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# The USPTO's Historic Struggle with Markush Claims: Will the 2011

## Guidelines Provide Relief?

Kimberly J. Prior

### I. Introduction

Historically, United States Patent and Trademark Office (the "Patent Office") policy prohibited reciting elements in a patent claim in the alternative, i.e. A, B or C.<sup>1</sup> Even so, in the chemical arts, applicants commonly claimed chemical compounds in terms of a chemical core structure containing optional substituents designated by a generic "R" group, defined as a list of alternatives in the claims.<sup>2</sup>

Where an application described different alternative embodiments, the Patent Office required each alternative to be claimed in a different application.<sup>3</sup> In *Ex parte Eagle*,<sup>4</sup> applicant disclosed a box in combination with a number of different followers and provided a generic claim encompassing the various embodiments.<sup>5</sup> The examiner rejected the claims on the basis that only one of the disclosed embodiments could be claimed in a given application.<sup>6</sup> The Commissioner of Patents held that this rejection was in error and that applicant could claim a genus encompassing all of the species.<sup>7</sup> Thus, the Patent Office confirmed that generic claims

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<sup>1</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,992 (proposed August 10, 2007, never enacted).

<sup>2</sup> HAROLD C. WEGNER, THE EAGLE RIGHT TO GENERIC PROTECTION, ATTACHED TO AUGUST 10, 2007, TESTIMONY IN RESPONSE TO EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, § II-A-2 (discussing the origins of chemical Markush practice).

<sup>3</sup> *Id.* at § II-A-1.

<sup>4</sup> *Ex parte Eagle*, 1870 C.D. 137 (Comm'r Dec. 1870).

<sup>5</sup> *Id.* at 137.

<sup>6</sup> *Id.* at 137.

<sup>7</sup> *Id.* at 137.

covering independent and distinct embodiments are permissible.<sup>8</sup>

In 1924, the Commissioner of Patents decided *Ex parte Markush*,<sup>9</sup> holding where no generic expression exists by which a group of alternative elements can be claimed applicants are permitted to recite the elements in the alternative.<sup>10</sup> In *Ex parte Markush*, applicant's original claims recited the individual embodiments of the invention, the examiner objected to applicant's claims as being alternative.<sup>11</sup> When applicant amended the claims to use a generic term, they were rejected as unpatentable over art.<sup>12</sup> In response, the claims were ultimately rewritten using the phrase "material selected from the group consisting of aniline, homologues of aniline and halogen substitutes of aniline."<sup>13</sup> The examiner maintained the alternative claim rejection, but the Commissioner of Patents reversed, finding a truly generic term covers more than one element, and so there should be no objection to claiming those same elements with different language.<sup>14</sup>

Today, an applicant generally may use any type of language, including alternative expressions to claim his invention, so long as the meaning of the claim is clear.<sup>15</sup> The Patent Office accepts recitation of a Markush group either by using the language from *Ex parte*

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<sup>8</sup> *Id.* at 137.

<sup>9</sup> *Ex parte Markush*, 1925 C.D. 126 (Comm'r Dec. 1924)(originally reported at 340 O.G. 839).

<sup>10</sup> Manual of Patent Examining Procedure § 803.02 (8<sup>th</sup> ed., Rev. 5, Aug. 2006). Manual of Patent Examining Procedure will hereinafter be abbreviated M.P.E.P. as is commonly used in patent practice. The most current version of the M.P.E.P. is the 8<sup>th</sup> edition, revision 8, published July 2010. In examining the evolution of Patent Office Policy related to Markush practice, the specific revision of the manual discussing the point made will be cited.

<sup>11</sup> *Ex parte Markush*, 1925 C.D. at 127.

<sup>12</sup> *Id.* at 127.

<sup>13</sup> *Id.* at 127.

<sup>14</sup> *Id.* at 128.

<sup>15</sup> M.P.E.P. § 2173.01 (8<sup>th</sup> ed., Rev. 6, Sept. 2007).

*Markush*, “wherein R is selected from the group consisting of A, B, and C,” or alternative language, “wherein R is A, B, or C.”<sup>16</sup>

The members of a *Markush* group “ordinarily must belong to a recognized physical or chemical class or to an art recognized class.”<sup>17</sup> However, “[w]here a *Markush* expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compounds as a whole, and does not depend on there being a community of properties in the members of the *Markush* expression.”<sup>18</sup>

Since the *Markush* decision, the use of so-called *Markush*-type claims has grown, particularly in the chemical and biotechnological arts, resulting in ever increasing challenges for examination of such claims by the Patent Office.<sup>19</sup> However, this practice has resulted in claims of increasing scope and complexity.<sup>20</sup> It is not unusual for chemical cases to contain a claim that is several pages in length and includes thousands of compounds.<sup>21</sup> The complexity of such claims is directly proportional to the number of alternative embodiments they encompass.<sup>22</sup>

The Patent Office has expressed frustration over applicant’s filing of such claims. In particular, one of the Patent Office’s concerns is that broad *Markush*-type claims require a disproportionate amount of Examiner time and Patent Office resources as compared to simpler claims containing a single embodiment or small number of alternatives.<sup>23</sup> Another of the Patent Office’s concerns is that separate search and examination of each of the alternatives is often

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<sup>16</sup> *Id.* § 2173.05(h).

<sup>17</sup> *Id.* § 2173.05(h).

<sup>18</sup> *Id.* § 2173.05(h).

<sup>19</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,994 (proposed August 10, 2007, never enacted).

<sup>20</sup> *Id.* at 44,992.

<sup>21</sup> *Id.* at 44,992.

<sup>22</sup> *See, e.g., Id.* at 44,994.

<sup>23</sup> *Id.* at 44,992.

necessary because different alternatives often raise different patentability issues.<sup>24</sup> This increase in the number and complexity of applications containing Markush claims has contributed to an increase in prosecution pendency,<sup>25</sup> an ongoing battle for the Patent Office.

Since section 121<sup>26</sup> was introduced in the Patent Act of 1952, the Patent Office has adopted several approaches to facilitate examination of applications containing Markush claims. The first three of these approaches have failed to provide a workable solution for examination of Markush-type claims. The first of these approaches, rejection of such claims under 35 U.S.C. § 121 as misjoinder and as an improper Markush group,<sup>27</sup> failed due to court decisions holding these rejections improper. The second of these approaches, intra-claim restriction<sup>28</sup> has failed because the size and complexity of Markush-type claims is outpacing the Patent Office's ability to examine them.<sup>29</sup> The third of these approaches, the proposed Alternative Claims Rules,<sup>30</sup> was never adopted by the Patent Office probably because the many negative public comments.<sup>31</sup>

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<sup>24</sup> *Id.* at 44,992.

<sup>25</sup> *Id.* at 44,992.

<sup>26</sup> 35 U.S.C. § 121 (1999). 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, which 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.

<sup>27</sup> *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978), footnote 3; and *Practice Re Markush-type Claims*, 922 O.G. 1016 (May 1, 1974).

<sup>28</sup> M.P.E.P. § 803.02 (8<sup>th</sup> ed., Rev. 5, August 2006).

<sup>29</sup> *Examination of Patent Applications that Include Claims Containing Alternative Language*, 72 Fed. Reg. at 44,994.

The Patent Office adopted its latest approach in the Supplementary 112 Guidelines,<sup>32</sup> effective February 9, 2011. The new Guidelines provide for rejection of Markush claims under certain circumstances. As examiners begin to apply these Guidelines, applicants are likely to appeal the rejections. While it remains to be seen how successful the new Guidelines will be in easing the Patent Office's burden of examining applications containing Markush-type claims, it is possible that applicant challenges will result in court decisions, which like the Patent Office's early approach, frustrates the Patent Office's efforts.

This paper explores the various approaches previously applied by the Patent Office to handle examination of Markush claims, possible challenges under the new Guidelines, and whether the Guidelines are likely to be successful in easing the Patent Office's burden or result in an even greater burden on examiners.

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<sup>30</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,992 (proposed August 10, 2007, never enacted).

<sup>31</sup> *See, generally*, JAPAN INTELLECTUAL PROPERTY ASSOCIATION COMMENTS (OCTOBER 5, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; NATIONAL INSTITUTES OF HEALTH COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; THE NATIONAL ASSOCIATION OF PATENT PRACTITIONERS COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; INTELLECTUAL PROPERTY OWNERS ORGANIZATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992.

<sup>32</sup> Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162 (February 9, 2011).

## II. The Patent Office's Approaches to Examination of Markush Claims

### A. Rejection of Markush Claims as Misjoinder and as an Improper Markush Grouping under 35 U.S.C. 121: An Early Approach

Section 121 of the Patent Act of 1952 allows the Patent Office to restrict a patent application claiming two or more independent and distinct inventions to one of those inventions provided that it allows applicant to claim the additional subject matter in additional applications.<sup>33</sup> In the early 1970s, the Patent Office developed an approach to examination of Markush claims and published its new guidelines in the Official Gazette.<sup>34</sup> The Patent Office asserted that a Markush-type claim was directed to independent and distinct inventions where “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).”<sup>35</sup> Under this approach, examiners were authorized to reject a claim containing such independent and distinct inventions as an improper Markush claim and for misjoinder under 35 U.S.C. § 121. The examiner was further authorized to require applicant to limit his application to one of these inventions.<sup>36</sup> It is clear this authorization provided both for “intra-claim” restriction between groups the examiner believed to be independent and distinct inventions and for a requirement that applicant amend his claims to recite only the elected inventions.<sup>37</sup> This policy was a change from the previous practice of restricting only between separate claims.<sup>38</sup>

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<sup>33</sup> 35 U.S.C. § 121 (1999).

