group.” *Id.* at 386. *Ex parte Holt and Randell* is supported by *Harnisch* language in analyzing a Markush grouping “*as a whole*”, and not as separately dissected parts of an invention, or separately dissected sections of claims when analyzing Markush-type claims. Thus, enacting aspects of the International Unity Invention standard, i.e., considering claimed inventions as a “*whole*” and utilizing the Unity of Invention elements presented in MPEP §1850 of PCT Rule 13.2, would result in reflecting the correct U.S. law on Restriction practice per 35 U.S.C. §121 and the *Harnisch cases*.

¹⁸ See MPEP §803, Restriction-When Proper states: “Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP §806.04 - §806.04(i)) or distinct (MPEP §806.05 - §806.05(i)). If the search and examination can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS There are two criteria for proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP §802.01, §806.04, §808.01) or distinct as claimed (see MPEP §806.05 - §806.05(i)); and (B) There must be a serious burden on the examiner if restriction is required (see MPEP §803.02, §806.04(a) – §806.04 (i), §808.01(a), and §808.02).”

(b) MPEP 803.02 Contravenes Current U.S. Restriction Laws

MPEP §803.02¹⁹ defines Unity of Invention to exist broadly where “*compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.*” Emphasis added by submitters. Thus, the MPEP actually requires three elements under its “unity of invention” analysis, i.e., the three elements are that the Markush claimed structure must: (a) share a *common utility*, (b) share a *substantial structural feature*, and (c) have *that utility as disclosed arise from and be essential to* that substantial feature. The third element, that the Markush claimed structure must “have *that utility as disclosed as arising from and being essential to* that substantial feature” is what creates the improper contravention and dissection of the compound in to its parts, and parceling of the activity of the compound thereto. There is no rational technical basis for ascribing that the utility of a compound would arise solely from a particular portion of a compound. In fact, there is a scientific rationale for ascribing the activity of a compound to the compound in its entirety. MPEP §803.02 runs afoul of 35 U.S.C. §121 which says that the invention should be considered as a whole. Likewise, it contradicts the *Harnisch* requirements that dictates the compounds of a Markush grouping as a whole share a “*single structural similarity*” and exhibit a “*common utility*”, and not ascribe the activity to the “*single structural similarity*”.

(iii) MPEP §1850 is Already in Accord with the Aspects of Unity of Invention from PCT Rule 13.2.

It must be finally noted that MPEP §1850²⁰ is already in accord with the Unity of Invention aspects that this Comment proposes to adopt. That is, “Markush practice [,] wherein a single claim defines alternatives (chemical or non-chemical) is governed by PCT Rule 13.2.”²¹

¹⁹ See MPEP §803.02, Restriction-Markush Claims, PRACTICE RE MARKUSH-TYPE CLAIMS states in part: “Since the decisions in *In re Weber*, 580 F. 2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnis[c]h*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ.2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.”

²⁰ See MPEP §1850, D. Markush Practice, states: “The situation involving the so-called Markush practice wherein a single claim defines alternative (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, 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. When the Markush grouping 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 (C)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.”

²¹ *Id.*

Unlike MPEP §§ 803 and 803.02, Markush practice under MPEP §1850 properly fleshes out the requirements of Unity of Invention pursuant to both *In re Harnisch* and PCT Rule 13.2. Markush Practice under MPEP §1850 is akin to the *Harnisch* elements because it does not require an additional third element wherein a “*substantial structural feature*” must arise from the “*shared common utility*”, like MPEP §803.02 requires. MPEP §1850 requires only two elements that parallel the shared “*common utility*” and a shared “*single structural similarity*” of both *Harnisch* and PCT Rule 13.2.

Thus, to enact the International standards of Unity of Invention from PCT Rule 13.2 would require no change to MPEP §1850, but would support the procedure in place as it currently reads, and which would also be consistent with the existing U.S. Restriction Laws of 35 U.S.C. §121 and the *Harnisch* cases.

In conclusion for this section of the Comment, the following solutions have been proposed to the USPTO for consideration: (a) that 35 U.S.C. §121 will not need modification; (b) that 37 C.F.R., in particular 37 C.F.R. §1.141, although consistent with 35 U.S.C. §121, would need to be modified to add the elements of the *Harnisch* cases; and (c) that the MPEP requires modification of §803 and §803.02, but not MPEP §1850.

