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OFFICE OF PETITIONS

In re Application of Magnus PFAHL et al. Application No. 10/224,288 Filed: August 19, 2008 Attorney Docket No.: 13099.0017U2

ON PETITION

This is a decision on the petition filed July 11, 2006, under 37 CFR 1.181(a)(3) requesting that the Director exercise his supervisory authority and overturn the decision of the Director, Technology Center 1600 (Technology Center Director), dated May 9, 2006, which refused to withdraw the restriction requirement of March 11, 2005.

A Notice of Abandonment was mailed March 4, 2009. As the application is now abandoned, the petition to overturn the decision of the Technology Center Director is **DISMISSED** as moot.

Telephone inquiries concerning this decision should be directed to David A. Bucci at (571) 272-7099.

Anthon y Knight Director Office of Petitions

	Annulis stinu bla	A	
	Application No.	Applicant(s)	
Notice of Abandonment	10/224,288	PFAHL ET AL.	
Notice of Abandonment	Examiner	Art Unit	
	PAUL V. WARD	1624	
The MAILING DATE of this communication app			
This application is abandoned in view of:			
1×1 Applicant's failure to timely file a proper reply to the Offic	e letter mailed on 11 August 2005		
 1. Applicant's failure to timely file a proper reply to the Office letter mailed on <u>11 August 2005</u>. (a) A reply was received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the period for reply (including a total extension of time of month(s)) which expired on 			
(b) A proposed reply was received on, but it does	not constitute a proper reply under 3	7 CFR 1.113 (a) to the final rejection.	
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).			
(c) A reply was received on but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non- final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).			
(d) 🖾 No reply has been received.			
2. Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).			
(a) ☐ The issue fee and publication fee, if applicable, was received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).			
(b) The submitted fee of \$ is insufficient. A balanc	e of \$ is due.		
The issue fee required by 37 CFR 1.18 is \$ The publication fee, if required by 37 CFR 1.18(d), is \$			
(c) The issue fee and publication fee, if applicable, has not been received.			
3. Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).			
(a) ☐ Proposed corrected drawings were received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the period for reply.			
(b) I No corrected drawings have been received.			
4. The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.			
5. The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.			
6. The decision by the Board of Patent Appeals and Interference rendered on and because the period for seeking court review of the decision has expired and there are no allowed claims.			
7. 🔀 The reason(s) below:			
Please note an Interview Summary is attached and is to be mailed with this file.			
/James O. Wilson/	/PAUL V WARD/		
Supervisory Patent Examiner, Art Unit 1624	Examiner, Art Unit 1624		
Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term. U.S. Patent and Trademark Office			
	of Abandonment	Part of Paper No. 20090301	



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ATTORNEY DOCKET NO. 13099.0017U2

TRADE OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

PFAHL et al.

Application No. 10/224,288

Filed: August 19, 2002

Confirmation No. 8436

Group Art: 1623

Examiner: Ward, Paul V.

FOR: **"OXIME DERIVATIVES FOR THE TREATMENT OF DYSLIPIDEMIA AND HYPERCHOLESTEREMIA"**

PETITION TO REVIEW A DECISION OF A TECHNOLOGY CENTER DIRECTOR

Mail Stop Petition Commissioner for Patents c/o Deputy Commissioner for Patent Examination Policy P. O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. Customer Number 23859

July 07, 2006

Sir:

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This Petition under the authority of 37 C.F.R. §1.181 and/or MPEP § 1002.02(b) (15) is in response to the Decision of the Director of Technology Center 1600 issued May 09, 2006, which denied "Applicants Request to Reconsider Petition to Withdraw Restriction Requirement" filed February 28, 2006. Applicants' Request and previous petitions sought relief from the Examiner's actions in the Office Action mailed March 11, 2005, to impose Restriction Requirements that attempted to improperly subdivide Applicants individual claims into subclaims.

Applicants hereby respectfully Petition to the Office of the Deputy Commissioner for

Patent Examination Policy, under the authority of 37 C.F.R. §1.181 and/or MPEP § 1002.02(b)

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(15), for review of the May 09, 2006, and previous Decisions of the Director of Technology Center 1600, because

(1) the Decisions mischaracterize and ignore arguments presented in Applicants' Petition, (2) the May 09, 2006 Decision asserts, contrary to clear facts on the record, that no rejection was made under the authority of 35 USC 121. The earlier December 28, 2005 Decision misquoted, misinterpreted, and ignored binding law that clearly denies the authority of the Commissioner to subdivide a single claim under 35 U.S.C. § 121, (3) the Examiner never mentioned or addressed the potential for restrictions based on lack of Unity of Invention and/or MPEP § 803.02. The subsequent Decisions fail in their after-the-fact attempts to meet their burden to show the absence of Unity of Invention of any one of Applicants' claims, so as to be able to examine them as "improper Markush groups" under the procedure of MPEP § 803.02. Even if the Office's burdens on the Unity of Invention issue had arguendo been met, which they have not, the restriction requirement imposed by the Examiner does not actually follow the election of species examination procedure described in MPEP § 803.02, but instead attempts to impose an ad-hoc and legally improper substantive subdivision of Applicants claims into subclaims, an action, which would violate Applicants' rights under 35 U.S.C. § 112, second paragraph, and

(4) the examiner and both Decisions attempt to justify the Restriction Requirement based on "burden to search" arguments that have been clearly rejected by the Courts.

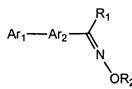
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FACTS AND HISTORY

Applicant's original 26 claims related to "oxime" compounds having the formula illustrated below, and uses thereof related to the treatment of diabetes and/or related metabolic diseases:



the claims recite that the Ar_1 and Ar_2 residues can be substituted aryl or heteroaryl residues. See the record.

Applicants' complaints result from the Office Action mailed March 11, 2005, which attempted to impose a Restriction Requirement of Applicants' claims into 13 separate Restriction Groups, each of which Restriction Groups purported to subdivide each of Applicants original 26 claims into multiple subclaims, based on the alternative classifications of the Ar₁ and Ar₂ residues as aryl or heteroaryl groups. Applicant's response filed May 05, 2006 traversed the restriction requirement on many of the grounds discussed below, asserting that a restriction requirement that subdivided individual claims into subclaims was legally improper under 35 USC 121, the applicable case law of the CCPA and/or Federal Circuit, as well as the relevant portions of MPEP, and asserted that the Examiner had failed to meet his burden to show the claims lacked Unity of Invention, so as to be examinable under the procedure of MPEP § 803.02. The Office Action mailed August 11, 2006 maintained and finalized the original Restriction Requirement.

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On October 07, 2005, Applicants filed a response that included a Petition to Withdraw the Restriction Requirement that again traversed the restriction requirement on many of the grounds discussed above and below. A Decision on Applicant's original Petition issued December 28, 2005, and denied Applicants' Petition to Withdraw the Restriction Requirement. On February 28, 2005, Applicants filed with the Director of Technology Group 1600 a Request for Reconsideration of the December 28, 2005 Petition Decision that asserted almost all the arguments recited again below. On May 09, 2005, the Director of Technology Center 1600 mailed the Petition Decision complained of herein.

RESPONSE

Applicants first note that the Decision of May 09, 2006 literally repeats most of the text of the Decision issued December 28, 2005 (starting on page 1 of the May 09, 2006 Decision at "BACKGROUND," up to the bottom of page 3 of the May 09, 2006 Decision). The new arguments of the May 09, 2006 Decision appear to be confined to the text at the top half of page 4 of the May 09, 2006 Decision. Accordingly, much of Applicant's response below is duplicative of Applicants previous Responses, but Applicants have attempted to identify and/or differentiate and/or address the arguments newly raised in the May 09, 2006 Decision.

1. <u>THE DECISIONS MISCHARACTERIZE AND/OR IGNORE APPLICANTS'</u> <u>ARGUMENTS</u>

The December 28th Decision mischaracterized Applicants' arguments at least twice, and the May 09, 2006 Decision repeats and/or only slightly modifies the earlier mischaracterizations.

First, both Decisions state that "Applicants also appear to argue that aryl and heteroaryl are sufficiently similar that they should be searchable together." Applicants made no such contention, and have explicitly denied the same. The May 09, 2006 Decision acknowledges

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Applicants denial of the allegations, but then asserts on line 4 of page 4 that Applicant's position is "in effect such an argument." This again mischaracterizes Applicants' position.

While Applicants recognize the Office's concerns related to "Burden to Search" questions, Applicants' actual position, earlier and now, is that the Courts have made it clear <u>that</u> <u>the Commissioner's concerns regarding "Burden to Search" issues must yield to Applicants</u> <u>statutory rights, as a matter of law</u>. *See* further discussion under Section 4 below.

Second, both Decisions contend that "Applicants' arguments are primarily based on consideration of MPEP § 803.02 which applies only to election of species within an elected group of compounds." Applicants deny such contention, and note that these assertions conflict with other assertions of both Decisions that "Applicants argue that the restriction group is improper in view of the decisions of the CCPA in *In re Weber*, and *In re Hass*, and others."

Applicants' original Petition referenced MPEP § 803.02, at least in part, because it constituted evidence that the Office has recognized the applicability of, *inter alia*, the *In re Weber*, *In re Hass*, and *In re Harnisch* cases discussed at length by Applicants, but Applicants' arguments are by no means "primarily based" on MPEP § 803.02. To the contrary, many of Applicants arguments (then and now) were based on the statute referenced in the original Office Action (35 U.S.C. § 121), as repeatedly interpreted by the Courts, as exemplified by cases such as *In re Weber*, *In re Hass*, and *In re Harnisch*, and subsequent cases, *see* Section 2 below.

Applicants also referenced MPEP § 803.02 because it evidences the Commissioner's policy that in order to challenge a Markush claim on the legal grounds that it is an "improper" Markush claim, the Examiner had the burden of showing that the claims lack Unity of Invention, a burden which was not addressed in any fashion by the Examiner in either his original

Restriction requirement or the Office Action "finalizing" the Restriction Requirement issued August 11, 2005. Applicant raised and addressed this issue on pages 13 and 14 of their May 05, 2005 response, and amplified their responses on this issue in all subsequent Petitions, including the current one. See Section 3 below.

The December 28th Decision also failed to substantively address the issue of the applicability of MPEP § 803.02 and/or the Unity of Invention standard for proper Markush groups, stating only brief conclusory allegations regarding Unity of Invention that were unsupported by any reasoning or evidence for the assertions. Only now, on page 4 of the May 09, 2006 Decision, does the Commisioner attempt to substantively and retroactively address the question of Unity of Invention, and it does so by misquoting and misinterpreting the relevant law, yet still fails to carry the burden of the Office on this question. See Section 3 below.

Even if the Examiner and/or Commissioner had *arguendo* carried their burden with respect to the Unity of Invention question, which they did not, the Examiner's proposed restrictions did <u>not</u> follow the election of species examination procedure actually recited in MPEP § 803.02, but instead attempted to impose an *ad hoc* and legally improper subdivision of Applicants claims into subclaims. *See* Section 3 below.

2. <u>BINDING LAW HOLDS THAT THE COMMISSIONER HAS NO LEGAL</u> <u>AUTHORITY UNDER 35 U.S.C. § 121 TO SUBDIVIDE AN INDIVIDUAL</u> <u>CLAIM</u>

The May 09, 2006 Decision asserts on page 4, line 12, for the first time, that "Here no rejection of a claim under 35 U.S.C. 121 has been made." This assertion obviously contradicts the relevant statement of the original Office Action, dated March 11, 2005, that "Restriction ... is

required under 35 U.S.C. § 121." *See* page 2, line 1 of the Office Action. Clearly, this new assertion that "no rejection of a claim under 35 U.S.C. 121 has been made" is incorrect when compared to the plain facts, and the relevant case law.¹ Applicants assert this statement of the May 09, 2006 Decision has the effect of abandoning the only legal source of authority actually cited by the Examiner for the asserted restriction requirements.

No source of ultimate legal authority for the Restriction Requirement other than 35 U.S.C. § 121 was subsequently identified by the Examiner in the Office Actions, or the Director in the December 28, 2005 Decision, despite Applicants' multiple written requests that they do so (see for example Applicants May 05, 2005 request on page 9, lines 3-5).

Applicants reiterate that it is quite clear under the law, as discussed in their previous Responses and Petitions, that the Commissioner simply does NOT have the authority to subdivide a single claim under 35 U.S.C. § 121. The *Weber* and *Hass* courts, as quoted again below, made this point clear, as a matter of law:

As a general proposition, an applicant has a right to have each claim examined on the merits. . . If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.²

(cont'd on next page)

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¹ As Applicants have previously pointed out, the *In re Hass* Court made it clear that a restriction requirement allegedly justified by the Examiner under 35 USC 121 "did in fact amount to a rejection," and that a withdrawal of claims from prosecution pursuant to such a restriction requirement under 35 USC 121 "cannot properly be characterized as merely a 'requirement' or 'objection'.... An examiner's adverse action of this nature is a rejection, a denial of substantive rights." *In re Haas*, 486 F.2d 1053, 1056 (CCPA 1973).

² Applicants have related concerns for this and other applications currently under prosecution. The Office recently instituted a policy that no claim to a method of treatment can be allowed unless it is supported by examples. If the current restriction requirement is upheld, so that compounds from a single independent compound claim comprising aryls are subdivided away from compounds comprising heteroaryls, Applicants' dependent method of

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It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

In re Weber at 458, (underlining added for emphasis).