<sup>34</sup> *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978), footnote 3; and Practice Re Markush-type Claims, 922 O.G. 1016 (May 1, 1974).

<sup>35</sup> M.P.E.P. § 803 (3<sup>rd</sup> ed., Rev. 45, July 1975).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *See*, HAROLD C. WEGNER, THE EAGLE RIGHT TO GENERIC PROTECTION, ATTACHED TO AUGUST 10, 2007, TESTIMONY IN RESPONSE TO EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, § III-A at 9-10.

Applicants challenged the Patent Office’s policy through appeal of the improper Markush and misjoinder rejections. The leading cases on such challenges are *In re Weber*<sup>39</sup> and *In re Haas*.<sup>40</sup> In *Weber*, applicant claimed cyclic diamine derivatives having psychotherapeutic effectiveness.<sup>41</sup> The compounds were claimed in Markush format<sup>42</sup> and, although of modest scope today, were of moderate breadth for the time. The examiner rejected the claims on two separate bases: (1) being improper Markush claims and (2) misjoinder under 35 U.S.C. § 121. These rejections were in accordance with the Patent Office policy of the time, allowing rejection where a Markush claim is directed to “independent and distinct inventions.”<sup>43</sup> This rejection is reminiscent of that made in *Ex parte Eagle* found to be proper as far back as 1870.

The Board of Patent Appeals affirmed the examiner’s rejections but did not consider them separately, instead considering them together as one rejection.<sup>44</sup> The United States Court of Customs and Patent Appeals (CCPA) did not address the propriety of the improper Markush rejection. Instead, it remanded this rejection to the board, but cautioned the board that its decision on reconsideration must be consistent with the court’s “analysis of applicant’s rights under the second paragraph of 35 U.S.C. § 112.”<sup>45</sup> The court then addressed the rejection for misjoinder under § 121.

The court confirmed its previous decision that 35 U.S.C. § 112, second paragraph, allows an inventor to claim the invention as he contemplates it,<sup>46</sup> employing those limitations he considers necessary to circumscribe the invention so long as the application complies with 35

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<sup>39</sup> *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978).

<sup>40</sup> *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978) (*Haas II*).

<sup>41</sup> *In re Weber* at. 456.

<sup>42</sup> *See, Id.*

<sup>43</sup> *Id.* at footnote 3.

<sup>44</sup> *Id.* at 458.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* (citing *In re Wolfrum*, 486 F.2 588 (C.C.P.A. 1973)).



U.S.C. § 112.<sup>47</sup> The court held that “an applicant has a right to have each claim examined on the merits.”<sup>48</sup> It found that while the Patent Office may properly restrict between separate claims of an application without affecting applicant’s rights, if the Patent Office divides a single claim, requiring it to be presented in several applications, the claim as a whole would never be considered on its merits.<sup>49</sup> This is because “the resulting fragmentary claims would not necessarily be the equivalent of the original claim.”<sup>50</sup> The court further recognized that where the Patent Office divides a single claim, two problems under 35 U.S.C. § 112 could result.<sup>51</sup> First, the resulting subgenera “would be defined by the examiner rather than by the applicant” in violation of § 112, second paragraph.<sup>52</sup> Second, some of the fragments created by such division may not be described by the specification in violation of § 112, first paragraph.<sup>53</sup>

The court went on to clarify that while § 121 allows the Patent Office to “*restrict an application* to one of several claimed inventions” where the inventions are “independent and distinct,” it does not allow an examiner “to *reject* a particular *claim* on that same basis.”<sup>54</sup> The court recognized that the Patent Office must have the ability to control its workflow, but held that an applicant’s “statutory rights are paramount” and that “a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses.”<sup>55</sup>

On the same day it decided *Weber*, the CCPA considered the same issues in the case of *In*

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<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id. at 458-59.*

*re Haas (Haas II)*.<sup>56</sup> The claims in *Haas II* were directed to benzoyl peroxide compounds having reactive groups attached to the benzene rings.<sup>57</sup> The reactive groups were defined using Markush language.<sup>58</sup> The compounds shared a common utility as reactants for the preparation of a particular type of polymers.<sup>59</sup> As in *Weber*, the court found that 35 U.S.C. § 121 cannot be a basis for rejecting a claim.<sup>60</sup>

Five years earlier, the CCPA initially considered the Haas application in *Haas I*.<sup>61</sup> The issue in *Haas I* was whether refusal of the Patent Office to examine a Markush-type claim subsequent to an “intra-claim” restriction requirement on the basis that it contained independent and distinct inventions was tantamount to a rejection.<sup>62</sup> The import of the answer is that a substantive rejection is reviewable by the Board of Patent Appeals, while a restriction requirement is purely administrative and outside the jurisdiction of the board.<sup>63</sup> In *Haas I*, the court held that the Patent Office’s actions were in effect a rejection because the “claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because their content,”<sup>64</sup> which was essentially a denial of the claims’ patentability.<sup>65</sup> The court further noted that “only by dividing the subject matter into separate, and thus different, claims in plural application could an examination of the patentability of their subject matter be obtained.”<sup>66</sup>

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<sup>56</sup> *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978) (*Haas II*).

<sup>57</sup> *Id.* at 462.

<sup>58</sup> *See, Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 464.

<sup>61</sup> *In re Haas*, 486 F.2d 1053 (C.C.P.A. 1973) (*Haas I*).

<sup>62</sup> *See Id.* at 1054, 1056.

<sup>63</sup> *Id.* at 1054.

<sup>64</sup> *Id.* at 1056.

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

Thus, *Weber*, *Haas I*, and *Haas II* made it clear that rejection of a claim under 35 U.S.C. § 121 is improper and that “intra-claim” restriction of a Markush claim is actually a rejection of the claim under § 121 because it is a refusal to examine the claim.<sup>67</sup> Because each of these decisions subsumed the improper Markush rejections within the rejections under § 121, they leave open the question of whether it is proper to reject a claim as constituting an improper Markush claim solely on the basis that it contains independent and distinct inventions.

Two years later, the CCPA again addressed the propriety of an improper Markush rejection in *In re Harnisch*.<sup>68</sup> The claimed invention encompassed coumarin compounds that were useful as dyestuffs.<sup>69</sup> The compounds were claimed in Markush format.<sup>70</sup> As in *Weber*, the examiner rejected the claims under 35 U.S.C. § 121 on the combined bases that they contained an improper Markush group and for misjoinder.<sup>71</sup> The examiner followed the guidelines set forth by the Commissioner in the 1974 Official Gazette Notice,<sup>72</sup> arguing both that the claims were independent and distinct and that search and examination of the entire claim would be a serious burden.<sup>73</sup>

On appeal, the Board of Patent Appeals reversed the rejection under § 121 in accordance with the CCPA decisions in *Weber* and *Haas*. However, the board made a new rejection “under 37 C.F.R. § 1.196(b),<sup>74</sup> rejecting the claims as ‘drawn to improper Markush groups.’”<sup>75</sup> The

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<sup>67</sup> See, *In re Haas*, 486 F.2d 1053, 1056 (C.C.P.A. 1973), *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978), *In re Haas*, 580 F.2d 461, 464 (C.C.P.A. 1978).

<sup>68</sup> *In re Harnisch*, 631 F.2d 716 (C.C.P.A. 1980).

<sup>69</sup> *Id.* at 716.

<sup>70</sup> See, *Id.* at 716-17.

<sup>71</sup> *Id.* at 717.

<sup>72</sup> *In re Weber*, 580 F.2d 455, 456 (C.C.P.A. 1978); Footnote 3 (discussing the Official Gazette Notice at 922 O.G. 1016 issued by the Commissioner May 1, 1974).

<sup>73</sup> *In re Harnisch*, 631 F.2d 716, 717 (C.C.P.A. 1980).

<sup>74</sup> 37 C.F.R. § 1.196(b) (1989). Should the Board of Patent Appeals and Interferences have knowledge of any grounds not involved in the appeal for rejecting any appealed claim, it may

board did not rely on a statutory basis for its rejection.<sup>76</sup> Instead, it extensively reviewed previous Markush decisions and based its rejection solely on the “judicially created doctrine” of improper Markush grouping.<sup>77</sup> This appears to be the beginning of the Patent Office’s reliance on an improper Markush rejection as being “judicially created.” The board found “that the members of the Markush groups . . . do not belong to a known or recognized genus and possess widely different physical or chemical properties.”<sup>78</sup> The board then found that “[t]he mere fact that there is a single structural similarity is not in itself sufficient reason to render all the embodiments functionally equivalent, particularly when the ultimate properties of the final products would not be expected to possess any recognized functional relationships,”<sup>79</sup> holding that even though all of the compounds were disclosed as dyestuffs, they were not functionally equivalent.<sup>80</sup>

The CCPA held that there is no judicially created “Markush doctrine” and that no single rule exists with regard to Markush practice.<sup>81</sup> In fact the Patent Office had, and still does have, two different practices depending on whether the claims are directed to compounds or to processes or compositions employing a combination of steps or ingredients, respectively.<sup>82</sup> The court confirmed that each case must be considered on its own facts and, for the first time, defined

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include in the decision a statement to that effect with its reasons for so holding, which statement shall constitute a new rejection of the claims. A new rejection shall not be considered final for the purposes of judicial review.

<sup>75</sup> *In re Harnisch*, 631 F.2d 716, 717 (C.C.P.A. 1980)

<sup>76</sup> *Id.* at 718.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.* at 719.