II. A New Strategy for Searching Markush-type Claims should be adopted by the USPTO.

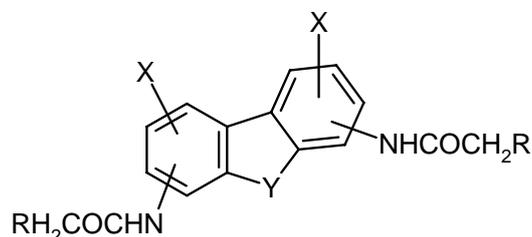
The applicable standard for Restriction requirement cases should not be based upon the “serious burden on the examiner if restriction is required,” as suggested by MPEP §803²². Rather, the standard should align with the holdings in the *Harnisch* cases. The two cases that the USPTO should recognize regarding Restriction Practice of Markush-type claims are *Ex parte Dahlen and Zwilmeyer*, 42 U.S.P.Q. 208, and *Ex parte Brouard et al.*, 201 U.S.P.Q. 538. These two cases support the law of *In re Harnisch*, 35 U.S.C. §121 and the PCT Rule 13.2 Unity of Invention, as presented in MPEP §1850.²³

The USPTO should adopt a new standard because the criteria for restriction per MPEP §803 regarding the “serious burden on the examiner” does not apply to search strategies that are currently available for Markush-type claims today. That is, the USPTO’s routine application of the Classification System is no longer applicable relative to how examiners conduct their searches. The Classification System is arcane and outdated for Markush-type claim searching because, the Classification System is not appropriate for considering an invention as a whole, it only examines fragments of a claimed Markush compound. Furthermore, modernized systems such as STN, Merged Markush System (MMS), both are types of substructure searches, and Derwent Fragmentation Code can, and are, regularly available to achieve more efficient and tapered searches over what the Classification System allows when examining Markush-type claims.

²² See *supra* text accompanying note 18.

²³ See *supra*. Section I.

These modernized search engines fully support maintaining a key structural element of a Markush-type claim, while allowing for structural diversity of substituents from the core of a molecule, and further variations on that core. For example, in *Ex parte Dahlen and Zwilgmeyer*, the PTO Board of Appeals did not object to a compound of formula



Wherein Y was defined as a bivalent bridge radical that was further defined in Markush format as -CH₂-, -CO-, -C=C-, -CH₂CH₂-, -NH-, -N-alkyl-, -O-, -S-, -N=N-, -N=O-, -SO₂- and -COCO-. Particularly noteworthy was that such a Markush grouping was acceptable even though the variability of the Y variable would have resulted in patentably distinct and independent compounds according to the Examiner's analysis in that case. Thus *Ex parte Dahlen and Zwilgmeyer* directly contravenes any examiner's possible assertion that patentably independent and distinct compounds should be arrived at, where there is a variable Markush group as a constituent element of the core in a compound.

Further, the fact that different fields of search are involved does not establish that a Markush group is improper under *Ex parte Brouard et al.* The PTO Board of Appeals stated, that "the fact that [six] different fields of search are involved does not establish that the Markush group is improper." Contrary to the dictates of *Ex parte Brouard, Leroy, and Stiot*, any examiner that supports an Improper Markush grouping rejection on the sole basis that each of the groups of compounds, as defined by an examiner, happen to involve different fields of search, would be completely inconsistent with established law.

Thus, the USPTO should adopt a new strategy for searching Markush-type claims by changing the current standard of "serious burden on the examiner if restriction is required," to align with the holdings from the *Harnisch cases*, in particular, *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208, and *Ex parte Brouard et al.*, 201 U.S.P.Q. 538.

III. Comments on the Assorted Restriction Practice Options Noted By the USPTO

The submitters have repeatedly noted herein the impropriety of certain positions set forth by the USPTO relative to the rules regarding the restriction of claimed subject matter.

A. Option 1 Comment

The USPTO's interpretation of 35 U.S.C. §121 as "independent or distinct" is clearly at odds with the language of the statute, as the statute requires "independent and distinct" to be properly

subject to restriction. Thus, retaining the “independent or distinct” language of option 1 should be statutorily barred. Furthermore, placing restrictions on the number of species that an applicant can pursue in a single application would have disastrous consequences relative to filing practices by filers who might incorrectly anticipate species they may believe initially are most important versus all that they should have a right to claim and might later be determined to be important, i.e., thousands of compounds made in the course of one’s research efforts should be patentable and capable of being protected without one having to pay extra for the particular number of species. In fact, there appears to be no legal basis to charge for species, or restriction of their number, because the case usually is such that a patentable genus is finally determined, covering all species therein, and not a select few.

B. Option 2 Comment

Restriction practices in Option 2 are clearly more consistent with the submitter’s position regarding how a Markush claimed invention should be assessed relative to restriction practice. More particularly, having a “special technical/common feature” would be an acceptable issue for consideration relative to the propriety of a Restriction. Such a requirement is also in line with the case law as noted above. The analysis also works well in the context of assessing whether inventions are linked. Thus, option 2 would be an appropriate approach to consider for assessing the propriety of a restriction.

C. Option 4 Comment

The underlying basis for the proposed Restriction practices in Option 4 is the best aligned to the statutory provisions of 35 U.S.C. §121, i.e., inventions would only be subject to restriction where they would be “independent and distinct”. However, the submitter remains perplexed as to complexity that the USPTO alleges would be required to implement this option.

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