In *Haas II* (see note 6, supra), this court held that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made.

In re Harnisch at 721, (underlining added for emphasis).

These holdings have been reaffirmed by the Federal Circuit in *In re Watkinson*,³ which stated "Under *In re Weber*, 580 F.2d 455, 458, 198 USPQ (BNA) 328, 332 (CCPA 1978), and *In re Haas*, 580 F.2d 461, 464, 198 USPQ (BNA) 334, 336 (CCPA 1978), it is *never* proper for an examiner to reject a Markush claim under 35 U.S.C. § 121. Section 121 simply does not authorize such a rejection. *Id.*" (Italics in original).

treatment claims would also be similarly subdivided. Applicants' specification may not include examples from each and every sub-genus of compounds recited in the method of treatment claims that is subsequently and arbitrarily subdivided pursuant to the Commissioner's restriction requirements. This could easily result in a situation in which the Restriction Requirement, which is solely a procedural/administrative convenience for the Commissioner, would result in a substantive denial of the patentability of some of the resulting subdivided method of treatment claims. Such an outcome <u>cannot</u> be a permissible result under the law.

³ See In re Watkinson, 900 F2d 230, 232 (Fed Cir. 1990). The Board of Patent Appeals and Interferences has also stated that "Therefore, the examiner rejected Markush-type claim 79 in the parent application under 35 USC § 121. There is no doubt that the examiner's rejection of claim 79 in the original application under 35 USC § 121 was improper; In re Weber, supra; In re Haas I, supra." See Ex Parte Holt, 214 USPQ 381, Board of Patent Appeals and Interferences, 1982.

3. <u>THE EXAMINER AND DECISIONS FAILED TO SHOW THE LACK OF</u> <u>UNITY OF INVENTION OF APPLICANTS CLAIMS, AND DID NOT FOLLOW</u> <u>THE EXAMINATION PROCEDURE OF MPEP 803.02</u>

MPEP § 803.02 describes an election of species procedure for the step-wise examination of allegedly "improper" Markush Groups and/or claims, provided the examiner initially

demonstrates the relevant Markush claims lack Unity of Invention.

The December 28, 2006 Decision failed to properly address one of the Applicants' major

legal contentions, namely that the Examiner completely failed to address any initial burden of

proof to show that any of Applicants' individual claims lack Unity of Invention, so as to be

properly examinable under MPEP § 803.02 and/or the applicable case law relating to "improper"

Markush groups.⁴ MPEP § 803.02 (which is admitted by the Decision to primarily relate to an

election of species procedure for examining Markush groups) mentions that under the case law:

...it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

⁴ Aside from questions of authority for restriction under 35 U.S.C. § 121 discussed above, *In re Harnisch* also addressed potential questions of "improper Markush grouping", stating "we think it should be clear from our actions in Weber and Haas II that we there recognized the possibility of such a thing as an "improper Markush grouping." We were and are aware that it does not have a specific statutory basis." "...there remains a body of Markush-practice law regarding Markush-type claims, particularly in the chemical field, concerned more with the concept of what might be better described as the concept of unity of invention." The *Harnisch* Court found that the compounds claimed with Markush groups were all coumarin compounds, and that they shared a utility as dyes, and the Court held that "we consider the claimed compounds to be part of a single invention so that there is unity of invention as was held to be the case in *Ex parte Brouard*, *supra*, 201 USPQ at 540. The Markush groupings of claims 1 and 3-8 are therefore proper." *In re Harnisch* at 721-721.

The Examiner made no attempts in either Office Action to reject Applicants' claims as "improper Markush groups," made no references to MPEP § 803.02, or Unity of Invention, and/or made no attempt to meet his burden to show the claims lacked Unity of Invention.

The December 28, 2006 Decision, addressing the question for the first time, merely made a brief conclusory allegation that "The examiner here has restricted the compounds as well as the methods claimed based upon the compound's structures into four separate chemical compound types. Within each of these four groups unity of invention exists, but not between them." That conclusory assertion completely failed to provide or identify any reasoning or evidence to support its contention, and hence failed to meet its burden to show the claims lacked Unity of Invention.

Even if the Examiner or Director had, *arguendo*, carried their burden on the Unity of Invention question, the Restriction Requirement issued by the Examiner does not follow the election of species examination procedure actually described in MPEP § 803.02⁵, but instead attempts to substitute an *ad hoc* and legally improper restriction requirement that subdivides Applicants' individual claims into subclaims. This attempt to subdivide Applicants' individual claims violates Applicants rights under 35 USC 112, 2nd paragraph, which "allows the inventor to claim the invention as he contemplates it." *In re Weber*, 580 F2d at 458.

Both Decisions do however allege alternative justifications for the Examiner's improper subdivision of Applicants claims into subclaims, in purported connection with Applicants'

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⁵ The election of species procedure actually described in MPEP provides for an election of species from the Markush Group, followed by an initial examination of the elected species over the prior art. If no prior art that anticipates or makes the elected species obvious is discovered, the procedure calls for expansion of the prior art search and examination to non-elected species, until appropriate prior art has been found and a rejection formulated. The Examiner of the current case has <u>not</u> proposed to follow this procedure.

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reliance on the *In re Weber* and *In re Hass* cases. The Decisions allege that "The principal enunciated in these court decisions is that compounds having a substantial common core wherein the compounds differ only in the radicals attached to the common core and wherein the activity of the compound is provided by the core have unity of invention and should not be subjected to restriction requirement."

The May 09, 2006 Decision attempts to elaborate on a "Common Core" theory, stating on page 4, lines 24-26, that "the only common structure, as noted above, is insignificant when compared to the ring structures and would not ...form a substantial structural feature for the compound/composition.

These "interpretations" of *In re Weber* and *In re Hass* as supporting some sort of "common core" basis for restriction are unsupported by any citation of reasoning or quotations from the cases themselves. Applicants can identify no support in those cases for this asserted "interpretation." To the contrary, such a "common nucleus" argument was explicitly asserted by the Examiner in the *In re Weber* case, but the examiner's actions and arguments were rejected by the Court of Customs and Patent Appeals. *See In re Weber*, 580 F2d at 457-458.

The Decisions attempt to interpret and/or apply the recitations of MPEP § 803.02, and/or the cases cited above, that the compounds must share a "substantial structural feature" so narrowly as to ignore the many structural similarities shared by the aryl and heteroaryl residues of Applicants' Ar1 and Ar2 groups. One of ordinary skill in the art would obviously recognize, despite a substitution of nitrogen or oxygen atoms for carbon atoms in the aromatic Ar₁ and Ar₂ aryl rings, the structural features that are common in these rigid, planar, conjugated, aromatic rings. Furthermore, the narrow substructural restrictions advocated in the Decisions are contrary

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to other binding law, as exemplified by *In re Harnisch*, 631 F2d 716, 722 (CCPA 1980) wherein it was stated, while discussing *In re Jones*, 162 F2d 479 (CCPA 1947), that

"The court noted that in any Markush group the compounds 'will differ from each other in certain respects.' It laid down the proposition, with which the PTO agrees in its MPEP, 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."

In view of this requirement that the compounds be consideres "as wholes" it is clearly improper for the Examiner or Director to arbitrarily demand an selection of either aryl or heteroaryl alternatives for isolated Ar1 and Ar2 radicals, and/or require an "identical core," while ignoring the many other overall structural similarities of the of the claimed oxime compounds that are readily apparent to one of ordinary skill in the art, when the compounds are properly considered <u>as a whole</u>.

The May 09, 2006 Decision also misquotes, misinterprets, and misapplies the law of "improper Markush Groups," the relevant cases, MPEP § 803.02, and Unity of Invention. On page 4, at line 8, the May 09, 2006 Decision asserts that "Unity of Invention is based on there being a common property or use AND a significant common structural element essential to that property or use." This is a self serving and factually inaccurate recitation of the actual quotations from the caselaw and/or MPEP § 803.02. MPEP actually states that "Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility." Neither the cases nor MPEP § 803.02 mention "properties" as asserted in the May 09, 2006 Decision.

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In response to Applicants' several arguments that substitution of oxygen or nitrogen atoms into planar aryl rings leaves many structural and geometrical features of those planar aromatic rings intact, the May 09, 2006 Decision argues on page 4, lines 17-18, that such substitution "does change the properties of the compound /composition." This "changed properties" argument is simply irrelevant to the standard for Unity of Invention that is actually recited in MPEP § 803.02, which does not mention "properties" at all.

In view of the arguments above, it is clear that the Decisions ignored, misinterpreted, and misapplied the law of "improper Markush Groups" and "Unity of Invention." Moreover, none of these misquotations or mis-interpretations of the law can however hide the fact that neither the Examiner, nor either of the two Decisions, properly addressed or met their burden of proof on the Unity of Invention issue, and as such failed to raise or support a proper *prima facie* justification for rejecting Applicants claims for having "improper Markush groups" or for imposing an improper subdivision of Applicants claims into subclaims that violates Applicants' rights under 35 USC 112, 2nd paragraph, to claim the inventions as they see fit.

4. <u>THE DECISIONS ATTEMPT TO JUSTIFY THE "RESTRICTIONS" ON</u> <u>"BURDEN TO SEARCH" ARGUMENTS THAT HAVE BEEN REJECTED BY</u> <u>THE COURTS</u>

Both the Decisions state that "The examiner also provided proper reasons for the restriction requirement including burden on the Office to search and examine all possible inventions claimed." While Applicants are not unsympathetic to such concerns of the Office, the Courts have made it absolutely clear that such a "Burden" argument cannot prevail over an applicant's legal rights granted by the statute:

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Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. n8 But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount. We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber at 458-459.

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Accordingly, "Burden to search" arguments such as those alleged by the Examiner and the Decisions have been clearly rejected by Court decisions that bind the Commissioner.

CONCLUSION

Applicants deny, via the arguments presented above, the legal authority of either the Examiner or the Commissioner to unilaterally restrict an individual claim into sub-claims under the authority 35 U.S.C. § 121, or unilaterally force amendment of the claims of the application in a manner that is the effective equivalent thereof, as the Examiner has done.

Neither the Examiner nor the two Decisions properly raised, properly interpreted, or identified proper evidence or reasoning to support a prima-facie subdivision of Applicants' claims as an "improper Markush Group" lacking Unity of Invention, as understood from the cases cited herein, and/or MPEP § 803.02, and hence have not provide a proper *prima facie* basis for subdividing individual claims on such a legal theory. Moreover, even if the Examiner or Decisions had, *arguendo*, shown the claims lacked Unity of Invention, MPEP § 803.02 does NOT authorize a legally improper substantive subdivision of an Applicants' claim, as imposed by the examiner, an action, which would violate Applicants' rights under 35 U.S.C. § 112,

In view of the arguments recited above, the original Restriction Requirement was legally improper, and the two Decisions of the Director of Technology Center upholding that restriction requirement are erroneous, and should be withdrawn.

It is noted that the CCPA has unambiguously held that such an adverse action by the Examiner or the Commissioner on the restriction requirements at issue here are appealable, since they are deemed equivalent to a substantive rejection. *See In re Haas*, 486 F.2d at 1056, 179 USPQ at 626, CCPA 1973. Therefore, in the event that this Petition is not granted, Applicants reserve the right to appeal this issue to the Board of Patent Appeals and Interferences.

Applicants have already replied to the substantive rejections of the Office Action dated August 11, 2005, in their response filed October 7, 2005, even though Applicants declined to amend the original claims to comport with the original improper restriction requirement, and Applicants reserve the right to continue to do so.

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After investigation, Applicants are uncertain, but believe the fee of \$130.00 due under 37CFR 1.182 and/or 37 CFR 117(h) may be due. Applicants therefore include herewith a Credit Card Payment form in the amount of \$130.00. If there are any additional fees due in connection with this Petition, please charge any such additional fees to our Deposit Account No. 14-0629. If the \$130.000 fee submitted herewith is not required, please credit the payment to the same Deposit Account.

Respectfully submitted,

Mupl Mark A. Murphy, Ph.D

Mark A. Murphy, Ph.D Registration No. 42,915

NEEDLE & ROSENBERG, P.C. Customer Number 23859 (678) 420-9300 Phone (678) 420-9301 Fax

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8 I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to:Mail Stop Petition, c/o Deputy Commissioner for Patent Examination Policy, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below. Mark A. Murphy July 2006

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NEEDLE & ROSENBERG, PC SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915

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: PETITION DECISION
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This is in response to the renewed petition under 37 CFR 1.144, filed February 28, 2006, requesting withdrawal of an improper restriction requirement.

BACKGROUND

The file history below is identical to that in the previous decision and is included on for reference purposes.