<sup>82</sup> *Id.* at 720.

the issue of a proper Markush group as an issue of “unity of invention.”<sup>83</sup>

In *In re Jones*,<sup>84</sup> the CCPA established that “in determining the propriety of a Markush grouping, the compounds must be considered as wholes and not broken down into elements or other components.”<sup>85</sup> In *Harnisch*, the court found that the board erred in holding that the compounds did not possess a common function as all of the claimed compounds were disclosed as dyes.<sup>86</sup> Further, all of the compounds were coumarin compounds and thus had a “single structural similarity.”<sup>87</sup> The court held that the “compounds all belong to a subgenus, as defined by appellant, which is not repugnant to scientific classification.”<sup>88</sup> Thus, the court held that the claims possessed unity of invention and constituted a proper Markush group.<sup>89</sup> The decision appears to leave open the possibility that an improper Markush rejection might be available where the group of compounds either do not share a common function or do not have some structural similarity that would define a group that is not repugnant to one having ordinary skill in the art.

After *Harnisch*, the Board of Appeals and Interferences considered an improper Markush rejection in *Ex parte Hozumi*.<sup>90</sup> The claims were directed to “phosphoric acid diesters in which one esterifying moiety is derived from a poly(ethylene glycol) monoether and the other is derived from a beta-aminoethanol,”<sup>91</sup> and all of the compounds were disclosed as having

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<sup>83</sup> *Id.* at 721.

<sup>84</sup> *In re Jones*, 162 F.2d 479 (C.C.P.A. 1947).

<sup>85</sup> *In re Harnisch* at 722 (*citing In re Jones*, 162 F.2d 479 (C.C.P.A. 1947)).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Ex parte Hozumi*, 3 U.S.P.Q.2d 1059 (B.P.A.I. 1984).

<sup>91</sup> *Id.*

antimycotic activity.<sup>92</sup> The board held that the compounds contained “a substantial structural feature of the class of compounds claimed and disclosed as being essential to at least one disclosed utility.”<sup>93</sup> Further, the board found that the compounds had unity of invention because there was “a relatively large proportion of the structure of the compounds in the claimed class which is common to the entire class.”<sup>94</sup>

The decision purports to follow guidelines set forth in *Harnisch*.<sup>95</sup> However, the board’s decision establishes two requirements for a proper Markush claim that appear nowhere in *Harnisch*. The first of these is the concept that the common physical or structural feature of the compounds must be “a substantial structural feature.”<sup>96</sup> The second is that this substantial structural feature must be essential to a disclosed utility.<sup>97</sup> These two concepts have become a hallmark of the Patent Office’s approaches to examination of Markush claims.<sup>98</sup>

### **B. Restriction Practice – Election of a Single Disclosed Species: The Longstanding Approach**

After the CCPA decisions in *Weber*, *Haas II*, and *Harnisch*, and the board’s decision in *Hozumi*, the Patent Office changed approach. It recognized the futility of rejecting claims as

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *See*, M.P.E.P. § 803.02 (8<sup>th</sup> ed., Rev. 5, Aug. 2006); Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,994 (August 10, 2007). *Compare*, Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162, 7,166 (February 9, 2011) which states “A Markush claim contains an ‘improper Markush grouping’ if: (1) The species of the Markush group do not share a ‘single structural similarity,’ or (2) the species do not share a common use. Members of a Markush group share a ‘single structural similarity’ when they belong to the same recognized physical or chemical class or to the same art-recognized class. Members of a Markush group share a common use when they are disclosed in the specification or known in the art to be functionally equivalent.” (citations omitted).

improper Markush claims whether under 35 U.S.C. § 121 or based on judicial precedent.<sup>99</sup> Although the Patent Office has long indicated that an “improper Markush” rejection could be made, the latest revision of the Manual of Patent Examining Procedure (M.P.E.P.)<sup>100</sup> does not even discuss making such rejections. The Patent Office further recognized there was an approach that could avoid judicial review. The CCPA, in *Weber*, acknowledged the Patent Office’s need for latitude in controlling administrative matters so long as its actions did not impinge upon applicants’ statutory rights.<sup>101</sup> Additionally, in *Haas I*, the CCPA acknowledged that while rejections were appealable, restriction requirements were administrative and outside the jurisdiction of the board<sup>102</sup> and thus the courts. As a result, the Patent Office abandoned its rejection of Markush claims and continued its practice of restricting within a Markush claim, adopting an election of species practice.<sup>103</sup>

The Patent Office’s policy with regard to restriction of Markush claims is set forth in Chapter 800 of the M.P.E.P.<sup>104</sup> Prior to the *Weber* and the *Haas I and Haas II* decisions, this policy instructed the examiner to restrict a Markush claim he believed to contain multiple ‘independent and distinct inventions,’ to a single invention.<sup>105</sup> In restricting, the examiner was instructed to “(1) clearly delineate the members or groups of members believed to constitute improperly joined inventions, and (2) state reasons fully explaining why they are independent and distinct.”<sup>106</sup> It is clear from these instructions that the Patent Office’s intent was an intra-

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<sup>99</sup> See, e.g., M.P.E.P. § 803 (4<sup>th</sup> ed., Rev. 0, June 1979)(stating that revision of the section was due to the decisions in *Haas* and *Weber*).

<sup>100</sup> M.P.E.P. §§ 802-803 (8<sup>th</sup> ed., Rev. 5, Aug. 2006).

<sup>101</sup> *In re Weber*, 580 F.2d 455, 458-59 (C.C.P.A. 1978).

<sup>102</sup> *In re Haas*, 486 F.2d 1053, 1054 (C.C.P.A. 1973).

<sup>103</sup> M.P.E.P. § 803 (4<sup>th</sup> ed., Rev. 0, June 1979).

<sup>104</sup> M.P.E.P. § 800 (8<sup>th</sup> Ed., Rev. 8, July 2010).

<sup>105</sup> M.P.E.P. § 803 (3<sup>rd</sup> ed., Rev. 45, July 1975).

<sup>106</sup> *Id.*

claim restriction in which each delineated group contained subject matter the examiner believed was independent and distinct from the subject matter of each other group. Patent Office policy also stated that, “Applicant’s response to such a requirement should be an election of a single adequately disclosed and supported invention, with or without restriction of the claim(s) to that invention.”<sup>107</sup> The examiner was instructed to maintain the restriction requirement and not examine any claims that were not limited to the elected invention.<sup>108</sup> Thus, Patent Office policy was to refuse examination of any subject matter it believed independent and distinct from the elected subject matter, even where the subject matter is present in a single Markush claim.<sup>109</sup>

Following the decisions in *Weber* and *Haas II*, these instructions were removed from the M.P.E.P.<sup>110</sup> The Patent Office revised its practice in view of the CCPA’s decisions.<sup>111</sup> The revised practice requires an examiner to examine “all of the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions”<sup>112</sup> where “the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden.”<sup>113</sup> However, it is rare that today’s Markush claims contain embodiments that are closely related and few in number for this practice to be followed.<sup>114</sup> Instead, the vast majority of chemical and biotechnological patent applications are restricted.<sup>115</sup> Where claims are too

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<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> M.P.E.P. § 803 (3<sup>rd</sup> ed., Rev. 56, July 1978).

<sup>111</sup> M.P.E.P. § 803 (4<sup>th</sup> ed. Rev. 0, June 1979).

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *See*, Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,992 (proposed August 10, 2007, never enacted).

<sup>115</sup> EIFION PHILLIPS, FISH AND RICHARDSON RESTRICTION PRACTICE WEBINAR at slide 2 (May 11, 2011).



broad or complex to be examined as presented and considered to “encompasses at least two independent and distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits.”<sup>116</sup> The examiner should then fully examine the elected species and any other species that are not patentably distinct from the elected species.<sup>117</sup> If the claim is not allowable, the claim is rejected and the patentably distinct, nonelected species are withdrawn from consideration.<sup>118</sup> If, however, the elected species is found allowable, examination of the Markush claim then is to be extended to the extent necessary to determine patentability of the Markush claim.<sup>119</sup> These basic instructions to examiners have not changed since 1979.<sup>120</sup> However, what has changed is the Patent Office’s approach to what constitutes an independent and distinct invention.

In May 1988, the Patent Office separated the procedure for restricting Markush claims into section 803.02 of the M.P.E.P.<sup>121</sup> and added a single paragraph that has had significant import to the restriction of such claims.<sup>122</sup> This new paragraph cites to the *Weber, Haas II*, *Harnisch*, and *Hozumi* decisions and states in pertinent part that “[s]ince the decisions in *In re Weber et. al.* and *In re Haas*, 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.*”<sup>123</sup> (emphasis added). “Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature

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<sup>116</sup> M.P.E.P. § 803 (4<sup>th</sup> ed., Rev. 0, June 1979).

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> M.P.E.P. § 803.02 (8<sup>th</sup> ed. Rev. 5, Aug. 2006).

<sup>121</sup> M.P.E.P. § 803.02 (5<sup>th</sup> ed. Rev. 8, May 1988).

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

disclosed as being essential to that utility.”<sup>124</sup>

This added paragraph misinterprets the cited decisions and creates a greater burden on applicant than any established by the court. *Weber* and *Haas II* each held that 35 U.S.C. § 121 was not a proper basis for rejecting claim.<sup>125</sup> The only reference to restriction in these cases was *Weber*'s recognition of the Patent Office's need to control its workload.<sup>126</sup> However, the court specifically held that where the Patent Office's actions conflicted with applicant's statutory rights, applicant's rights are dominant.<sup>127</sup> Further, these decisions must be considered in light of the CCPA's holding in *Haas I*. In that case, the court held that withdrawal of a subject matter within a claim through restriction was synonymous with rejecting the claim because it prevented applicant from ever having his claim as presented examined.<sup>128</sup> Thus, *Haas I* found that restriction of subject matter within a claim was essentially a rejection of the claim, and *Weber* and *Haas II* found that rejection under 35 U.S.C. § 121 is improper. The *Weber* and *Haas* decisions did not hold that a refusal to examine that which applicants regard as their invention was improper unless the subject matter in a claim lacks unity of invention, but that a refusal to examine that which applicants regard as their invention and have claimed in a single claim is improper. Thus, it would appear these decisions foreclose restriction within a Markush claim, and yet it has been standard practice to require restriction, through election of species practice at least since 1988.<sup>129</sup>

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<sup>124</sup> *Id.*

<sup>125</sup> *In re Weber*, 580 F.2d. 455, 458 (C.C.P.A. 1978); *In re Haas*, 580 F.2d 461, 464 (C.C.P.A. 1978).

<sup>126</sup> *In re Weber* at 459.

<sup>127</sup> *Id.*

<sup>128</sup> *In re Haas*, 486 F.2d 1053, 1056 (C.C.P.A. 1973).

<sup>129</sup> M.P.E.P. § 803.02 (5<sup>th</sup> ed., Rev. 8, May 1988).

This leaves *Harnisch* and *Hozumi* which are cited for the proposition that 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.”<sup>130</sup> The M.P.E.P. does not provide any additional instructions to the examiner with regard to unity of invention. However, the clear implication is that where the members of a Markush group do not have a common utility or do not share a substantial structural feature *that is disclosed as being essential to that utility* the claim lacks unity of invention. The first issue with this position is that both *Harnisch* and *Hozumi* found the claims were proper Markush groups having a common utility and a common structural feature.<sup>131</sup> These decisions did not, however, hold that this is the only way in which a claim can be found to be a proper Markush claim. In fact, they found that each case must be considered upon its own facts.<sup>132</sup> Another issue is that although the Board of Patent Appeals and Interferences in *Hozumi* found that the members of the claims at issue shared a substantial structural feature that was essential to the disclosed common utility, *Harnisch* found only that there was a common utility and a common single structural feature.<sup>133</sup> There was no requirement that the structural feature be “substantial” or that it be “essential” to the compounds utility.

As noted by the court in *Haas I*,<sup>134</sup> restriction requirements are outside the jurisdiction of the board and courts.<sup>135</sup> Therefore, the Patent Office’s switch from rejection of the claims to restriction practice has forestalled development of these issues through appellate review.

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<sup>130</sup> *Id.*

<sup>131</sup> *In re Harnisch*, 631 F.2d 716, 722 (C.C.P.A. 1980); *Ex parte Hozumi*, 3 U.S.P.Q.2d 1059, 1059 (B.P.A.I. 1984).

<sup>132</sup> *In re Harnisch* at 722; *Ex parte Hozumi* at 1059.

<sup>133</sup> *In re Harnish* at 722.

<sup>134</sup> *In re Haas*, 486 F.2d 1053, 1056 (C.C.P.A. 1973).

<sup>135</sup> *Id.* at 1054.

Although the above election of species procedure was the official Patent Office policy until adoption of the new Guidelines<sup>136</sup> discuss in section II-D *infra*. There are in reality two separate restriction practices that occur in the Patent Office, particularly in Technology Center 1600, with regard to Markush claims. Some examiners essentially follow the official practice. Some examiners strictly follow this policy,<sup>137</sup> while others refuse to extend the search when the elected species is allowable, object to the claims as containing nonelected subject matter, and require applicants to cancel that subject matter to obtain allowance. Because the claims are subject to an objection rather than to a rejection, applicants have no right of appeal.<sup>138</sup> The only recourse is to file a petition,<sup>139</sup> which Applicants may be reluctant to do with allowable subject matter indicated.

The second procedure followed by some examiners is to restrict within a single claim to create several groups of subgenera.<sup>140</sup> For example, the examiner may divide the claims as follows:

- Group I: Claims 1 to 5, directed to compounds of formula I where R is heteroaryl,
- Group II: Claims 1 to 5, directed to compounds of formula I where R is aryl,
- Group III: Claims 1 to 5, directed to compounds of formula I where R is cycloalkyl.

The examiner then proceeds to examine only the elected group. When the elected invention becomes allowable, the examiner objects to the claims and requires cancellation of the

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<sup>136</sup> Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162 (February 9, 2011).

<sup>137</sup> *See, for example*, US PATENT APPLICATION NO. 12/361,569, FILED JANUARY 29, 2009.

<sup>138</sup> *In re Haas*, 486 F.2d 1053, 1054 (C.C.P.A. 1973).

<sup>139</sup> 37 C.F.R. § 1.144 (2003). After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested.

<sup>140</sup> *See, for example*, U.S. PATENT APPLICATIONS NO. 12/711,275, FILED FEBRUARY 24, 2010 AND 12/692,680, FILED JANUARY 25, 2010.

nonelected subject matter.<sup>141</sup>

Both of these processes can result in several patentability issues for the patent applicant. One of the most severe issues is that the claims ultimately allowed may not be fully supported by the specification.<sup>142</sup> Even though the original broad claim scope was fully supported by the specification, the ultimate narrower scope may not be supported. This situation can occur because the narrower claim is usually defined, not by the applicant, but by the examiner.<sup>143</sup> Additionally, even if the claims that issue in the original application are supported, the remaining nonelected subject matter may not find support, preventing applicant's ability to receive a patent to the remaining subject matter in a divisional application.<sup>144</sup>

Another issue raised by current restriction practice is that where the examiner requires amendment to a species or a specific subgeneric concept, the issued claims are defined, not by the applicant, but by the examiner. As noted in *Weber*, 35 U.S.C. § 112, second paragraph, provides that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter *which the applicant regards as his invention.*”<sup>145</sup> Thus, capitulation to the examiner's requirements denies applicant of his statutory right.

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<sup>141</sup> *See, for example*, U.S. PATENT APPLICATION NO. 12/692,680, FILED JANUARY 25, 2010, in which an intra-claim restriction requirement was made. In the first office action on the merits, no rejections were made. The claims were objected to as containing nonelected subject matter, leaving applicant to accept the narrower scope or petition.

<sup>142</sup> *See, In re Weber*, 580 F.2d. 455, 458 (C.C.P.A. 1978). *See also*, HAROLD C. WEGNER, THE EAGLE RIGHT TO GENERIC PROTECTION, ATTACHED TO AUGUST 10, 2007, TESTIMONY IN RESPONSE TO EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, § II-B at 6-7.

<sup>143</sup> *See*, HAROLD C. WEGNER, THE EAGLE RIGHT TO GENERIC PROTECTION, ATTACHED TO AUGUST 10, 2007, TESTIMONY IN RESPONSE TO EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, § II-B at 6-7.

<sup>144</sup> *Id.*

<sup>145</sup> *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978). *See also*, 35 U.S.C. § 112, ¶ 2 (1975). 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.

Another issue presented by restriction practice is that restrictions are not appealable – only petitionable.<sup>146</sup> Petitions for restriction requirements are made to the Group Director.<sup>147</sup> Decisions are highly fact specific and because they are rendered by a variety of individuals can result in vast inconsistencies, which go unchecked. Decisions are difficult to search because while entered in a specific patent application, there is no database or repository for them. Unlike appeals and court cases, petition decisions are not published and have no precedential value. This lack of transparency can be frustrating. Further, as Markush claims have become increasingly broad and complex, restriction practice has not been able to ease the Patent Office’s burdens.<sup>148</sup>

### **C. The Proposed Alternative Claims Rules: An Approach Never Implemented**

In 2007, the Patent Office sought to establish new rules for the examination of Markush-type claims.<sup>149</sup> The proposed rules would have fundamentally changed examination practice both with regard to how claims are drafted and how they are examined.<sup>150</sup> The proposed rules contained two general provisions: that each claim must be limited to a single invention and that the claims must conform to a simplified format.<sup>151</sup>

The first provision of the proposed rules provided that each claim must be limited to a single invention.<sup>152</sup> Claims directed to two or more independent and distinct inventions would

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<sup>146</sup> *In re Haas*, 486 F.2d 1053, 1054 (C.C.P.A. 1973).

<sup>147</sup> 37 C.F.R. § 1.144 (2003).

<sup>148</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,993-94 (August 10, 2007).

<sup>149</sup> *Id.* at 44,992.

<sup>150</sup> *See*, HAROLD C. WEGNER, THE EAGLE RIGHT TO GENERIC PROTECTION, ATTACHED TO AUGUST 10, 2007, TESTIMONY IN RESPONSE TO EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, § I at 1-3.

<sup>151</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. at 44,995-97.

<sup>152</sup> *Id.* at 44,995.

be subject to an objection<sup>153</sup> with applicants being required to cancel nonelected subject matter from the claim to obtain allowance of the elected invention.<sup>154</sup> It was the Patent Office’s position that restriction between inventions within such a claim is proper under 35 U.S.C. § 121.<sup>155</sup> The propriety of such a requirement would be determined “without regard to whether the plural inventions are recited in separate claims or as alternatives within a single claim.”<sup>156</sup> The Patent Office distinguished between a generic claim that does not contain any list of alternatives, which was considered drawn to a single invention, and a claim that provides one or more lists of alternatives, which is presumptively directed to more than one invention.<sup>157</sup> The proposed rules acknowledged that even where a claim uses alternative language, it is directed to a single invention “when at least one of the following two conditions is met: (1) All of the species encompassed by the claim share a substantial feature essential for a common utility, or (2) all of the species are prima facie obvious over each other.”<sup>158</sup> The first of these conditions is from *In re Harnisch* (actually from *Ex parte Hozumi*).<sup>159</sup> In determining whether a claim meets this condition, “common utility” was defined as a utility that complies with 35 U.S.C. § 101,<sup>160</sup> and a “substantial feature” was defined as “a particular structure, material, or act, without which the claimed alternatives would not retain the shared utility.”<sup>161</sup> The second of these conditions conforms “the long-standing principle that it is improper to restrict between species that are

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<sup>153</sup> *Id.* at 44,997.