A review of the file history shows that this application was filed under 35 U.S.C. 111 on August 19, 2002, and contained claims 1-26. In a first Office action, mailed March 11, 2005, the examiner set forth a restriction requirement, dividing the claims into 13 groups, as follows:

Group I, claim1, compounds where Ar₁ is aryl and Ar₂ is aryl;
Group II, claim 1, compounds where Ar₁ is aryl and Ar₂ is heteroaryl;
Group III, claim 1, compounds where Ar₁ is heteroaryl and Ar₂ is aryl;
Group IV, claim 1, compounds where Ar₁ is heteroaryl and Ar₂ is heteroaryl;
Group IV, claim 1, compounds where Ar₁ is heteroaryl and Ar₂ is heteroaryl;
Group V, claim 18, a process for preparing;
Group VI, claims 23-24, method of modulating where Ar₁ is aryl and Ar₂ is aryl;
Group VII, claims 25-26, method of treating where Ar₁ is aryl and Ar₂ is heteroaryl;
Group VIII, claims 23-24, method of modulating where Ar₁ is aryl and Ar₂ is heteroaryl;
Group IX, claims 25-26, method of treating where Ar₁ is aryl and Ar₂ is heteroaryl;
Group IX, claims 23-24, methods of modulating where Ar₁ is aryl and Ar₂ is heteroaryl;
Group XI, claims 23-24, methods of modulating where Ar₁ is heteroaryl and Ar₂ is aryl;
Group XI, claims 23-24, methods of modulating where Ar₁ is heteroaryl and Ar₂ is aryl;
Group XI, claims 23-24, methods of modulating where Ar₁ is heteroaryl and Ar₂ is aryl;
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Group XI, claims 23-24, methods of modulating where Ar₁ is heteroaryl and Ar₂ is aryl;
Group XI, claims 23-24, methods of modulating where Ar₁ is heteroaryl and Ar₂ is aryl;
Group XII, claims 23-24, methods of modulating where Ar₁ is heteroaryl and Ar₂ is aryl;

Group XIII, claims 25-26, methods of treating where Ar_1 is heteroaryl and Ar_2 is heteroaryl.

Note – Groups I-IV relate to claims 1-17 and 19-22, not just claim 1 which is the only independent claim.

The examiner reasoned that Groups I-IV and V were related as product and process of making and Groups I-IV and VI-XIII were related as product and methods of use and were distinct and there was no coaction among them. Applicants replied on May 5, 2005, amending claims 1 and 17-18 and electing for prosecution Group I, with traverse. Applicants argued that the restriction was improper based on court decisions such as *In re Weber* and *In re Harnish* and that the structure possessed unity of invention as defined therein. Applicants also requested that the Office modify their assignment records. Applicants further elected the species of Example 20 in a telephone interview on June 8, 2005.

The examiner mailed an action on the merits to applicants on August 11, 2005, setting a three month shortened statutory period for reply, responding to applicants' traversal of the restriction requirement by noting that the differences in Ar_1 and Ar_2 and the structures created by them did not provide a structure common to all compounds and the structures therefor did not meet the unity of invention test cited in the court decisions. The requirement was then made Final. The examiner noted that process of making and method of treating claims commensurate in scope with the elected compound claims would also be examined upon allowance of a compound claim. Claims 1-17 and 21 were rejected under 35 U.S.C. 102(b) as anticipated by Bach et al or under 35 U.S.C. 103(a) as obvious over Bach et al. Claims 1-17 and 21 were also rejected under 35 U.S.C. 103(a) as obvious over Lee et al.

Applicants filed a reply on October 7, 2005, again traversing the restriction requirement and responding to each of the rejections of record. Applicants also filed this petition to withdraw the restriction requirement on October 11, 1005.

No action on the reply filed October 7, 2005 has been taken by the examiner due to the pending decision on petition.

DISCUSSION

The discussion from the previous decision is included for reference purposes.

A review of the claims shows that claim 1 is directed to compounds having the following formula:



A review of the four variables shows that R_1 and R_2 are hydrogen or organic radicals of 12 carbons or less (or an amino group for R_1). Such radicals are fairly common and offer no definitive difference over prior art. Ar₁ and Ar₂, however, are aryl or heteroaryl radicals which may be substituted and may include additional ring systems or create a fused ring system. The examiner divided the compound claims into four separate groups depending on the values for Ar_1 and Ar_2 as to whether they are aryl or herteroaryl. (Note that claim 7 presents 7 different fused ring systems for Ar_1 and claim 12 presents at least 3 heteroaryl ring systems for Ar_2 .)

Claims 18-20 are directed to a process for making the compounds in general. Claims 21-22 are directed to a pharmaceutical composition of claim 1 are included with the compound claims. Claims 23-24 are directed to a method of modulating lipid metabolism and claims 25-26 are directed to treating type 2 diabetes.

The examiner has properly separated compound/composition claims from the method of making claims and the two methods of using claims based on different statutory class of invention. The examiner has also properly separated the three method type claims based on their different uses. The examiner also correctly indicated that upon a finding of allowability of product claims, method of making or using claims of commensurate scope would be rejoined and examined for compliance with all applicable statutes.

The examiner also provided proper reasons for the restriction requirement including burden on the Office to search and examine all possible inventions claimed.

Applicants argue that the restriction is improper in view of the decisions of *In re Weber* and *In re Haas* and others. The principle enunciated in these court decisions is that compounds having a substantial common core wherein the compounds differ only in the radicals attached to the common core and wherein the activity of the compound is provided by the core have unity of invention and should not be subject to restriction requirement. As noted above there is a common core here, but it consists of only a "-C=N-O-" core which likely does not provide the activity of the claimed compounds. All of the rest of the structure is variable. It is noted that two of the four variables are of a general nature, the R_1 and R_2 . However the two aryl or herteroaryl variables, which in essence form the major portion of the compounds, vary significantly. That the examiner separated the compounds into four groups based on aryl/aryl, aryl/heteroaryl, heteroaryl/aryl and heteroaryl/heteroaryl combinations is reasonable as these do not have a common core or structure as shown by the specification and dependent claims. Within each group defined by the examiner election of species is also permitted with the guidelines of M.P.E.P. 803.02 to be followed. It appears that the examiner has done this.

Applicants also appear to argue that aryl and heteroaryl are sufficiently similar that they should be searchable together. As stated by the examiner as well as by applicable classifications of the various groups, such is not a valid assumption. It is noted that classification is not the only criteria for determining a search burden on the Office. What must also be considered is the amount of non-patent literature contained in various databases that must also be searched in order to find the most pertinent prior art. Applicants' arguments are primarily based on consideration of M.P.E.P. 803.02 which applies only to election of species within an elected group of compounds. The examiner here has restricted the compounds as well as the methods claimed based on the compounds' structures into four separate chemical compound types. Within each of these four groups unity of invention exists, but not between them. In applicants' renewed petition applicants contend that they have made no statement that "aryl and heteroaryl are sufficiently similar that they are searchable together", as stated in the preceding paragraph. However applicants' argument that restriction within a claim, as was done here, is improper no matter what the circumstances is in effect such an argument. Applicants argue that *In re Weber* and *In re Haas* and *In re Harnisch* all hold that the Office has no authority to divide a claim up as has been done here. That is not necessarily the holding. The holding, similar in all three cases, is that where "unity of invention" exists it is improper to divide up a claim. Unity of invention is based on there being a common property or use AND a significant common structural element essential to that property or use. It is also noted that each of these cases involved a rejection under 35 U.S.C. 121 of claims subject to a restriction requirement and the basic holding of the Court was that such rejections of a claim were improper. Here no rejection of a claim under 35 U.S.C. 121 has been made. That a structure has been held to lack "unity of invention" has been made and restriction therefore is proper.

Applicants argue that one "would obviously recognize, despite the substitution of oxygen or nitrogen for carbon atoms, the common structural features such as rigid, planar or conjugated, aromatic rings." Granted that substitution of oxygen or nitrogen for carbon does not change the "geometry" or "spatial orientation" of the structure to any significant extent, but such substitution does change the properties of the compound/composition. Here, a small common structure is provided – the $-C(R_1)=N-OR_2$ structure. The major variables are Ar_1 and Ar_2 where Ar_2 is a single aromatic ring which contains 0, 1 or 2 nitrogen atoms and 0-3 substituents (see claims 10 and 11) and Ar_1 is at least a bicyclic structure containing 0, 1 or 2 nitrogen atoms and 0-5 substituents (see claims 6 and 7). In this particular instance the presence of heterocyclic rings would control classification which, as can be seen, would be variable depending on the number and location of the heteroatoms. Further, the only common structure, as noted above, is insignificant when compared to the ring structures and would not be the basis for classification nor form a substantial structural feature for the compound/composition.

The examiner's restriction between product and process claims is proper, but subject to rejoinder should product claims be determined to be allowable. The restriction between compounds as set forth by the examiner is also deemed to be proper for the reasons set forth above and in the previous petition decision.

DECISION

The petition is **DENIED**.

The application will be forwarded to the examiner for consideration of applicants' reply filed October 7, 2005.

Any request for reconsideration of this decision must be filed within two months of the mailing date of this decision and should be directed to the Director, Technology Center 1600.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number 571-273-8300.

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George C. Elliott Director, Technology Center 1600

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In re Application of:) .		
PFAHL et al.) Confirmation No. 8436		
Application No. 10/224,288) Group Art: 1623		

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FOR: **"OXIME DERIVATIVES FOR THE TREATMENT OF DYSLIPIDEMIA** AND HYPERCHOLESTEREMIA"

Examiner: Ward, Paul V.

REQUEST TO RECONSIDER PETITION TO WITHDRAW RESTRICTION REQUIREMENT

Director, Technology Center 1600 ATTN: William R. Dixon Jr. P. O. Box 1450 Alexandria, VA 22313-1450

Filed: August 19, 2002

NEEDLE & ROSENBERG, P.C. Customer Number 23859

February 28, 2006

Sir:

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In response to the Decision issued December 28, 2005 denying Applicants' Petition to Withdraw the Restriction Requirement for the captioned Application, Applicants respectfully Request Reconsideration of the Decision because (1) the Decision mischaracterizes and ignores arguments presented in Applicants' Petition, (2) the Decision misinterprets and ignores binding law that clearly denies the authority of the Commissioner to subdivide a single claim under 35 U.S.C. § 121, (3) the Decision neglects Applicants' argument that the failure of the Examiner to address his burden to show the absence of Unity of Invention of any one of Applicants' claims, and (4) the Decision attempts to justify the Restriction Requirement based on "burden to search" arguments that have been clearly rejected by the Courts.

1. <u>THE DECISION MISCHARACTERIZES AND IGNORES APPLICANTS'</u> <u>ARGUMENTS</u>

The Decision mischaracterizes Applicants' arguments at least twice. First, the Decision states that "Applicants also appear to argue that aryl and heteroaryl are sufficiently similar that they should be searchable together." Applicants made no such contention. While Applicants recognize the Office's "Burden to Search" concerns, Applicants' actual position is that the Courts have made it clear that the Commissioner's concerns regarding "Burden to Search" issues must nevertheless yield to Applicants statutory rights. *See* further discussion under Item 4 below.

Second, the Decision contends that "Applicants' arguments are primarily based on consideration of MPEP § 803.02 which applies only to election of species within an elected group of compounds." Applicants deny such contention, and note that this assertion conflicts with another assertion of the Decision that "Applicants argue that the restriction group is improper in view of the decisions of the *In re Weber*, and *In re Hass*, and others."

Applicants' Petition referenced MPEP § 803.02 because it constitutes evidence that the Office has recognized the applicability of, *inter alia*, the *In re Weber*, *In re Hass*, and *In re Harnisch* cases, but Applicants' arguments are by no means "primarily based" on MPEP § 803.02. To the contrary, Applicants' arguments are actually based on the applicable statute (35 U.S.C. § 121), as repeatedly interpreted by the Courts and as exemplified by cases such as *In re Weber*, *In re Hass*, and *In re Harnisch*, and subsequent cases, *see* Item 2 below. Indeed, the aforementioned cases, and their holdings that the Commissioner has no authority to subdivide individual claims under 35 U.S.C. § 121 all have binding legal effect on the Commissioner, completely independently of any relationships to MPEP § 803.02.

Applicants also referenced MPEP § 803.02 because it further illustrates the

Commissioner's recognition that in order to properly subdivide a Markush claim on the grounds that it is an "improper" Markush claim, the Examiner has the burden of showing that the claims lack Unity of Invention, a burden which was not even addressed by the Examiner in this case, and an issue which the Decision also fails to address, *see* Item 3 below.

2. <u>THE DECISION MISINTERPRETS AND IGNORES BINDING LAW HOLDING</u> <u>THAT THE COMMISSIONER HAS NO LEGAL AUTHORITY UNDER 35 U.S.C.</u> § 121 TO SUBDIVIDE AN INDIVIDUAL CLAIM

The original Office Action, dated March 11, 2005, required restriction "under 35 U.S.C. § 121." *See* page 2, line 1 of the Office Action. No other source of ultimate legal authority for the Restriction Requirement was or has been subsequently identified by either the Examiner or the Commissioner. It is however quite clear under the law that the Commissioner simply does NOT have the authority to subdivide a single claim under 35 U.S.C. § 121. The *Weber* and *Hass* courts, as quoted again below in more extended form, made this point clear, as a matter of law:

As a general proposition, an applicant has a right to have each claim examined on the merits. . . If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.¹

¹ Applicants have related concerns for this and other applications currently under prosecution. The Office recently instituted a policy that no claim to a method of treatment can be allowed unless it is supported by examples. If the current restriction requirement is upheld, so that compounds from a single independent compound claim comprising aryls are subdivided away from compounds comprising heteroaryls, Applicants' dependent method of treatment claims would also be similarly subdivided. Applicants' specification may not include examples from each and every sub-genus of compounds recited in the method of treatment claims that is subsequently and arbitrarily subdivided pursuant to the Commissioner's restriction requirements. This could easily result in a situation in which the Restriction Requirement, which is solely a procedural/administrative convenience for the (cont'd on next page)

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

In re Weber at 458, (underlining added for emphasis).

In *Haas II* (see note 6, supra), this court held that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made.

In re Harnisch at 721, (underlining added for emphasis).

These holdings have been reaffirmed by the Federal Circuit in In re Watkinson,² which

stated "Under In re Weber, 580 F.2d 455, 458, 198 USPQ (BNA) 328, 332 (CCPA 1978), and

In re Haas, 580 F.2d 461, 464, 198 USPQ (BNA) 334, 336 (CCPA 1978), it is never proper for

an examiner to reject a Markush claim under 35 U.S.C. § 121. Section 121 simply does not

authorize such a rejection. Id." (Italics in original).

The December 28, 2005 Decision on Applicants' Petition simply cannot ignore these

binding legal precedents that are clearly contrary to the Examiner and Commissioner's reliance

on 35 U.S.C. § 121 for legal authority. The Commissioner has also yet to identify an alternate

source of proper legal authority for the Restriction Requirement.

Commissioner, would result in a substantive denial of the patentability of some of the resulting subdivided method of treatment claims. Such an outcome <u>cannot</u> be a permissible result under the law.

² See In re Watkinson, 900 F2d 230, 232 (Fed Cir. 1990). The Board of Patent Appeals and Interferences has also stated that "Therefore, the examiner rejected Markush-type claim 79 in the parent application under 35 USC § 121. There is no doubt that the examiner's rejection of claim 79 in the original application under 35 USC § 121 was improper; In re Weber, supra; In re Haas I, supra." See Ex Parte Holt, 214 USPQ 381, Board of Patent Appeals and Interferences, 1982.

The Decision states on page 3 that "Applicants' arguments are primarily based on consideration of MPEP § 803.02 which applies only to election of species within an elected group of compounds." This statement completely mischaracterizes Applicants arguments, which also rely on 35 U.S.C. § 121, as interpreted by the case law quoted above.

The Decision also alleged, in connection with Applicants' reliance on the *In re Weber* and *In re Hass* cases, that "The principal enunciated in these court decisions is that compounds having a substantial common core wherein the compounds differ only in the radicals attached to the common core and wherein the activity of the compound is provided by the core have unity of invention and should not be subjected to restriction requirement."

This conclusory "interpretation" of *In re Weber* and *In re Hass* by the Decision is unsupported by any further reasoning or quotations from the cases themselves. Applicants can identify no support in those cases for this asserted "interpretation." To the contrary, such a "common core" argument was actually asserted by the Office in *In re Weber*, and <u>rejected</u> by the Court of Customs and Patent Appeals. *See In re Weber*, 580 F2d at 457-458.

Moreover, the Decision then attempts to interpret and/or apply the recitations of MPEP § 803.02, and/or the cases cited above, *i.e.*, that the compounds must share a "substantial structural feature," so narrowly as to ignore the structural similarities of aryl and heteroaryl residues that would be obvious to one of ordinary skill in the art. One of ordinary skill in the art would obviously recognize, despite the substitution of nitrogen or oxygen for carbon atoms in aryl rings, the common structural features such as rigid, planar, conjugated, aromatic rings. Moreover, the extremely narrow substructural selections advocated in the Decision are clearly

contrary to other binding law, as exemplified by In re Harnisch, 631 F2d 716, 722 (CCPA 1980)

wherein it was stated, while discussing In re Jones, 162 F2d 479 (CCPA 1947), that

"The court noted that in any Markush group the compounds 'will differ from each other in certain respects.' It laid down the proposition, with which the PTO agrees in its MPEP, 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."

In view of *In re Harnisch*, it is clearly improper for the Commissioner to demand election based an arbitrary and identical single radical from within Applicants' compounds, and/or require an "identical core," while ignoring the many other overall structural similarities of the compounds that are readily apparent to one of ordinary skill in the art when the compounds are properly considered <u>as a whole</u>. In view of the arguments above, it is clear that the Decision ignored, misinterpreted, and misapplied the law.

3. <u>THE DECISION IGNORES THE EXAMINER'S FAILURE TO SHOW THE</u> <u>ABSENCE OF UNITY OF INVENTION</u>

The Decision ignores one of the Petition's major legal contentions, namely that the Examiner <u>completely failed to address any initial burden of proof to show that any of the individual claims lack Unity of Invention</u>, so as to be properly restrictable under MPEP § 803.02 and/or the applicable case law relating to "improper Markush groups."³ MPEP § 803.02, which

³ Aside from questions of authority for restriction under 35 U.S.C. § 121, *In re Harnisch* also addressed potential questions of "improper Markush grouping", stating "we think it should be clear from our actions in Weber and Haas II that we there recognized the possibility of such a thing as an "improper Markush grouping." We were and are aware that it does not have a specific statutory basis." "...there remains a body of Markush-practice law regarding Markush-type claims, particularly in the chemical field, concerned more with the concept of what might be better described as the concept of unity of invention." The *Harnisch* Court found that the compounds claimed with Markush groups were all coumarin compounds, and that they shared a utility as dyes, and the Court held that "we consider the claimed compounds to be part of a single invention so that there is unity of invention as was held (*cont'd* on next page)

is admitted by the Decision to primarily relate to an election of species procedure for Markush groups, also mentions that under the case law:

> ...it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

The Examiner made no attempt to reject Applicants' claims as "improper Markush groups" and/or made no attempt to show the claims lacked Unity of Invention. The Decision makes some very brief conclusory statements alluding to the Unity of Invention question, but it fails to provide or identify any evidence to support those conclusory statements. Therefore, both the Examiner and the Decision failed to carry their initial burden to reject or subdivide the claims as containing "Improper Markush claims," and as such failed to raise or support a proper *prima facie* justification for such an action. Accordingly, the Restriction Requirement should be withdrawn.

4. <u>THE DECISION ATTEMPTS TO JUSTIFY THE "RESTRICTIONS" ON</u> <u>"BURDEN TO SEARCH" ARGUMENTS THAT HAVE BEEN REJECTED BY</u> <u>THE COURTS</u>

The Decision states that "The examiner also provided proper reasons for the restriction requirement including burden on the Office to search and examine all possible inventions claimed." While Applicants are not unsympathetic to such concerns of the Office, the Courts

to be the case in *Ex parte Brouard*, supra, 201 USPQ at 540. The Markush groupings of claims 1 and 3-8 are therefore proper. In re Harnisch at 721-721.

have made it absolutely clear that such a "Burden" argument cannot prevail over an applicant's

legal rights under the statute:

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Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. n8 But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount. We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses.

In re Weber at 458-459.

Accordingly, "Burden to search" arguments such as those alleged by the Examiner and the Decision have been rejected by Court decisions that bind the Commissioner.

The restriction requirements imposed by the March 11, 2005 and May 5, 2005 Office Actions, and any similar restriction requirements that propose to subdivide Applicants' individual claims into subclaims, are procedurally and legally improper and must be withdrawn. Applicants challenge and/or deny the legal authority of either the Examiner or the Commissioner to unilaterally restrict an individual claim into sub-claims under 35 U.S.C. § 121, or unilaterally force amendment of the claims of the application in a manner that is the effective equivalent thereof.

CONCLUSION

In view of the arguments recited above, the original Restriction Requirement was legally improper, and the Decision upholding that restriction requirement was erroneous, and should be reconsidered and withdrawn. It is noted that the CCPA has unambiguously held that such an adverse action by the Examiner or the Commissioner on the restriction requirements that are the subject of this request for Reconsideration are appealable, since they are deemed equivalent to a substantive rejection. *See In re Haas*, 486 F.2d at 1056, 179 USPQ at 626, CCPA 1973. Therefore, in the event that this Request for Reconsideration is not granted, Applicants reserve the right to appeal this issue to the Board of Patent Appeals and Interferences.

•••

Applicants have already replied to the substantive rejections of the Office Action dated August 11, 2005, in their response filed October 7, 2005, even though Applicants declined to amend the original claims to comport with the original improper restriction requirement, and Applicants reserve the right to continue to do so.

No fees are believed due in conjunction with this Request for Reconsideration, but if there are any other fees due in connection with this Request or the original Petition, please charge any such fees to our Deposit Account No. 14-0629.

Respectfully submitted,

Mark A. Murphy/Ph

Registration No. 42,915

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Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 www.uspto.gov

DEC 28 2005

NEEDLE & ROSENBERG, PC SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915

In re Application of	:
Magnus Pfahl et al	:
Serial No.: 10/224,288	: PETITION DECISION
Filed: August 19, 2002	:
Attorney Docket No.: 13099.0017U2	:

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The examiner has properly separated compound/composition claims from the method of making claims and the two methods of using claims based on different statutory class of invention. The examiner has also properly separated the three method type claims based on their different uses. The examiner also correctly indicated that upon a finding of allowability of product claims, method of making or using claims of commensurate scope would be rejoined and examined for compliance with all applicable statutes.

The examiner also provided proper reasons for the restriction requirement including burden on the Office to search and examine all possible inventions claimed.

Applicants argue that the restriction is improper in view of the decisions of *In re Weber* and *In re Haas* and others. The principle enunciated in these court decisions is that compounds having a substantial common core wherein the compounds differ only in the radicals attached to the common core and wherein the activity of the compound is provided by the core have unity of invention and should not be subject to restriction requirement. As noted above there is a common core here, but it consists of only a "-C=N-O-" core which likely does not provide the activity of the claimed compounds. All of the rest of the structure is variable. It is noted that two of the four variables are of a general nature, the R_1 and R_2 . However the two aryl or herteroaryl variables, which in essence form the major portion of the compounds, vary significantly. That the examiner separated the compounds into four groups based on aryl/aryl, aryl/heteroaryl, heteroaryl/aryl and heteroaryl/heteroaryl combinations is reasonable as these do not have a common core or structure as shown by the specification and dependent claims. Within each group defined by the examiner election of species is also permitted with the guidelines of M.P.E.P. 803.02 to be followed. It appears that the examiner has done this.

Applicants also appear to argue that aryl and heteroaryl are sufficiently similar that they should be searchable together. As stated by the examiner as well as by applicable classifications of the various groups, such is not a valid assumption. It is noted that classification is not the only criteria for determining a search burden on the Office. What must also be considered is the amount of non-patent literature contained in various databases that must also be searched in order to find the most pertinent prior art. Applicants' arguments are primarily based on consideration of M.P.E.P. 803.02 which applies only to election of species within an elected group of compounds. The examiner here has restricted the compounds as well as the methods claimed based on the compounds' structures into four separate chemical compound types. Within each of these four groups unity of invention exists, but not between them.

The requirement is deemed to be proper and is maintained.

DECISION

The petition is **DENIED**.

The application will be forwarded to the examiner for consideration of applicants' reply filed October 7, 2005.

Any request for reconsideration of this decision must be filed within two months of the mailing date of this decision and should be directed to the Director, Technology Center 1600.

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number 571-273-8300.

Long C. Ellist

George C. Elliott Director, Technology Center 1600



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

PFAHL et al.

Application No. 10/224,288

Filed: August 19, 2002

Confirmation No. 8436

Group Art: 1623

Examiner: Ward, Paul V.

FOR: **"OXIME DERIVATIVES FOR THE TREATMENT OF DYSLIPIDEMIA AND HYPERCHOLESTEREMIA"**

PETITION TO WITHDRAW RESTRICTION REQUIREMENT

MAIL STOP PETITION Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. Customer Number 23859

October 7, 2005

Sir:

In response to the Office Actions dated March 11, 2005 and August 11, 2005, Applicants

hereby Petition to Withdraw the Restriction Requirement set forth by the Examiner under 37

C.F.R. § 1.144 for the reasons set forth below.

I. <u>THE RESTRICTION REQUIREMENTS</u>

In the Office Action dated March 11, 2005, the Examiner set forth a restriction

requirement that restricted the 26 original claims of the Application into the thirteen groups listed

below:

Group I	Claim 1, wherein Ar_1 is an aryl, and Ar_2 is an aryl (classifiable in class 585, subclass various);
Group II	Claim 1, wherein Ar_1 is an aryl, and Ar_2 is a heteroaryl (classifiable in class 546, subclass various);
Group III	Claim 1, wherein Ar_1 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 546, subclass various);

Group IV	Claim 1, wherein Ar_1 is a heteroaryl, and Ar_2 is a heteroaryl (classifiable in class 549, subclass various);
Group V	The process of preparing according to claim 18;
Group VI	Claims 23-24, wherein Ar_1 is an aryl, and Ar_2 is a aryl (classifiable in class 424);
Group VII	Claims 25-26, wherein Ar_1 is an aryl, and Ar_2 is an aryl (classifiable in class 514);
Group VIII	Claims 23-24, wherein Ar_1 is an aryl, and Ar_2 is a heteroaryl (classifiable in class 424);
Group IX	Claims 25-26, wherein Ar1 is an aryl, and Ar2 is a heteroaryl (classifiable in class 514);
Group X	Claims 23-24, wherein Ar_1 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 424);
Group XI	Claims 25-26, wherein Ar_1 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 514);
Group XII	Claims 23-24, wherein Ar_1 is a heteroaryl and Ar_2 is an heteroaryl (classifiable in class 424); and
Group XIII	Claims 25-26, wherein Ar_1 is a heteroaryl, and Ar_2 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 514).