<sup>154</sup> *Id.* at 44,998.

<sup>155</sup> *Id.* at 44,995.

<sup>156</sup> *Id.* at 44,997.

<sup>157</sup> *Id.* at 44,996.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.* at 44,997.

<sup>161</sup> *Id.*

prima facie obvious over each other.”<sup>162</sup> If either of these situations exist, restriction would not be proper.<sup>163</sup>

The proposed rule suggested that applicants, sua sponte, provide an explanation as to why the claim is directed to a single invention.<sup>164</sup> Rather naively, the Patent Office’s position was that such statements would lessen the number of restriction requirements and expedite prosecution.<sup>165</sup>

The second provision of the proposed rules would have required that applicants use a simplified format for claims containing alternative language.<sup>166</sup> This provision had four requirements. The first two requirements were that “the number and presentation of alternatives in the claim not make that claim difficult to construe,”<sup>167</sup> and that “each alternative within a list of alternatives must be substitutable one for another.”<sup>168</sup> These first two provisions are consistent with the “unity of invention” provisions of the PCT Guidelines.<sup>169</sup> According to the Patent Office, they also are consistent with U.S. practice at the time.<sup>170</sup> Third, “no alternative may itself be defined as a set of further alternatives.”<sup>171</sup> This requirement would reduce the complexity of the claims.<sup>172</sup> Fourth, “no alternative may be encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the

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<sup>162</sup> *Id.* at 44,996.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at 44,997.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*



invention.”<sup>173</sup> The proposed rule stated that “[a]pplicants should narrow the scope of protection sought via separate claims and not via nested sets of overlapping alternatives.”<sup>174</sup> Claims that in any way did not meet the simplified format requirements would be subject to objection.<sup>175</sup>

In response to the proposed rule, several organizations and individual companies provided comments.<sup>176</sup> Although most of the commenters sympathized with the difficulties faced by the Patent Office, several did not believe that the proposed rules would achieve the Patent Office’s stated purposes.<sup>177</sup> In particular, BIO stated that, “The PTO reports that this

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<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *See*, JAPAN INTELLECTUAL PROPERTY ASSOCIATION COMMENTS (OCTOBER 5, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; NATIONAL INSTITUTES OF HEALTH COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; THE NATIONAL ASSOCIATION OF PATENT PRACTITIONERS COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; GENENTECH COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; INTELLECTUAL PROPERTY OWNERS ORGANIZATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; GLAXOSMITHKLINE COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992; IBM COMMENTS (OCTOBER 16, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992.

<sup>177</sup> BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 3.

proposed rule is part of the effort to increase the quality of patents and decrease backlog of pending patent applications. However, allowing Examiners to restrict within a single claim will not decrease the number of applications being filed by an applicant. Rather it will increase the number of applications ... and add to the growing backlog of unexamined applications at the PTO.”<sup>178</sup>

Several major concerns were expressed in the comments and are summarized here. First, there was concern that the rules created disparate treatment for those using true generic language and those using alternative language.<sup>179</sup> The rules placed individuals claiming inventions for which no generic terms is available at a disadvantage. BIO expressed concern that the biotechnology industry was particularly vulnerable to this disparity.<sup>180</sup> A second concern was that the rules gave the examiners too much authority to define the invention, which by statute is applicants purview.<sup>181</sup> The American Intellectual Property Association (AIPPLA) stated that “[w]e believe the proposed rules place too much authority in the hands of patent examiners to

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<sup>178</sup> BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 3. *See also, id.* at 7.

<sup>179</sup> *See, e.g.*, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 1 (“[t]he proposed rules place artificial limits on those who use alternatives to define what they regard as their invention, when no such limits are placed on those who define their invention with different generic terminology”).

<sup>180</sup> BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 3.

<sup>181</sup> *See, e.g.*, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 1); BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 6-7; INTELLECTUAL PROPERTY OWNERS ORGANIZATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 2.

determine the subject matter that applicants regard as their invention. The practical application of the rules as proposed will effectively permit an examiner to limit the scope of claims to subject matter which an examiner believes can be adequately searched.”<sup>182</sup> Third, the commenters acknowledged the continuing issues related to written description for subgenres created by examiner,<sup>183</sup> a problem also recognized by the court in *Weber*.<sup>184</sup> Fourth, the commenters noted that the requirement that each of the alternatives be substitutable appears to focus on interchangeability of alternatives rather than compound as a whole as required by *In re Jones*.<sup>185</sup>

Many commenters also noted that the “difficult to construe” language of the proposed rules is nebulous.<sup>186</sup> In particular AIPLA argued that “[t]he PTO should continue to rely on 35 U.S.C. § 112, second paragraph, to determine whether a claim is ‘difficult to construe,’ or is otherwise unclear. The proposed language would not provide any guidance for either examiners or applicants and is capable of many interpretations. Applicants should be held to the statutory standard for clarity, but should not be held to any further nebulous standard that will only detract

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<sup>182</sup> AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 1.

<sup>183</sup> *See, e.g.*, BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 4.

<sup>184</sup> *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978).

<sup>185</sup> *See, e.g.*, INTELLECTUAL PROPERTY OWNERS ORGANIZATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 3.

<sup>186</sup> *See, e.g.*, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 1; BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 3; INTELLECTUAL PROPERTY OWNERS ORGANIZATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 2.

attention away from the objective of determining patentability.”<sup>187</sup>

It was also noted that several of the provisions would circumvent the appeals process by allowing examiners to restrict where they otherwise would be required to reject the claims.<sup>188</sup> For example, the standard for “common utility” is said to be that of § 101.<sup>189</sup> If the examiner does not believe all of the compounds meet the utility requirement of § 101, he could simply restrict the claims, and applicant would never be able to challenge the underlying utility rejection. Similarly, if the examiner finds the claims difficult to construe and restricts, applicant would never be able to challenge the underlying § 112, second paragraph rejection. The proposed rules state that “where an elected species is patentable, but the claims are not enabled or adequately described over their entire scope, the proposed rule would permit an examiner to require restriction of the claims to the elected species and allowable variants thereof,”<sup>190</sup> forestalling any challenge by applicant regarding the propriety of the underlying § 112, first paragraph rejection.<sup>191</sup>

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<sup>187</sup> AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 1.

<sup>188</sup> *See, e.g.*, BIOTECHNOLOGY INDUSTRY ORGANIZATION COMMENTS (OCTOBER 9, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 3.

<sup>189</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,997 (proposed August 10, 2007, never enacted).

<sup>190</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,998 (proposed August 10, 2007, never enacted).

<sup>191</sup> AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 6.

## **D. Markush Practice under the Supplementary Guidelines: A New/Old Approach**

### **1. The Guidelines**

In February 2011, the Patent Office issued “Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications.”<sup>192</sup> The Guidelines became effective February 9, 2011, and apply to all applications.<sup>193</sup> One of the Patent Office’s stated purposes is to optimize patent quality by providing clear notice as to the metes and bounds of the claims.<sup>194</sup> Another stated purpose is “to assist United States Patent and Trademark Office personnel in the examination of claims in patent applications for compliance with 35 U.S.C. 112, second paragraph.”<sup>195</sup> The Guidelines are not substantive rulemaking. Instead, the Patent Office indicates that the Guidelines “relate only to interpretative rules, general statements of policy, or rules of agency, organization, procedure or practice”<sup>196</sup> and are intended to “merely update USPTO examination practice for consistency with the USPTO’s current understanding of the case law regarding the requirements of 35 U.S.C. 112.”<sup>197</sup>

The Guidelines discuss a number of different issues, including examination of Markush claims.<sup>198</sup> A Markush claim is defined as one that “recites a list of alternatively useable species.”<sup>199</sup> The Guidelines indicate that two rejections may be appropriate upon examination of a Markush claim: a rejection for indefiniteness under 35 U.S.C. § 112, second paragraph, and a

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<sup>192</sup> Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162 (February 9, 2011).

<sup>193</sup> *Id.* at 7,163.

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 7,162.

<sup>196</sup> *Id.* at 7,163.

<sup>197</sup> *Id.*

<sup>198</sup> *Id.* at 7,166.

<sup>199</sup> *Id.*

rejection under the supposed judicial doctrine of improper Markush grouping.<sup>200</sup> The Patent Office acknowledges that while Markush claims, “may encompass a large number of alternative species,” breadth is not necessarily indefiniteness.<sup>201</sup> However, the Guidelines indicate that, “a Markush group may be so expansive that persons skilled in the art cannot determine the metes and bounds of the claimed invention. For example, a Markush group that encompasses a massive number of distinct alternative species may be indefinite under § 112, ¶2 if one skilled in the art cannot determine the metes and bounds of the claim due to an inability to envision all of the members of the Markush group.”<sup>202</sup> In such circumstances, the examiner is directed to reject the claims as indefinite under 35 U.S.C. § 112, second paragraph.<sup>203</sup> Further, examiners are instructed to reject the claims under “the judicially approved ‘improper Markush grouping’ doctrine when the claim contains an improper grouping of alternatively useable species.”<sup>204</sup> A Markush claim contains an ‘improper Markush grouping’ if: (1) the species of the Markush group do not share a ‘single structural similarity,’ or (2) the species do not share a common use.”<sup>205</sup> The Guidelines state that “[m]embers of a Markush group share a ‘single structural similarity’ when they belong to the same recognized physical or chemical class or to the same art-recognized class.”<sup>206</sup> They share a common use “when they are disclosed in the specification or known in the art to be functionally equivalent.”<sup>207</sup> The Guidelines instruct the examiner to maintain the improper Markush rejection until “the claim is amended to include only the species

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<sup>200</sup> *Id.*

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

that share a single structural similarity and a common use, or the applicant presents a sufficient showing that the species in fact share a single structural similarity and a common use.”<sup>208</sup>

The Guidelines continue to support current Patent Office restriction procedures in which applicant is required to elect a single species or group of indistinct species, with one exception.<sup>209</sup> Instead of indicating the examiner should extend search and examination to determine patentability of the generic claim, the Guidelines provide that the examiner should extend the search to those additional species that “share a single structural similarity and a common use with the elected species.”<sup>210</sup>

## **2. Ex parte DeGrado – Looking for Validation of the Guidelines**

The Guidelines are a radical change from the longstanding restriction practice, and the Patent Office appears eager to test them in the court system. In May 2011, the Board of Patent Appeals and Interferences (BPAI) sua sponte ordered further briefing on issues under the Guidelines that were not before it in the appeal.<sup>211</sup>

The DeGrado application claims a method for treating microbial infections by administering compositions that include an amphiphilic oligomer.<sup>212</sup> The oligomers are claimed in Markush format.<sup>213</sup> The claims are quite broad, with the BPAI estimating that they encompass “in excess of 400 billion oligomers.”<sup>214</sup> During prosecution of the application, the examiner issued several restriction requirements, including a requirement for election of a single disclosed

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<sup>208</sup> *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., ORDER FOR FURTHER BRIEFING at 7 (June 20, 2011).