Applicants' response dated May 5, 2005 provisionally elected Group I, but traversed and requested reconsideration of the restriction requirement, because Restriction Groups I-IV and VI-XIII each improperly divide one or more of Applicants claims into subclaims, based on the chemical classification of the aromatic Ar_1 and Ar_2 groups as aryl or heteroaryl groups. See Restriction Groups I-IV, which purport to subdivide independent compound claim 1 among four restriction groups based on the classifications of the Ar₁ and Ar₂ groups as aryls or heteroaryls, and similar subdivisions of dependent method claims 23-26 into eight additional restriction groups.

The Office Action dated March 11, 2005 attempted to justify these divisions of individual claims into subclaims because:

The inventions of Groups I-XIII are separate and patentably distinct because there is no patentable co-action among them and a reference anticipating one member will not render another obvious.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, a search of the thirteen groups designated above would impose an undue burden upon the examiner, and restriction for examination purposes is proper.

Applicants' May 5, 2005 response traversed by pointing out that a restriction requirement

that splits Applicants individual claims into subclaims violates well established law.¹

As noted in MPEP § 803.02:

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which Applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The Office Action dated March 11, 2005 had made no attempt to show that any of

Applicants' individual claims lack Unity of Invention, and had therefore failed to establish a

prima facie basis for restricting Applicants' individual claims into subclaims.

Moreover, Applicants' May 5, 2005 response positively recited that independent claim 1

and all of its dependent claims share common utilities as illustrated by the dependent method

¹ Applicants have over the past 2-3 years been repeatedly subjected in related applications to similar impositions of procedurally improper restriction requirements that attempt to sub-divide individual claims, by various other examiners in "1600" art units that examine claims directed to "small molecule pharmaceuticals." To cite merely one example, some of the Applicants very recently petitioned against a similar improper restriction requirement in Applicants' co-pending Application Serial No. 10/384,391. The Commissioner should be aware that the current Petition illustrates only one example of a practice that being regularly employed in the relevant art units.

claims, as well as a <u>combination</u> of structural features possessed by all the compounds, that establish that all the claims do in fact possess Unity of Invention. Applicants' response also recited case law, to be described again below, that makes it very clear that the Commissioner cannot properly subdivide a single claim merely because of the presence of "separate and patentably distinct" inventions within the scope of a single claim.

Nevertheless, the Office Action dated August 11, 2005 finalized the initial restriction requirement. On page 2, the August 11, 2005 Office Action states:

Applicants' election with traverse of Group I in the reply filed on May 5, 2005 is acknowledged. The traversal is on the ground that the restriction of groups I-IV and VI-XIII improperly divides one or more claims into sub-claims based on the chemical classification of the aromatic Ar_1 and Ar_2 groups as aryl or heteroaryl groups, and thus, the compounds possess "Unity of Invention". This not found persuasive because Groups I-XIII are separate and patentably distinct since there is no patentable coaction among them. For example, when Ar_1 is an aryl compound or when Ar₂ is a heteroaryl compound, a reference anticipating one will not render the other obvious. Hence, Applicants inventions are distinct and have acquired a separate status in the art due their recognized divergent subject matter and different classification. A search of the thirteen groups would impose an unfair burden upon the Examiner. Thus, the restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Groups II-XIII are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable or generic or linking claim.

The Office Actions Did Not Meet Their Burden to Justify Subdivision of Individual Claims

Applicants' response dated May 5, 2005 argued in considerable detail that the proposed

subdivision of individual claims into subclaims was legally improper because the Office Action

failed to even address its legal burden (as described in MPEP § 803.02 recited above) to establish that the claims lack Unity of Invention. As can be seen from the statements reproduced above, the Office Action dated August 11, 2005 did not dispute the legal relevance of Unity of Invention, and did not even attempt to address its legal burden on the matter. Therefore, on that basis alone, the restriction requirements imposed by the March 11, 2005 and August 11, 2005 Office Actions were improper and should be withdrawn.

The Examiner's Alleged Justifications for Subdividing Individual Claims Are Inadequate

Both Office Actions attempted to argue that the restriction requirement is proper because the compounds and/or claims encompass "separate and patentably distinct" embodiments, and/or that an "unfair burden" to examine compounds that could be classified into more than one group was purportedly being imposed on the Examiner. The Federal Circuit has however made it clear that neither of those arguments are sufficient basis to justify a subdivision of individual claims into subclaims. In *Weber*, one of the cases recited by MPEP § 803.02, the invention related to cyclic diamine derivatives possessing a common psychotherapeutic property and identified by a single generic formula expressed in Markush format. The Examiner rejected claim 1 as embracing 24 enumerated independent and distinct inventions and rejected claims 1-6 as being improper Markush claims and for misjoinder under 35 U.S.C. § 121. In commenting on the rejection, the court stated as follows:

> An Applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of § 112. We have decided in the past that § 112, second paragraph, which says in part "[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," allows the inventor to claim the

invention as he contemplates it. *In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (CCPA 1973).

As was further explained by the Weber court:

As a general proposition, an applicant has a right to have each claim examined on the merits.... If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits....

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." <u>It does not, however, provide a</u> <u>basis for an examiner acting under the authority of the</u> <u>Commissioner to reject a particular claim on that same basis</u>.

In re Weber at 458, (underlining added for emphasis).

In his concurrence in Weber, Judge Rich further stated that:

The practice here challenged is tantamount to a refusal by the PTO to examine a single Markush claim in a single application because, in its opinion, it is <u>broad</u> enough to "embrace" or "cover" a plurality of inventions which, if presented separately, would be separately patentable, <u>assuming</u> any one of them to be prior art. The label it attaches to such a broad claim is "improper Markush" and the situation is described as "misjoinder."

The fault in the PTO position is that it overlooks the obvious fact that almost any reasonably broad claim "embraces" or "covers" a multiplicity of inventions, in the sense of "dominating" them, which inventions might be separately patentable if and when presented in separate applications. Logically, this is not a sufficient excuse for refusing to examine a claim on its merits for compliance with 35 U.S.C. §§ 101, 102, 103 and 112. None of those statutory sections, of course, justifies a refusal to examine.

The only justification or statutory authority put forward for refusing to examine is 35 U.S.C. § 121. There is nothing therein, however, to excuse a refusal to examine an elected invention or an applicant's generic (broad) claim reading thereon, notwithstanding

the generic claim reads on nonelected inventions and possibly many others, all potentially separately patentable. . . .

So the discretionary power to limit one application to one invention 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. . . .

The only basis here claimed in support of the labels "improper" and "misjoinder" is the scope of the claim. That is not sufficient excuse. (Emphasis in original.)

Furthermore, In re Harnisch, also referenced in § 803.02, stated the following:

In *Haas II* (see note 6, supra), this court held that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made.

In re Harnisch at 721.

The binding case-law recited above make it clear that <u>the presence of "separate and</u> <u>patentably distinct" embodiments within a single claim cannot be used by the Examiner or the</u> <u>Commissioner to justify the division of a single claim into subclaims</u>. Therefore the arguments of the Office Actions along these lines are directly contrary to binding case law, and therefore must be rejected.

Second, the Office Actions argue that an "unfair burden" would be imposed if the Examiner is forced to examine Applicants 26 original claims (directed to a relatively simple genus of compounds having a core structure of connected structurally related groups) without subdivision according to the classifications of peripheral substituents of the compounds within the claims. Nevertheless, the quotations from the binding case law recited above make it quite clear that breadth "is no excuse at all for refusing to examine a broad generic claim -- no matter how broad." Thus, even if Applicants claims were *arguendo* extraordinarily broad, which

Applicants dispute, the law is quite clear that <u>the Commissioner cannot use breadth alone (as</u> reflected by classifications) as a justification for attempting to subdivide a single claim.

Furthermore, if this Petition is denied, Applicants will be required to file at least three, and perhaps as many as twelve, or more, additional divisional applications, in order to prosecute each of the withdrawn groups set forth by the Examiner in connection with a set of 26 claims directed to a genus of relatively simple compounds that possess both common utilities and Unity of Invention. Such a result would be far more unjustifiably burdensome and unfair to Applicants than to the Examiner, as well as being legally improper in view of § 121 and the cited case law.

Accordingly, the restriction requirements imposed by the March 11, 2005 and/or May 5, 2005 Office Actions, and any similar restriction requirements that propose to subdivide Applicants' individual claims into subclaims are procedurally and legally improper and must be withdrawn. It is noted that the CCPA further held that such an adverse action by the examiner is appealable, since it is tantamount to a rejection. *In re Haas*, 486 F.2d at 1056, 179 USPQ at 626. Therefore, in the event that this petition is not granted, Applicants reserve the right to appeal this issue to the Board of Patent Appeals and Interferences.

The Office Action dated August 11, 2005 purported to proceed with substantive examination of the claims of provisionally elected Group I, even though Applicants declined to amend the original claims, and purported to reject the claims as being allegedly anticipated and/or obvious over two references. Presumably during the purported examination the examiner speculated as to what the text of the claims purportedly being examined would eventually be. Applicants can only speculate as to what the actual text of the various independent and dependent claims purportedly examined was, and therefore Applicants find it difficult to respond

to the purported rejections over the prior art, let alone any issues related to 35 U.S.C § 112 that might be caused by the Examiner's attempts to improperly and unilaterally impose claim amendments. Applicants challenge and deny the legal authority of either the Examiner or the Commissioner to unilaterally amend the claims, or any effective equivalent thereof that results in such unjustifiable uncertainties and inefficiencies.²

Nevertheless, in an attempt to facilitate prosecution of the current application, Applicants have prepared and file concurrently a substantive response to the rejections imposed in the August 11, 2005 Office Action, and show therein that the none of the <u>unamended</u> claims are in fact either anticipated by or obvious over the recited prior art. A copy of that response is included herewith.

II. <u>CONCLUSION</u>

Applicants respectfully petition the Commissioner to review the restriction requirement and, for the reasons stated above, instruct the Examiner to withdraw the improper restriction requirements that attempt to subdivide Applicants individual claims into subclaims. The Examiner should search and examine the entirety of claim 1 and all the compound claims 2-17 dependent thereon. If dependent method claims 18-26 are withdrawn by the Examiner, upon

² Applicants suffered an extended and unjustifiably costly and burdensome experience in such uncertainties in a similar situation in a previous related case, U.S. Application Serial No 10/655,460, wherein an examiner repeatedly attempted to impose a subdivision of Applicants individual claims into subclaims, *via* combination of multiple purported amendments of a single claim, without <u>ever</u> being willing to reasonably clearly describe or define what constituted the text of the amendments being imposed, or the claims purportedly being examined was. Applicants literally never learned what the text of the claims purportedly being examined was. Moreover, in that case, and several other cases prosecuted by the undersigned, the examiners have, after arbitrarily selecting subgroups from dependent claims as restriction groups, attempted to define one of the purported restriction groups as "everything else that's not in one of the other restriction groups." leaving Applicants and the undersigned utterly helpless to reasonably know what the text of the claims in those purported restriction group would have been.

allowance of any compound claims, Applicants anticipate requesting rejoinder and reexamination of the method claims under the procedure of MPEP § 821.04.

Enclosed herewith are copies of the recited court cases, and Credit Card Payment Form PTO-2038 in the amount of \$400.00 for the Petition Fee due under 37 C.F.R. § 1.17(f). If there are any other fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, please charge any such fees to our Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Mark A. Murphy, Ph.D. Registration No. 42,915

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580.F.2d 455, *; 1978 CCPA LEXIS 261, **; 198 U.S.P.Q. (BNA) 328

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LEXSEE 580 F.2D 455

IN THE MATTER OF THE APPLICATION OF ROLF-ORTWIN WEBER, ALFONS SODER and ISTUAN BOKSAY

Appeal No. 77-622.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

580 F.2d 455; 1978 CCPA LEXIS 261; 198 U.S.P.Q. (BNA) 328

June 30, 1978, Decided; As Amended August 1, 1978

PRIOR HISTORY: [**1]

Serial No. 307,406.

LexisNexis(R) Headnotes

COUNSEL:

David R. Murphy, attorney of record, for appellants, Charles A. Wendel, Harold C. Wegner on behalf of the Patent, Trademark and Copyright Section, Virginia State Bar.

Joseph F. Nakamura for the Commissioner of Patents, Fred E. McKelvey for the Patent and Trademark Office.

OPINIONBY:

BALDWIN

OPINION: [*455]

Before MARKEY, Chief Judge, RICH, BALDWIN, LANE and MILLER, Associate Judges.

BALDWIN, Judge.