<sup>212</sup> *Id.* at 2.

<sup>213</sup> *Id.* at 2-4.

<sup>214</sup> *Id.* at 5.

species, which resulted in examination of a subset of the originally presented claims.<sup>215</sup> These restriction requirements were made prior to issuance of the current Guidelines.

At the close of prosecution, only one issue remained for appeal – a rejection of the examined claims under the judicially created doctrine of obviousness-type double patenting over a previously issued patent.<sup>216</sup> DeGrado appealed the examiner’s rejection, and both the Appeal Brief and the Examiner’s Answer dealt only with this issue.<sup>217</sup> Then, on May 9, 2011, the BPAI issued an Order for Further Briefing, requiring under 37 C.F.R. § 41.50(d),<sup>218</sup> that applicants brief two issues not before it on appeal:

1. Whether applicants may be required to restrict their claims to a single invention under the provisions of 35 U.S.C. § 121; and
2. Whether Claim 16 is a proper “Markush Claim.”<sup>219</sup>

The Patent Office has long held the viewpoint that 35 U.S.C. § 121,<sup>220</sup> which states, “[i]f 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”<sup>221</sup> includes restriction within a

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<sup>215</sup> *Id.* at 5-9.

<sup>216</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 5 (May 9, 2011).

<sup>217</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37 (September 23, 2009, 2011); U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., EXAMINER’S ANSWER (December 8, 2009).

<sup>218</sup> 37 C.F.R. §41.50(d) (2004). The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order. Failure to timely comply with the order may result in the sua sponte dismissal of the appeal.

<sup>219</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., ORDER FOR FURTHER BRIEFING at 2 (June 20, 2011).

<sup>220</sup> 35 U.S.C. § 121 (1999).

<sup>221</sup> *Id.*



single claim where the claim contains “two or more independent and distinct inventions.”<sup>222</sup> *In re Weber* makes clear, however, that there is a difference between restricting *between* claims in an application and restricting *within a single claim* of an application,<sup>223</sup> the first being permissible, the second not being permissible. The board required applicants to brief what it views as a conflict between the statute and the court’s holding in *Weber*.<sup>224</sup> The board also required applicants to address whether the language of § 112, second paragraph, requiring “one or more claims ... claiming the subject matter the applicant regards as his invention”<sup>225</sup> necessarily prevents the Director from requiring “the *application* to be restricted to one of the inventions”<sup>226</sup> when more than one independent and distinct invention is encompassed within a single claim.<sup>227</sup>

This issue has long been contested between the Patent Office and the patent bar. The Patent Office has often argued that 35 US.C. § 121 authorizes restriction within a single claim where that claim contains two or more independent and distinct inventions.<sup>228</sup> In contrast, the patent bar has argued that under the CCPA decisions in *Weber* and *Haas* interpreting § 121 and § 112, the Patent Office is prohibited from restricting within a single claim.<sup>229</sup>

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<sup>222</sup> M.P.E.P. § 803 (3<sup>rd</sup> ed., Rev. 45, July 1975); Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,997 (proposed August 10, 2007, never enacted).

<sup>223</sup> *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978).

<sup>224</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., ORDER FOR FURTHER BRIEFING at 11 (June 20, 2011).

<sup>225</sup> *Id.* at 11.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.*

<sup>228</sup> M.P.E.P. § 803 (3<sup>rd</sup> ed., Rev. 45, July 1975); Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,997 (proposed August 10, 2007, never enacted).

<sup>229</sup> HAROLD C. WEGNER, THE EAGLE RIGHT TO GENERIC PROTECTION, ATTACHED TO AUGUST 10, 2007, TESTIMONY IN RESPONSE TO EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE

The CCPA's decision in *Harnisch* refocused the discussion of Markush practice to one of "unity of invention."<sup>230</sup> The Patent Office has long held the viewpoint that *Harnisch* established the test for determining whether a Markush claim is or is not proper on the basis of whether it has or lacks "unity of invention."<sup>231</sup> According to the Patent Office, "[a] Markush claim is improper if the inventions (1) do not share a common use; or (2) do not share a 'single structural similarity,' that is, a substantial structure feature disclosed as being essential to the common utility."<sup>232</sup> DeGrado's independent claim recites a large number of oligomers, all of which are amphiphilic.<sup>233</sup> The board required DeGrado "to brief whether the recitation of a broad general formula covering a very large group of compounds, the recitation of a general chemical property (amphiphilicity) that may be possessed by those compounds, and the recitation of a single broad step of 'administering an effective amount' is per se sufficient to create 'unity of invention' as that concept was used by the *Harnisch* court."<sup>234</sup> The board further required applicants to brief whether the compounds encompassed by the independent claim "share any additional structural or functional features that would establish unity of invention."<sup>235</sup>

This issue also has long been contested between the Patent Office and the patent bar. The Patent Office has consistently argued that under *Harnisch*, to have "unity of invention," a

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CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, § II-A at 9-10 (discussing the origins of chemical Markush practice).

<sup>230</sup> *In re Harnisch*, 631 F.2d 716, 721 (1980).

<sup>231</sup> M.P.E.P. § 803.02 (5<sup>th</sup> ed., Rev. 8, May 1988).

<sup>232</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., ORDER FOR FURTHER BRIEFING at 11 (June 20, 2011).

<sup>233</sup> *Id.*

<sup>234</sup> *Id.* at 12.

<sup>235</sup> *Id.*

Markush group must possess a common structural feature that is essential to its utility.<sup>236</sup> The patent bar has argued that this requirement is not found in the *Harnisch* decision. The bar argues that *Harnisch* only requires a common structural feature and a common utility, not that the common structural feature give rise to, or be essential for, the common utility.<sup>237</sup> As noted by the patent bar, the Patent Office's long subscribed language can be found nowhere in the *Harnisch* decision.<sup>238</sup> In fact, it appears that this standard was actually introduced in *Ex parte Hozumi*, based on its interpretation of the *Harnisch* decision.<sup>239</sup>

Applicant's brief in response to the board's order provides an excellent discussion of the law related to the Markush issues raised by the board. As an initial matter, the brief asserts that the board has no jurisdiction to decide the specific issues it raised.<sup>240</sup> First, it is clear that disputes involving restriction requirements are not appealable; instead they are petitionable to the Director.<sup>241</sup> Thus, the board has no jurisdiction over disputes related to restriction practice. Second, even if a determination of such disputes were within the jurisdiction of the board, no such dispute was at issue in the application.<sup>242</sup> Although during prosecution of the application, applicant argued the propriety of various aspects of the restriction requirements raised by the examiner, he acquiesced to the final restriction requirement long before appeal without even

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<sup>236</sup> M.P.E.P. § 803.02 (5<sup>th</sup> ed., Rev. 8, May 1988); Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,997 (proposed August 10, 2007, never enacted).

<sup>237</sup> AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION COMMENTS (OCTOBER 15, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 4.

<sup>238</sup> *Id.*

<sup>239</sup> *Ex parte Hozumi*, 3 U.S.P.Q.2d 1053 (B.P.A.I. 1984).

<sup>240</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 5-7 (May 9, 2011).

<sup>241</sup> *Id.* at 6. See also, 37 C.F.R. § 1.144 (2003).

<sup>242</sup> *Id.*

filing a petition.<sup>243</sup> Third, 37 C.F.R. § 41.50(d),<sup>244</sup> only authorizes the board to order additional briefing on matters that could assist the board in reaching decision on the pending appeal.<sup>245</sup> The only issue properly before the board is the obviousness-type double patenting rejection.<sup>246</sup> The two issues for which briefing were ordered have no bearing on the double patenting issue. That the board would require briefing on issues not raised in prosecution and not properly within its jurisdiction is a clear indication of the Patent Office's desire to advance its position and perhaps have the U.S. Court of Appeals for the Federal Circuit consider the Patent Office's new practice under the Guidelines.<sup>247</sup>

DeGrado has advanced arguments similar to those expressed by the patent bar for years. He argues that *Weber* and *Haas* were correctly decided and do not conflict with 35 U.S.C. § 121 because language of § 121 does not provide a basis for the Patent Office to restrict within a single claim nor to reject a claim.<sup>248</sup> *Weber* confirms that restriction is only proper where there are two or more independent and distinct inventions.<sup>249</sup> DeGrado urges that, “[a] single claim cannot be considered ‘two or more independent and distinct inventions’ because the claim is the invention, as determined by the inventors.”<sup>250</sup>

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<sup>243</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., ORDER FOR FURTHER BRIEFING at 5-9 (June 20, 2011).