This appeal is from a decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) affirming the examiner's rejection of claims 1-6 "as being improper Markush claims n1/ and misjoinder under 35 USC 121." n2/ The board also dismissed, for want of jurisdiction, the appeal of claims 8-13, 16, 17, 20, 22 and 23 in that the claims "were withdrawn from [*456] consideration since they were directed to non-elected inventions." We reverse and remand.

n1/ Section 706.03(y) (note 4, infra) of the Manual of Patent Examining Procedure (MPEP) provides guidance in the use of Markush format and is cited by the examiner in his Answer before the board. MPEP 803 (note 3, infra), which applies 35 USC 121 to Markush claims, is also cited by the examiner in his final office action.

n2/ Section 121 provides, in pertinent part:

Divisional applications

If two or more independent and distinct inventions are claimed in one application, the Commissioner 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. [**2]

Invention

The invention relates to cyclic diamine derivatives which possess the common property of psychotherapeutic effectiveness. The derivatives are identified by a single generic formula expressed in Markush format in representative claim 1:

1. A compound having the general formula [Graphic omitted. See illustration in original.] or an acid addition salt thereof in which formula R1 is selected from the group consisting of

A) an at least mononuclear heterocyclic group having 4 to 10 carbon atoms in the ring system bound to the group - C=(X) - N through a carbon atom and containing at least one oxygen, nitrogen or sulphur atom,

B) substitution products of A) containing at least one substituent selected from the group consisting of halogen, trifluoromethyl, hydroxy, alkoxy of 1 to 3 carbon atoms, unsubstituted amino, amino substituted by up to two alkyl groups each having 1 to 3 carbon atoms and alkyl groups having 1 to 6 carbon atoms,

X is oxygen, sulphur or an NH-group,

Y is an alkylene group having 1 to 3 carbon atoms in the chain, or an alkylene group having 1 to 3 carbon atoms in the chain substituted by a) up to 3 alkyl groups each having up to 3 carbon atoms [**3] and a total of not more than 8 carbon atoms, or b) substituted by one or two phenyl groups,

R2 is selected from the group consisting of

C) an at least mononuclear carbocyclic or heterocyclic group having 4 to 10 carbon atoms in the ring system, containing but one heteroatom in a ring,

D) substitution products of C) containing at least one substitutent selected from the group consisting of nitro, halogen, trifluoromethyl, alkyl having 1 to 6 carbon atoms, hydroxy, alkoxy having 1 to 3 carbon atoms, unsubstituted amino groups and amino groups substituted by up to two alkyl groups each having 1-3 carbon atoms,

R3 is hydrogen or up to two substitutents selected from alkyl groups having up to 2 carbon atoms and phenyl groups; n is 2 or 3.

Background

In the first office action dated January 17, 1974, the examiner "objected" to claims 1-6, 8-13 and 23 and required applicants to elect one of three groups of claims: group I (claims 7 and 14-22), group II (claims 8-13), or group III (claim 23)8. Applicants elected, with traverse, group I and brought to the examiner's attention his failure to include claims 1-6 in the groups. The status of claims 1-6 was clarified in the second [**4] and final action, dated December 26, 1974, in which those claims were "rejected." The examiner also stated that claim 1

embraced 24 enumerated independent and distinct inventions. The examiner, in conclusion, stated that:

Markush claims 1 to 6 are rejected as being improper Markush claims and for misjoinder under 35 U.S.C. 121. (922 O.G. 1016, 4th and 6th paragraph). n3/

> n³/ The examiner exercised his discretion under 922 O.G. 1016 which was a notice issued by the Commissioner on May 1, 1974, (now MPEP 803) which provides in part:

> A Markush-type claim is directed to "independent and distinct inventions," if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other (members).

[Paragraph 4.]

If the claim is of that nature, the examiner is authorized to reject it as an improper Markush claim and for misjoinder under 35 U.S.C. 121 and to require the applicant to restrict the application to a single invention. In making such a requirement, the examiner will (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. 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 (claims) to that invention. Of course, the response must not introduce new matter into the application. See 35 U.S.C. 132 and In re Welstead, 59 CCPA 1105, 463 F.2d 1110, 174 USPQ 449 (1972). A refusal to elect a single invention will be treated as a non-responsive reply.

If 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, the examiner is encouraged to examine it on the merits, even though it is directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure outlined in the preceding paragraph and will not require restriction.

Where the examiner has rejected the claim and required restriction and the applicant has responded without restricting the (claims) to a

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single invention, the examiner shall, if the position is adhered to, again reject,he claim and any other Markush claims not restricted to the elected invention. No further examination of these claims is required unless and until such rejection has been overcome. However, if the search of the single elected invention develops prior art which would render both the elected invention and the improper Markush (claims) unpatentable, such prior art may be applied in rejections of both without a complete search of the subject matter of the improper Markush (claims). Otherwise, only true generic claims and those restricted to the elected invention will be examined in the usual manner.

[Paragraph present in MPEP 803 deleted.]

Review of the rejection will be by appeal to the Board of Appeals under *35 U.S.C. 134.* [**5] [*457]

In his Answer, the examiner expanded upon the basis of the rejection. He discussed MPEP 803, in particular the phrase "independent and distinct" of § 121 and applied the phrase to the claims. Continuing, the examiner discussed the Markush claims and stated:

The compounds embraced do not have a common nucleus and are improperly Markushed under the criteria set forth in M.P.E.P. 706.03(y) * * *. n4/ * * * The specification discloses that certain compounds have activities not shared by all of the scope claimed * * *.

n4/ MPEP 706.03(y) provides, in pertinent part

Ex parte Markush, 1925 C.D. 126; 340 O.G. 839, sanctions, in chemical cases, claiming a genus expressed as a group consisting of certain specified materials. This type of claim is employed when there is no commonly accepted generic expression which is commensurate in scope with the field which the applicant desires to cover.

* * *

Where 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 compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation then "wherein R is A, B, C or D" shall also be considered proper. [**6]

At the outset, the board decided that § 121 was an adequate legal basis for the examiner to reject a single claim "embracing" more than one independent and distinct invention. In support thereof, the board incorporated two board decisions n5/ which discussed the interrelated rejections of "misjoinder under 35 U.S.C. 121" and "as being improper Markush claims" as applied here. The board analyzed the claims in light of those decisions and found them to contain multiple independent and distinct inventions.

n5/ The board incorporated both Ex parte Dorlars, Appeal No. 148-56, decided May 2, 1975, reproduced in the record, and *Ex parte Haas, 188 USPQ 374 (Bd. App. 1975)*. The board stated in Dorlars that:

What we do find relevant is the single question: does the Examiner have legal authority to attack the propriety of an individual claim, whether of the Markush-type or otherwise, which includes a plurality of independent and distinct inventions? We think clearly the answer is "yes."

The board based its conclusion in Dorlars on § 121 and further stated:

Clearly the mere fact that review of decisions requiring restriction within a single claim is available under 35 USC 134, whereas decisions requiring restriction between claims are not, cannot serve to limit application of the statute. That relates only to the issue of jurisdiction to review; it has no bearing on the scope of the statute itself--on the scope of authority conferred.

In Ex parte Haas, the board decided that Rule 141, 37 CFR 1.141 regards an allowable generic claim as one that does not include more than one independent and distinct invention. The board decided that § 121 is a legal basis for rejecting a single claim as an improper Markush claim. [**7]

Appellants argue before this Court that each of the claims is directed to but a single invention and § 121 is not a proper ground for rejection in any event. [*458]

OPINION

The board affirmed the examiner's rejection of claims 1-6 "as being improper Markush claims and

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misjoinder under 35 U.S.C. 121." However, the reasoning of the board shows that the analysis of the "improper Markush claims" rejection was to be supportive of the rejection under § 121 rather than alternative to it. We have jurisdiction over both rejections, n6/ but since the Markush rejection is inextricably intertwined with the § 121 rejection, we make no decision on the propriety of the Markush rejection. However, the result of any such consideration must be consistent with our analysis of an applicant's rights under the second paragraph of 35 USC 112.

n6/ 37 CFR 1.196(a) provides that in decisions of the board:

The affirmance of the rejection of a claim on any of the grounds specified constitutes a general affirmance of the decision of the primary examiner on that claim, except as to any ground specifically reversed.

See also In re Sichert, 566 F.2d 1154, 1164, 196 USPQ 209, 217 (CCPA 1977). [**8]

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of § 112. We have decided in the past that § 112, second paragraph, which says in part "[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," allows the inventor to claim the invention as he contemplates it. In re Wolfrum, 486 F.2d 588, 179 USPQ 620 (CCPA 1973).

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention.If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the [**9] resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. n7/

n7/ See Fields v. Conover, 58 CCPA 1366, 443 F.2d 1386, 170 USPQ 276 (1971), wherein a subgenus was not described and In re Ruschig, 54 CCPA 1551, 379 F.2d 990, 154 USPQ 118 (1967), wherein a species of a properly described genus was found not to be described.

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. n8/ But, [**10] in drawing priorities between [*459] the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount. We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses.

n8/ We take notice of a practice formerly utilized by the PTO and found in the MPEP:

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Where an application, properly assigned to one examining group, is found to contain one or more claims per se classifiable in one or more other groups, which claims are not divisible inter se or from the claims which govern classification of the application in the first group, the application may be referred to the other group or groups concerned for a report as to the patentability of certain designated claims. This report will be known as a Patentability Report (P.R.) and will be signed by the primary examiner in the reporting group.

The report, if legibly written, need not be typed.

Note that the Patentability Report practice is suspended, except in extraordinary circumstances. See § 705.01(e).

We further note the authority of the Commissioner under 35 USC 41(b) to "establish charges for * * * services furnished by the Patent and Trademark Office." [**11]

Appellants contend that the examiner's action in withdrawing claims 8-13, 16, 17, 20, 22 and 23 from consideration as drawn to nonelected inventions constitutes a rejection under the holding of In re Haas. 486 F.2d 1053, 179 USPO 623 (CCPA 1973), and, therefore, the board improperly found a lack of jurisdiction. We do not agree. Clearly our decision in In re Hengehold, 58 CCPA 1099, 440 F.2d 1395, 169 USPQ 473 (1971), disposed of the theory that a restriction requirement and the subsequent action of the examiner in withdrawing nonelected claims from consideration, n9/ per se, constitutes a rejection. An exception is found in In re Haas, supra, wherein we determined that the examiner's action in withdrawing claims was a rejection because the "claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content." 486 F.2d at 1056, 179 USPQ at 625. (Emphasis ours.) We do not understand the PTO to make such a holding with respect to claims 8-13, 16, 17, 20, 22 and 23, nor that appellants argue that the PTO does so. Indeed, we note that appellants admitted in their brief before the board that claims 8-13 and 23 [**12] were "properly withdrawable." Consequently, the board's dismissal of the appeal to claims 8-13 and 23 was correct. The Commissioner's brief admits that claims 16, 17, 20 and 22 contain species of the invention of generic claim 1 and would be provided an examination on the merits should the § 121 rejection be reversed. We remand for appropriate action on claims 16, 17, 20 and 22, and dismiss the appeal of claims 8-13 and 23 for lack of jurisdiction.

n9/ 37 CFR 1.142(b) provides:

(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

The decision of the board affirming the rejection under § 121 is reversed, and the case is remanded for consideration of the "improper Markush" rejection of claims 1-6 and appropriate action on claims 16, 17, 20 and 22. The appeal of claims 8-13 and 23 is dismissed for lack of jurisdiction.

REVERSED AND REMANDED

CONCURBY:

RICH

CONCUR:

RICH, Judge, concurring.

I concur in the result reached in the main opinion, but there are few points [**13] I wish to make clear.

35 USC 121 deals with a matter of PTO practice known as "requirements for division" prior to the 1952 Patent Act which, for the first time, provided a statutory provision on this subject. It did so, under the heading "Divisional Applications," by giving the Commissioner a discretionary, unappealable power to restrict an application to one of several claimed inventions when those inventions were found to be "independent and distinct." 35 USC 121, first sentence; see also P.J. Federico, "Commentary on the New Patent Act" 35 USCA p. 1, at p. 34 (1954).

Ever since Ex parte Eagle, 1870 *C.D.* 137 (Com'r. Pats. 1870), at least, the expression used in § 121, "two or more * * * inventions are claimed," has connoted separate claims to separate inventions. It has no reference to generic or broad claims which "embrace" (the term used by the examiner and the board herein) or "cover" (the term used in the solicitor's brief in support of the board) two or more inventions. Section 121 nowhere uses the words "embraced" or "covered." It says "claimed," and that I take to mean what it has always referred to in the terminology [*460] of the patent law, a "claim" or definitional [**14] paragraph which, in the words of § 112, second paragraph, is "particularly pointing out and distinctly claiming the subject matter the applicant regards as his invention."

Dealing, as it does, with requirements for restriction, § 121 says nothing whatever about the rejection of claims, a matter entirely separate from restriction. For one thing, rejections are appealable to the board and restriction requirements are not. Federico, op. cit. p. 34; 37 CFR§ 1.144.

On this appeal from the rejection of claims 1-6 we do not have before us a restriction requirement under § 121. Such a requirement would not have been appealable to the board. We have before us an appeal from affirmance of a rejection. The examiner purported to base it on § 121 and the board accepted that theory, citing in support its own prior decision in *Ex parte Haas, 188 USPQ 374*, wherein it had said, "We believe the referred to section of the patent statute [§ 121] does provide a basis for such a rejection," namely, a rejection of a single claim "drawn to a multiplicity of independent and distinct inventions." n1/

ю.

n1/ Even the dissenting member of the board, who felt the "Markush" claims there involved were not to "independent and distinct" inventions, agreed that § 121 was a proper "legal basis" for a rejection. [**15]

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In dealing with claims 1-6, in spite of the fact there are multiple claims, we are not dealing with separate claims to separate inventions. Claim 1 is a generic claim and claims 2-6 are dependent thereon. They are all generic claims but of varying scope. They are treated together and each claim is rejected on the same ground, as being drawn to multiple allegedly independent and distinct inventions. Careful review of all statements by the examiner and the board makes it clear beyond question that the only basis asserted for rejecting claims 1-6 is that they cover or embrace or are directed to a plurality of independent and distinct inventions, and this is the sole reason given for saying they are "improper Markush claims" or for saying there is "misjoinder [of inventions] under 35 USC 121." Section 121 is asserted as the only legal basis for this rejection.n2/

> n2/ In addition to § 121, the examiner relied on the Commissioner's notice published May 1, 1974, in 922 O.G. 1016, now MPEP 803, as authorizing the rejection. That notice also, and solely, relies on § 121 for authority. In view of our decision here, it is obvious that the substance of the notice and the MPEP provision corresponding to it are as lacking in foundation as the rejection we are reversing. [**16]

The practice here challenged is tantamount to a refusal by the PTO to examine a single Markush claim in a single application because, in its opinion, it is broad enough to "embrace" or "cover" a plurality of inventions which, if presented separately, would be separately patentable, assuming any one of them to be prior art. n3/ The label it attaches to such a broad claim is "improper Markush" and the situation is described as "misjoinder."

n3/ This is the essence of the test for independence and distinctness set forth in the third paragraph of the Commissioner's notice of May 1, 1974, in determining whether the examiner has authority to reject a claim, under the fourth paragraph of the notice.

The fault in the PTO position is that it overlooks the obvious fact that almost any reasonably broad claim "embraces" or "covers" a multiplicity of inventions, in the sense of "dominating" them, which inventions might be separately patentable if and when presented in separate applications. Logically, this is not a sufficient excuse for refusing to examine a claim on its merits for compliance with 35 USC 101, 102, 103, and 112. None of those statutory sections, of course, justifies [**17] a refusal to examine.

The only justification or statutory authority put forward for refusing to examine is 35 USC 121. There is nothing therein, however, to excuse a refusal to examine an elected invention or an applicant's generic (broad) claim reading thereon, notwithstanding the generic claim reads on nonelected inventions and possibly many others, all potentially separately patentable. The PTO's own rules recognize the distinction between generic claims and separately [*461] patentable inventions encompassed or covered thereby. 37 CFR § 1.141 deals explicitly with "independent and distinct inventions" n4/ even permitting five of them to be patented on one application along with a generic claim. As to species in excess of five specifically claimed, it is implicit that they may still fall within the "coverage" of the generic claim even if separately patented. It is elementary patent law that the number of "species" "covered" by a patent having a generic claim is virtually without limit notwithstanding the limitation of Rule 141 to five species "specifically claimed." So the discretionary power to limit one application to one invention is no excuse at all for refusing to [**18] examine a broad generic claim -no matter how broad, which means no matter how many independently patentable inventions may fall within it.

n4/ Note Rule 141's wording: "Two or more independent and distinct inventions may not be claimed in one application, except * * *." (My emphasis.) Compare the wording of 35 USC 121.

Of course a broad claim may be unpatentable for any number of reasons, but we are not here dealing with a question of patentability under the statute but with a refusal to examine.

The only basis here claimed in support of the labels "improper" and "misjoinder" is the scope of the claim. That is not sufficient excuse.

As for the true meaning of the words "two or more independent and distinct inventions are claimed" in § 121, being based -- as they were -- on the "division" practice existing in the then Patent Office in 1952, there can be no doubt they refer to separate inventions separately claimed and to a requirement to put separate claims in separate applications or at least to restrict one application to one claimed invention. There is no indication that enactment of § 121 contemplated refusing examination to generic claims because of their scope [**19] or that applicants were to be denied the right to present single claims of any breadth they chose and have them examined.

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The PTO effort of the past few years to justify its refusal to examine by issuing a "rejection" pursuant to the May 1, 1974, notice (MPEP 803) on the basis of § 121 is mere semantic gamesmanship.

With respect to the remand to consider the "improper Markush" rejection of claims 1-6, it is my view, based on careful analysis of the rejections actually made, that the PTO, following the May 1, 1974, notice (922 OG 1016), created a new kind of "improper

Markush" rejection based on 35 USC 121 which we are reversing. There remains, however, a vast body of precedent antedating the 1974 notice on what proper "Markush" claims are. As I understand the majority's remand, it is for the purpose of examining claims 1-6 under the pre-notice law relating to Markush practice in the process of examining these claims on their merits. Until now, such examination has been refused because they "cover" or "embrace" too much, a basis of rejection we find impermissible.

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LEXSEE 631 F.2D 716

IN RE HORST HARNISCH

Appeal No. 79-614.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

631 F.2d 716; 1980 CCPA LEXIS 226; 206 U.S.P.Q. (BNA) 300

June 12, 1980, Decided

PRIOR HISTORY: [**1]

Serial No. 559,978.

LexisNexis(R) Headnotes

COUNSEL:

Leonard Horn, attorney or record for appellant.

Joseph F. Nakamura, for the Commissioner of Patents and Trademarks, Fred E. McKelvey, of counsel.

OPINIONBY:

RICH

OPINION: [*716]

Before MARKEY, Chief Judge, RICH, BALDWIN, and MILLER, Associate Judges, and FORD, Judge. *

* The Honorable Morgan Ford, Judge, United States Customs Court, sitting by designation.

RICH, Judge.

This appeal is from the decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) rejecting, under 37 CFR 1.196(b), claims 1 and 3-8 n1/ of appellant's application, serial No. 559,978, filed March 19, 1975, for "Coumarin Compounds," on the sole ground that these claims are "drawn to improper Markush groups." We reverse.

n1/ The board also newly rejected claim 6 as indefinite under 35 USC 112 due to an improper dependence and claim 8 as improperly dependent from two claims, 7 and 4. Appellant acknowledges in his brief that no appeal is taken from either of these rejections, wherefore we need not consider them.

The Invention

The claimed compounds encompass coumarin compounds useful as dyestuffs. Some of them may be used as [**2] intermediates to make other dyestuffs. Claim 1 is representative and reads as follows:

1. Coumarin compounds which in one of their mesomeric limiting structures correspond to the general formula [See Illustration in Original] [*717]

wherein

X represents aldehyde, azomethine, or hydrazone,

R1 represents hydrogen or alkyl,

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

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

and wherein

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

Claims 3-6 depend from claim 1, adding further limitations with respect to the substituents; claim 7 is an independent claim of the same type as claim 1 but of much greater length in naming substituents, and claim 8 depends therefrom as well as from claim 4. [**3]

The instant coumarins are said to be useful for dyeing synthetic or natural fibers, plastics, and liquids such as oils and lacquers. Of apparently significant commercial value is the dyeing of either the aqueous or organic based inks preferred in rotary gravure printers for non-textile articles.

Clear shades of yellows to oranges are purportedly achieved with good fastness properties. In addition, a strong chartreuse to yellow fluorescence supposedly occurs upon exposure to either natural or ultraviolet light. The fluorescence is said to be especially suitable for tunable dye lasers.

The Rejection

The examiner, relying on no prior art, rejected claims 1 and 3-8 under 35 USC 121 "as containing an improper Markush group and misjoinder." More explicit reasons were said to be set forth in the earlier Office Action of May 12, 1976. In that action the examiner enumerated ten species of compounds encompassed by the claims. Beside each group he listed the various PTO class 260 subclasses into which the species fall.

The significance of this segmentation was declared to be twofold. In the examiner's words,

A reference anticipating one member [of the listed groups] would [**4] not render any other member obvious under 35 USC 103. The members are not so few in number or so closely related that a search and examination of the entire claim cannot be made with [sic, without?] serious burden.

The Board

The board summarily reversed the rejection of the appealed claims under 35 USC 121. Citing our decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978), and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), decided subsequent to the examiner's rejection, the board stated that " 35 USC 121 does not form the basis for rejection of claim * * *."

A new rejection was then made by the board under 37 CFR 1.196(b), n3/ rejecting the claims as "drawn to improper Markush groups." After a lengthy listing of decisions from 1925 to 1953 reviewing "Markush practice," by the Commissioner, the [*718] board, and this court, n4/ the board expounded its theory of the propriety of its new "improper Markush group" rejection solely on the basis of "judicially created doctrine," as follows (our emphasis):

n3/ 37 CFR 1.196(b), in relevant part, reads:

(b) Should the Board of Appeals have knowledge of any grounds not involved in the appeal for rejecting any appealed claim, it may include in its decision a statement to that effect with its reasons for so holding, which statement shall constitute a rejection of the claims. * * *

n4/ As detailed by the board:

Markush practice has a long history in the Office dating back to at least Ex parte Markush, 1925 CD 126, 340 OG 839. Since that time, the Office and the Court of Customs and Patent Appeals had considered rejections based on the propriety and/or limitations of Markush-type claims. See, for example, Ex parte Palmer et al, 1930 CD 3, 398 OG 707; Ex parte Burke, 1934 CD 5, 441 OG 509; Ex parte Dahlen, 1934 CD 9, 441 OG 510; In re Swenson et al, 30 CCPA 764, 132 F.2d 336, 1943 CD 175, 56 USPO 180 (1942); In re Hass et al, 31 CCPA 895, 141 F.2d 122, 1944 CD 234, 60 USPQ 544 (1944); In re Kingston, 32 CCPA 1013, 149 F.2d 181, 1945 CD 297, 65 USPO 371 (1945); In re Ruzicka et al, 32 CCPA 1165, 150 F.2d 550, 1945 CD 449, 66 USPO 226 (1945); In re Archbold, 33 CCPA 725, 151 F.2d 350, 1946 CD 63, 67 USPQ 102 (1945); In re Thompson et al, 33 CCPA 642, 154 F.2d 189, 1946 CD 280, 69 USPQ 148 (1946); In re Winnek, 34 CCPA 946, 160 F.2d 572, 1947 CD 280, 73 USPO 225 (1947); In re Jones, 34 CCPA 1150, 162 F.2d 479, 1947 CD 484, 74 USPQ 149 (1947); In re May et al, 36 CCPA 833, 172 F.2d 593, 1949 CD 119, 80 USPQ 515 (1949); In re Schechter et al, 40 CCPA 1009, 205 F.2d 185, 1953 CD 323, 98 USPQ 144 (1953). Additional analysis of Markush practice appears

Additional analysis of Markush practice appears particularly in the following articles:

Kelly et al., Markush Claims, 37 JPOS 164 (1955), (a 75-page exhaustive review of the practice by a committee of the Michigan Patent Law Association).

Walterscheid, Markush Practice Revisited, 61 JPOS 270 (1979). [**5]

Applying the facts of this case to the principles enunciated, we find that the members of the Markush groups of the claims do not belong to a known or recognized genus and possess widely different physical

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or chemical properties. Aside from the obvious fact that the compounds encompassed by the claims are not functionally equivalent, said compounds, considered as a whole, are so dissimilar and unrelated chemically or physically that it would be repugnant to accepted principles of scientific classification to associate them together as a generic group. For example, the types of derivatives encompassed by the Markush claim may include polyfused N-heterocyclics, cyclic, acyclic and aromatic aryloxyalkylamines, amides. amines. sulfonamides, phthalimides, quaternary ammonium salts, phosphorous heterocyclics, phosphates, aldehydes, azomethines, hydrazones, ethers, esters, halogens, alcohols, nitriles, piperidines, furanes, pyrroles, indoles, amongst others. It is clear that on this record the involved compounds cannot be considered functionally equivalent, in fact, some being no more than intermediates for the others. The foregoing is borne out by the record wherein appellant discloses [**6] that the various groups or compounds possess different physical or chemical properties. Nowhere in the record has it been established or even alleged that the variety of compounds included within the the explicit scope of the claims are recognized by the art as being functionally equivalent. The functional groups involved herein, as emplified above, are so structurally diverse they would be expected to possess dissimilar and unrelated chemical and physical properties. The mere fact that there is a single structural similarity (i.e., the coumarin group) 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 relationship. Thus, the fact that the coumarins are in most part indicated as being dyestuffs (others being intermediates for dyes) is not sufficient, since, depending upon their structure, they may be subject to different modes of application and use.

Appellant's Position

Appellant, picking up the board's statement that its rejection "has basis in judicially created doctrine," as shown by the cases it cited, rather [**7] than in the patent statutes, asks this court, first, whether claims can be rejected on a judically-created doctrine rather than on some statutory basis, such as 35 USC 121 on which the examiner relied. If they can, then appellant asks, second, whether the compounds [*719] claimed are sufficiently closely related to be joined in the same claim.

On the first point, appellant seems to assume some unstated specific "doctrine" on which the board acted, against which he inveighs, and which he says cannot stand, urging us not to create a "doctrine."

On the second point, appellant discusses the fact situation underlying the appealed claims, showing that the compounds are all dyestuffs, that the members of group X, claim 1, are closely related, that the compounds are all coumarins, and cites two board opinions reversing rejections by the examiner of claims structured similarly to appellant's claims, namely, Ex parte Brouard, 201 USPQ 538 (Bd. App. 1976), and Ex parte Taylor, 167 USPO 637 (Bd. App. 1969). The former case, like this one, involved a claim 24 to a dyestuff defined by structure containing, inter alia, a substituent "B" the definition of which included a list of alternatives [**8] occupying about a column in the USPQ report. The rejection reversed was on the ground of "improper Markush group" and misjoinder of independent and distinct inventions.