<sup>244</sup> 37 C.F.R. § 41.50(d) (2004).

<sup>245</sup> *Id.*

<sup>246</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 7 (May 9, 2011).

<sup>247</sup> Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162, 7,166 (February 9, 2011).

<sup>248</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 7 (May 9, 2011).

<sup>249</sup> *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978).

<sup>250</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 8 (May 9, 2011).

DeGrado further argues that 35 U.S.C. § 112, second paragraph, does not give the Patent Office discretion to require restriction within a single claim.<sup>251</sup> Rather, it “gives the applicant the sole right to define the invention.”<sup>252</sup> DeGrado provided a review of the relevant parts of the *Weber* decision, noting that *Weber* confirmed that it is applicant’s statutory right to define what he, not the examiner, regards as the invention and to have “each claim examined on the merits.”<sup>253</sup>

With regard to the Markush questions raised by the board, DeGrado argues first that there is no statutory basis for rejecting the claims as being an improper Markush grouping.<sup>254</sup> This fact does not seem to be in dispute. Since the decisions in *Weber* and *Haas* holding that rejection under § 121 was improper, the Patent Office has not asserted that it had statutory authority to reject such claims. DeGrado, however, appears to advance a more fundamental question: if the Patent Office is prohibited from rejecting a claim under § 121, can it circumvent that prohibition by rejecting the claim as encompassing an improper Markush group.<sup>255</sup> In *Harnisch* and *Hozumi*, the claims were held to constitute proper Markush groups, and so the propriety of an “improper Markush” rejection was not addressed. However, the courts permit the Patent Office to make other types of non-statutory rejections, such as the obviousness-type double patenting rejection actually at issue in this case.<sup>256</sup> Therefore, it is not inconceivable that the courts would permit the Patent Office to make such a rejection on appropriate facts.

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<sup>251</sup> *Id.*

<sup>252</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 9 (May 9, 2011).

<sup>253</sup> *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978).

<sup>254</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 12 (May 9, 2011).

<sup>255</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 11 (May 9, 2011).

<sup>256</sup> M.P.E.P. § 804 (8<sup>th</sup> ed., Rev. 5, Aug. 2006).

DeGrado further asserts that “there is no per se rule governing unity of invention.”<sup>257</sup> While the Patent Office generally applies the test from *Harnisch*, or more accurately *Hozumi*, there may be other ways in which to establish unity of invention. That said, DeGrado argues that the invention on appeal demonstrates unity of invention under the *Harnisch* and *Hozumi* tests as well as the somewhat different test applied under the Patent Cooperation Treaty (PCT).<sup>258</sup> His arguments focus on the Patent Office’s obligation to examine a claim, regardless of breadth, if it has unity of invention.<sup>259</sup> DeGrado argues that, “[t]he breadth of the formula and the number of compounds are not relevant to deciding whether a Markush claim is proper.”<sup>260</sup> He cites to Judge Rich’s concurrence in *Weber*, indicating that there is “no excuse at all for refusing to examine a broad generic claim – no matter how broad, which means no matter how many independently patentable inventions may fall within it.”<sup>261</sup> Since the Patent Office’s main reason for restricting or rejecting Markush-type claims has been to manage resources and examiner workflow,<sup>262</sup> a decision that broad claims, such as those at issue in this case, possess unity of invention and therefore must be examined in their entirety would place a significant burden on the Patent Office and likely result in increased pendency within Technology Center 1600.

### **III. The Future of Markush Practice under the Guidelines**

The Guidelines were published to assist examiners and practitioners with examination issues under 35 U.S.C. § 112, in particular with all sections of § 112 except first paragraph,

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<sup>257</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 11 (May 9, 2011).

<sup>258</sup> *Id.*

<sup>259</sup> *Id.* at 12-13.

<sup>260</sup> U.S. PATENT APPLICATION NO. 10/801,951, FILED MARCH 17, 2004 TO DEGRADO ET AL., RESPONSE TO ORDER FOR FURTHER BRIEFING at 13 (May 9, 2011).

<sup>261</sup> *Id.* (citing *In re Weber*, 580 F.2d 455, 461 (C.C.P.A. 1978)).

<sup>262</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,992 (proposed August 10, 2007, never enacted).

which is covered in the Patent Office's Enablement<sup>263</sup> and Written Description<sup>264</sup> guidelines and corresponding training materials.<sup>265</sup> The Guidelines shift the focus of Markush practice from restriction to a combination of restriction and rejection of the claims.<sup>266</sup>

While the Guidelines still include restriction of Markush claims in the form of election of species practice,<sup>267</sup> they now instruct the examiner to consider two possible claim rejections.<sup>268</sup> The first of these rejections is the "improper Markush" rejection.<sup>269</sup> The second of is an indefiniteness rejection under 35 U.S.C. § 112, second paragraph.<sup>270</sup> One result of this shift is that the Patent Office has revised its election of species practice.<sup>271</sup> Where the examiner does not find the elected species, he is only required to extend search and examination to those compounds he considers to fall within a proper Markush group<sup>272</sup> rather than the previous practice of extending the search to the extent required to determine patentability of the claim.<sup>273</sup> Another result of this shift is that the examiner's rejections of the claims are appealable, providing applicant with two avenues to challenge the Patent Office's position – petition of the election of species requirement and appeal of the improper Markush rejection. Any rejection

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<sup>263</sup> M.P.E.P. § 2164 (8<sup>th</sup> ed. Rev. 6, Sept. 2007).

<sup>264</sup> Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, 'Written Description' Requirement, 66 Fed. Reg. 1099 (January 5, 2001).

<sup>265</sup> TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH – ENABLEMENT OF CHEMICAL/BIOTECHNICAL APPLICATIONS (AUGUST 1996); WRITTEN DESCRIPTION TRAINING MATERIALS, REVISION 1, MARCH 2008.

<sup>266</sup> Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162, 7,166 (February 9, 2011).

<sup>267</sup> *Id.*

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

<sup>270</sup> *Id.*

<sup>271</sup> *Id.*

<sup>272</sup> *Id.*

<sup>273</sup> M.P.E.P. § 803.02 (8<sup>th</sup> ed., Rev. 5, Aug. 2006).

under 35 U.S.C. § 112, second paragraph also is appealable.<sup>274</sup> As examiners begin applying the Guidelines, it can be expected in certain circumstances applicants will appeal the rejections.

The Patent Office has long based its justification for restricting and/or rejecting a Markush-type claim on the basis that the claim contains independent and distinct inventions.<sup>275</sup> The court in *Harnisch* characterized this concept as “unity of invention.”<sup>276</sup> Where a claim contains independent and distinct inventions, it is said to lack unity of invention. The Guidelines allow examiners to restrict and reject claims where the lack unity of invention.

Although there are likely to be challenges under 35 U.S.C. § 112, second paragraph, the following discussion focuses on challenges related to improper Markush rejections. One such challenge will likely be whether the language of the test established in *Harnisch* is the only test for determining unity of invention. The courts will likely hold that there is no single test for determining whether unity exists or whether a Markush grouping is proper and that each case must be considered on its own facts.

In two recent cases, not relating to Markush practice, the Supreme Court held that tests established by the Federal Circuit were not exclusive.<sup>277</sup> The first of these cases was *KSR Int'l Co. v. Teleflex, Inc.*<sup>278</sup> decided in 2007. *KSR* dealt with the Federal Circuit’s longstanding test for evaluating the obviousness of patent claims known as the teaching-suggestion-motivation

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<sup>274</sup> 37 C.F.R. § 41.31(a) (2008). *Who may appeal and how to file an appeal*. (1) Every applicant, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

<sup>275</sup> *In re Weber*, 580 F.2d 455, 456 (C.C.P.A. 1978); *In re Haas*, 580 F.2d 461, 463 (C.C.P.A. 1978); *In re Harnisch*, 631 F.2d 716, 719 (C.C.P.A. 1980), Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,993 (proposed August 10, 2007, never enacted).

<sup>276</sup> *In re Harnisch*, 631 F.2d 716, 719 (C.C.P.A. 1980).

<sup>277</sup> Circuit Court for the Federal Circuit. The Federal Circuit replaced the Court of Customs and Patent Appeals in 1982.

<sup>278</sup> *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).



(TSM) test “under which a patent claim is only proved obvious if ‘some motivation or suggestion to combine the prior art teachings’ can be found in the prior art the nature of the problem, or the knowledge of a person having ordinary skill in the art.”<sup>279</sup> The Supreme Court rejected the Federal Circuit’s application of the TSM test as too rigid an approach.<sup>280</sup> The Court held that its precedent established that the analysis for considering obviousness should be flexible and encompass more than one approach.<sup>281</sup> Similarly, in 2010, the Supreme Court found the Federal Circuit’s “machine or transformation test” for determining the patent eligibility of a process to be only one of several possible tests for determining patent eligible subject matter.<sup>282</sup> An en banc panel of the Federal Circuit held that the only proper test for determining whether a process was directed to patentable subject matter under 35 U.S.C. § 101 was the machine or transformation test “under which a process is directed to patentable subject matter if (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”<sup>283</sup> It found *Bilski*’s claims did not meet the test.<sup>284</sup> The Supreme Court upheld the Federal Circuit’s judgment, but held that while the machine-or-transformation test is an important test for determining patent eligibility, it is not the exclusive test.<sup>285</sup> Based on these decisions, it is likely courts will find that there is no single test for determining whether a claim lacks unity or is a proper Markush claim. Even in *Harnisch*, the court held that each case had to be considered on its own facts.<sup>286</sup>

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<sup>279</sup> *Id.* at 407 (citing *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323-1324 (CA Fed. 1999)).

<sup>280</sup> *Id.* at 415.

<sup>281</sup> *See, Id.* at 415.

<sup>282</sup> *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>283</sup> *Id.* at 3220.

<sup>284</sup> *Id.*

<sup>285</sup> *Id.* at 3259.

<sup>286</sup> *In re Harnisch*, 631 F.2d 716, 722 (C.C.P.A. 1980).

In *Harnisch*, the claims were found to have unity of invention. All of the claimed compounds were all useful for the same purpose and all had a single structural similarity.<sup>287</sup> The court found this adequate to constitute a proper Markush group.<sup>288</sup> The board in *Hozumi* used a more stringent test, requiring that the claims have a common functional utility and a substantial, structural feature that is essential for that utility.<sup>289</sup> Both tests could be appropriate under particular factual circumstances.

Another test the court may find useful for determining unity of invention is the PCT test.<sup>290</sup> Under the PCT Guidelines,<sup>291</sup> where an application contains more than one invention, the inventions must be linked to form a general inventive concept.<sup>292</sup> Inventions have such a general inventive concept when they contain a “special technical feature” that defines over the prior art.<sup>293</sup> In evaluating unity of invention, the international searching authority first considers the claims on their face, before any search is performed.<sup>294</sup> If it is clear that the inventions have no technical feature in common, unity is lacking.<sup>295</sup> This is akin to the U.S. concept of independent

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<sup>287</sup> *Id.*

<sup>288</sup> *Id.*

<sup>289</sup> *Ex parte Hozumi*, 3 U.S.P.Q.2d 1053 (B.P.A.I. 1053).

<sup>290</sup> Patent Cooperation Treaty, Rule 13.2 and the International Search and Preliminary Examination Guidelines (November 1, 2011). Patent Cooperation Treaty (PCT) Rule 13.2 and Chapter 10 of the International Search and Preliminary Examination Guidelines (ISPE) control determination of unity of invention for international applications filed under the PCT. Rule 13.2 states that “[w]here 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.

<sup>291</sup> International Search and Preliminary Examination Guidelines, Chapter 10 (November 1, 2011).

<sup>292</sup> ISPE at 10.01.

<sup>293</sup> *Id.*

<sup>294</sup> *Id.* at 10.03.

<sup>295</sup> *Id.* (*a priori* lack of unity).

inventions. If, however, the inventions appear to be linked by a common technical feature, a search is performed. The results of such a search may indicate that the common technical feature does not define over the prior art, in such case the claims are considered to lack unity.<sup>296</sup> This is akin to the U.S. concept of distinct inventions. Adopting a PCT-like standard has been urged in the past to promote global harmonization.<sup>297</sup> However, it is not clear that such a standard is workable in the U.S. The U.S. standard of obviousness is based on structural similarity providing similar function, while the PCT lack of inventive step standard is based on a problem-solution approach.<sup>298</sup> Further, the special technical feature analysis focuses on the similarity of a particular part of the molecule and how it is different from the prior art.<sup>299</sup> This is directly contrary to CCPA precedent that requires consideration of the claimed compounds as a whole.<sup>300</sup>

Another standard for unity of invention could follow a typical obviousness analysis. The Patent Office asserts that a Markush-type claim is directed to independent and distinct inventions where “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

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<sup>296</sup> *Id.* (*a posteriori* lack of unity).

<sup>297</sup> JAPAN INTELLECTUAL PROPERTY ASSOCIATION COMMENTS (OCTOBER 5, 2007) ON EXAMINATION OF PATENT APPLICATIONS THAT INCLUDE CLAIMS CONTAINING ALTERNATIVE LANGUAGE, 72 FED. REG. 44,992, 1; USPTO STUDY ON RESTRICTION REFORMS (THE GREEN PAPER ON RESTRICTION); Notice of Availability of and Request for Comments on Green Paper Concerning Restriction Practice, 70 Fed. Reg. 32761 (June 6, 2005) (Request for Comments on USPTO Green Paper).

<sup>298</sup> Regional Seminar on Intellectual Property and Information Technology, organized by the World Intellectual Property Organization 2 (Moscow, July 10 to 12, 2001) (describing the examination of inventive step). Examination of Inventive Step follows a Problem and Solution Approach having the following steps: (1) “Determine the closest prior art;” (2) “Determine the differences between the claimed invention and the closest prior art;” (3) “Identify the effect of said difference with respect to the closest art;” (4) “Deduce the objective problem from said effect (i.e. define a problem which is solved by said differentiating features starting from the closest prior art);” (5) Determine if “there [is] an indication in the prior art that would prompt the skilled person to solve the problem in the way the invention does.

<sup>299</sup> *See*, ISPE at Chapter 10.

<sup>300</sup> *In re Harnisch*, 631 F.2d 716, 722 (C.C.P.A. 1980)

under 35 U.S.C. 103 with respect to the other member(s).”<sup>301</sup> Thus, if members of a Markush group would render one another obvious, they should be found to have unity of invention. The Patent Office said as much in its 2007 proposed rules, discussed *supra* in § II-C.<sup>302</sup> M.P.E.P. § 2144.09 states that, “a *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities.”<sup>303</sup> Thus, if the compounds are sufficiently close in structure for the examiner to make an obviousness rejection, then no lack of unity should be found absent a clear indication on the record that different compounds in the claim have different utilities.

As rejections are challenged, creative patent attorneys and judges are likely to develop additional tests for determination of unity. This will initially lead to more confusion, increased prosecution, and delays in obtaining protection due to the appeal process. However, as court decisions begin to establish precedent, applicants and examiners alike will gain clarity and be able to determine what standards should apply to individual claims. That said, an appellate approach is not a quick fix and will not reduce claim complexity or decrease pendency, two of the Patent Office’s goals in establishing procedures for addressing Markush claims,<sup>304</sup> in the short term.

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<sup>301</sup> M.P.E.P. § 803.02 (8<sup>th</sup> ed., Rev. 5, Aug. 2006).

<sup>302</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,997 (proposed August 10, 2007, never enacted).

<sup>303</sup> M.P.E.P. § 2144.09 (8<sup>th</sup> ed., Rev. 6, Sept. 2007). A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. “An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979).

<sup>304</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. at 44,992 (proposed August 10, 2007, never enacted).

To the extent that the standard set out in the Guidelines for determining whether a Markush group is improper is confirmed, there are likely to be further challenges regarding what constitutes a single structural similarity and what is necessary for a common use. The Guidelines state that “[m]embers of a Markush group share a ‘single structural similarity’ when they belong to the same recognized physical or chemical class or to the same art-recognized class.”<sup>305</sup> This is consistent with case law.<sup>306</sup> However, disputes are likely to arise over whether a specific group of compounds belong to the same class, and it remains to be seen whether nearly thirty years after *Harnisch*, the courts would apply the same standard.

The Guidelines further state that members of a Markush group share a common use “when they are disclosed in the specification or known in the art to be functionally equivalent.”<sup>307</sup> Disputes also are likely to arise over what is meant by functionally equivalent. One standard that might be applied by the courts is the utility standard of § 101 as urged by the Patent Office in its 2007 Proposed Rules.<sup>308</sup> Another standard may be a simple class of use test, i.e. all of the compounds are dyes or all are catalysts for the same type of reaction. To that end, it is not clear whether compounds having a common mechanism of action will be considered functionally equivalent, or if compounds having the same type but different degrees of activity would be functionally equivalent.

#### **IV. Summary**

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<sup>305</sup> Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. at 7,166.

<sup>306</sup> *In re Harnisch*, 631 F.2d 716, 719 (C.C.P.A. 1980) (discussing the Solicitor’s brief reviewing previous Markush decisions – “the materials set forth in the ‘Markush group’ ordinarily must belong to a recognized physical or chemical class or to an art-recognized class; and ... the claimed group must not be “repugnant to accepted principles of scientific classification.”)

<sup>307</sup> *Id.*

<sup>308</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992 (proposed August 10, 2007, never enacted).

Examination of Markush and other alternative claims has been a difficulty for the Patent Office as far back as *Ex parte Eagle*.<sup>309</sup> As more complex technologies have emerged, so too have patent claims become more complex. At the same time, the Patent Office is facing a huge backlog of applications and ever-increasing pendency.<sup>310</sup>

In the past, the Patent Office has adopted or proposed various approaches to improve the volume and complexity of applications faced by examiners.<sup>311</sup> To date none have been particularly successful. The new Guidelines show promise in part because they attempt to meet the tests laid out by the court in previous Markush cases<sup>312</sup> and in part because they address the concerns of applicants to appeal such decisions to the judicial system.

It is doubtful that the Guidelines will have much impact in reducing pendency in the near term. However, over time they should result in improved examination and clarity for both the examiners and applicants as to the scope and content of Markush-type claims.

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<sup>309</sup> *Ex parte Eagle*, 1870 C.D. 137 (Comm'r Dec. 1870).

<sup>310</sup> Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,992 (proposed August 10, 2007, never enacted).

<sup>311</sup> *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978), footnote 3; and Practice Re Markush-type Claims, 922 O.G. 1016 (May 1, 1974); M.P.E.P. § 803.02 (8<sup>th</sup> ed., Rev. 5, August 2006); Examination of Patent Applications that Include Claims Containing Alternative Language, 72 Fed. Reg. 44,992, 44,992 (proposed August 10, 2007, never enacted); Supplementary Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7,162, 7,166 (February 9, 2011).

<sup>312</sup> *In re Weber*, 580 F.2d 455 (C.C.P.A. 1978); *In re Haas*, 580 F.2d 461 (C.C.P.A. 1978); *In re Harnisch*, 631 F.2d 716 (C.C.P.A. 1980.)