The PTO Position

The solicitor's brief contains helpful digests of certain key cases selected from the many which discuss "Markush practice" from its inception in 1924 through 1979. It supports the board's new rejection on the ground the claims are drawn to "improper Markush groups." After stating that "Markush practice" is one of long standing and involves a vast body of precedent, the brief relies primarily on the following contentions: (1) there need not be a specific statutory basis for the rejection, citing by analogy obviousness-type double patenting rejections which are case-law based; (2) the materials set forth in the "Markush group" ordinarily must belong to a recognized physical or chemical class or to an artrecognized class; and (3) the claimed group must not be "repugnant to accepted principles of scientific classification."

A principal factual contention in the solicitor's brief is that appellant's claimed compounds include (1) dyestuffs, (2) intermediates for making dyestuffs, or (3) both, and [**9] fails to reveal the utility per se of each compound. However, at oral argument the solicitor announced with admirable candor that, having considered appellant's reply brief, he had concluded that there is in fact no class "(2)" because all of the claimed compounds are dyestuffs though some of them could also be used as intermediates to make still other dyestuffs.

The solicitor also cited authority to the effect that each "improper Markush" case must be decided on the basis of its own facts. He also stated that current PTO "Markush practice" is as set forth in section 706.03(y) of the Manual of Patent Examining Procedure (MPEP), 3d ed., Rev. 46, July 1976, reproduced in full as an appendix hereto.

OPINION

We will first express our views concerning the PTO's reliance on "judicially created doctrine" in its rejection of claims for "improper Markush grouping." Appellant injected this point into the case by contending that the PTO had no right to rely on doctrine because a statutory basis for rejection must be stated. He also seems to contend that there is no "doctrine" and that while this court could create one it should not do so. In consequence, much of the oral argument was [**10] involved with the court trying to find out from the solicitor what, if any, "doctrine" was being relied on by the PTO, no clear answer being forthcoming -- with good reason.

Upon reflection and consideration of the cases cited by the board, the discussion of those and others by the solicitor, and the recorded history of Markush practice, it appears to us that all of the discussion of "doctrine" is beside the point because there is no "Markush doctrine." Appellant never made clear or specific what "doctrine" he was referring to and the solicitor, justifiably, was unable to point one out to us.

"Markush" was the name of an applicant for patent (Eugene A. Markush) who happened to use in a claim a type of definition [*720] of a genus or subgenus by enumeration of species, which he did not devise and which had been used before in patent claims. n5/ The examiner considered the claim to be "alternative" in form, objected to it, and Markush petitioned the Commissioner. Assistant Commissioner Kinnan, in Ex parte Markush, 1925 CD 126 (Com. Pat. 1924), approved the form of claim and granted the petition, thus requiring the examiner to examine it for patentability. Thus the name "Markush" [**11] became attached to a type of claim expression, and that is all it connotes. As others rang changes on the type of expression used by Markush and approved by Assistant Commissioner Kinnan, further decisions and opinions on petitions and in appeals ensued and a considerable body of case law evolved, approving and disapproving various forms of Markush-type expression, from which cases a number of rules can be deduced. Like other bodies of case law, however, the body pertaining to what may properly be called Markush practice has not been altogether consistent and has evolved through the years. Among the inconsistent decisions, some of them were by this court. In the PTO, one of the changes that took place was the abandonment of the rule against the use of "or" in an enumeration of alternative materials that might be used in a claimed invention, which rule was the basis of the objection giving rise to the Markush decision. A specific example will be found in MPEP 706.03(y). Not long ago, by a Notice under date of May 1, 1974, the PTO set up a "Practice Re Markush-Type Claims" and later incorporated the Notice in MPEP section 803.

Since the MPEP revision of July 1978, that practice [**12] has not been followed because of two decisions of this court and MPEP 803 now contains this statement:

n5/ The Markush opinion points out that in another division of the Patent Office claims "of this character" have been allowed, citing Patents Nos. 1,472,048 and 1,486,635, and that, long before that, Patent No. 901,975 contained claims in which the letter R is used in a chemical formula as standing for CH3 or COOH" and that such claims had frequently been allowed. Markush ultimately obtained Patent No. 1,506,316, Aug. 26, 1924.

PRACTICE RE MARKUSH-TYPE CLAIMS

The subject matter formerly under this subtitle has been cancelled in view of the decisions *In re Weber et al., 198 USPQ 328 (CCPA 1978);* and *In re Haas, 198 USPQ 334 (CCPA 1978).*

Thus have decisions changed the Markush practice.

It is also clear that Markush practice does not refer to a single rule. As may be seen from MPEP 706.03(y) set forth in the appendix, the PTO has one practice with respect to claims directed to compounds per se and a different one when they are directed to a process or composition involving a combination of steps or ingredients wherein the Markush-type definition-byenumeration is used [**13] in defining a process step or composition element.

In summary, there is no "doctrine" to be considered but only a body of case law, emanating from both "higher" and "lower" authority, not altogether consistent, the latest decisions tending to carry the most weight as precedent.

Coming now to appellant's first contention that the board had no right to rely on "judicially created doctrine," we note that a doctrine, by definition, is, according to Black's Law Dictionary, revised 4th ed., "A rule, principle, theory, or tenet of the law." As is clear from the entire board opinion, what it meant was that it intended to rely on rules, principles, or tenets derivable from the cases it cited which would enable it to determine whether the claims before it were or were not in proper form to be examined for patentability. Our ruling on this point is that it had a perfect right to do so. But there is not one "doctrine" or rule; there are many.

The next questions are whether the board correctly interpreted the facts and whether it correctly applied the rules of law derivable from the cases to the facts. Before considering these questions, we take note of some recent history respecting [**14] Markush practice. [*721]

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In the PTO, patent applications are examined for compliance with the statutory provisions of Title 35, United States Code, as set forth in sections 100, 101, 102, 103, and 112. These are considered to be examinations "on the merits." There are also procedural questions arising under section 121 and related PTO rules concerned with "restriction practice." See MPEP, Chapter 800. As shown by the In re Haas cases, n6/ issues arose from PTO refusal to consider on the merits single claims to groups of chemical compounds of broad scope unless each claim was first broken up into a plurality of claims of lesser scope. The first PTO position was that it would neither consider nor reject the claims, thus foreclosing appeal to the board or to this court. After this position was held to be a rejection, the PTO promulgated its May 1, 1974 Notice, which authorized rejection on the basis of § 121, relating to restriction, thus combining the two matters of Markush practice and restriction practice. In Haas II (see note 6, supra), this court held that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality [**15] of narrower claims before examination on the merits would be made. Haas II was decided at the same time as In re Weber, supra, involving similar issues, and Haas II was decided on the basis of the opinion in Weber. We note that in Weber the majority opinion regarded the "improper Markush grouping" reasoning of the board as having been merely "supportive of the rejection under § 121 rather than alternative to it" and dealt only with the § 121 rejection, reversing it and remanding the case to the PTO for consideration, separately, of the "improper Markush" rejection. The concurring opinion, by the present writer, pointed out with respect to that remand, that there existed a vast body of case law relating to Markush practice. We have not yet heard again from Weber, but the present case comes to us in similar posture. Note that this case involves an improper Markush rejection by the examiner based on § 121 which the board reversed in view of Weber, substituting its own improper Markush rejection based only on judicial precedent and divorced from § 121.

> n6/ Ex parte Haas, 175 USPQ 217 (Bd. App. 1972), reversed, In re Haas, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973) ("Haas I"); Ex parte Haas, 188 USPQ 374 (Bd. App. 1975), reversed, In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978) ("Haas II"). [**16]

Anent appellant's argument that the board should not be allowed to rely solely on judicial precedent, we think it should be clear from our actions in Weber and Haas II that we there recognized the possibility of such a thing as an "improper Markush grouping." We were and are aware that it does not have a specific statutory basis, as we are aware of an applicant's right to define what he regards as his invention as he chooses, so long as his definition is distinct, as required by the second paragraph of § 112, and supported by enabling disclosure, as required by the first paragraph of § 112. In re Wakefield, 57 CCPA 959, 422 F.2d 897, 164 USPQ 636 (1970); In re Borkowski, 57 CCPA 946, 422 F.2d 904, 164 USPQ 642 (1970).

In the early years of the development of Markush practice, many of the cases involved the problem of clarity -- avoiding the uncertainties of alternatives and the like. More recently, the cases have centered on problems of scope, which are related to enablement. Assuming enablement, however, there remains a body of Markush-practice law regarding Markush-type claims, particularly in the chemical field, concerned more with the concept of what might be better described [**17] as the concept of unity of invention. At least the term would be more descriptive and more intelligible internationally than is the more esoteric and provincial expression "Markush practice." It is with this unity of invention concept in mind that we approach the propriety of the appealed claims.

Over thirty years ago this court decided In re Jones, 34 CCPA 1150, 162 F.2d 479, 74 USPO 149 (1947), reversing an "improper Markush group" rejection of claims to chemical compounds which were [*722] growth-regulating compositions for plants, fungicides, Notwithstanding their various and insecticides. properties, the court found all of the compounds included in the claims were plant growth stimulants, thus having a common function. The court noted that in any Markush group the compounds "will differ from each other in certain respects." It laid down the proposition, with which the PTO agrees in its MPEP, that in determining he propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components. It also held, in agreement with the board, that each case of this type must be considered on its own facts. Citing Ex parte [**18] Clark, 11 USPQ 52 (Com. Pat. 1931), a case decided by the author of the original Markush opinion, it noted that "the inclusion in Markush groups of compounds which differed widely in some respects," namely, aliphatic, aromatic, and aralkyl compounds, had been permitted. It cited Ex parte Dahlen, 42 USPO 208 (Bd. App. 1938) as permitting the grouping of compounds having the same nuclei but side chains wherein there was a wide It found the claims before it to cover variation. compounds all belonging to a genus of tetralyl compounds having a substituted methyl group at position 6 and ruled that they had a community of properties

justifying their grouping which was not repugnant to principles of scientific classification.

We regard the present case as similar to In re Jones, supra, and also the much later decision of the board in Ex parte Brouard, supra, in which the board reversed the examiner's "improper Markush" rejection. We conclude that the board here was factually in error in not recognizing that all of appellant's claimed compounds are dyes, as confirmed by the solicitor's admission. The board's reliance on its notion that some of the claimed compounds are "no more than [**19] intermediates" overlooked the now admitted fact that they are dyes as well. Clearly, they are all coumarin compounds which the board admitted to be "a single structural similarity." We hold, therefore, that the claimed compounds all belong to a subgenus, as defnied by appellant, which is not repugnant to scientific classification. Under these circumstances we consider the claimed compounds to be part of a single invention so that there is unity of invention as was held to be the case in Ex parte Brouard, supra, 201 USPO at 540. The Markush groupings of claims 1 and 3-8 are therefore proper.

As stated above, we decide this and like cases on their facts on a case-by-case basis. It should also be clear from what we have said that we adhere to our holdings in In re Weber, supra, and In re Hass (Hass II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be reasonably construed to have such an effect. The "unity of invention" concept is not to be confused with the "misjoinder under 35 USC 121" rejection employed in In re Weber. In Weber we dealt with the use of 35 USC 121, which deals only with restriction requirements, [**20] to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an "improper Markush group." Reference to the widely-recognized concept of "unity of invention" has been made in order to suggest an appropriate term to apply where unrelated inventions are involved -inventions which are truly independent and distinct. n7/ This case, we find, does not involve such inventions.

n7/ Having recognized the possibility of rejecting a Markush group type of claim on the basis of independent and distinct inventions, the PTO may wish to anticipate and forestall procedural problems by exercising its rulemaking powers under 35 USC 6(a), wherein the views of interested parties may be heard.

Appellant expressly stated in his brief that no appeal was being taken from the rejection of claim 6 under 35 USC 112 or of claim 8 as improperly dependent. In addition, while appellant's reasons of appeal alleged error in the board's supposed dismissal of claims 9-14 and 23-25, this [*723] alleged error has not been argued and is therefore deemed abandoned. The appeal with respect to claims 6, 8-14, and [**21] 23-25 is therefore dismissed.

The board's rejection of claims 1 and 3-8 as based on "improper Markush groups" is reversed.

REVERSED

APPENDIX

706.03(y) Improper Markush Group

[R-49]

Ex parte Markush, 1925 C.D. 126; 340 O.G. 809, sanctions, in chemical cases, claiming a genus expressed as a group consisting of certain specified materials. This type of claim is employed when there is no commonly accepted generic expression which is commensurate in scope with the field which the applicant desires to cover. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology, may be claimed under the Markush formula but it has consistently been held to be improper to extent it to purely mechanical features or process steps. It is improper to use the term "comprising" instead of "consisting of". Ex parte Dotter, 12 USPQ 382. Regarding the normally prohibited inclusion of Markush claims of varying scope in the same case, see Ex parte Burke, 1934 C.D. 5; 441 O.G. 509.

The use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims. However, if such a practice renders the claims [**22] indefinite or if it results in undue multiplicity, an appropriate rejection should be made. This practice with respect to Markush claims of diminishing scope is being continued.

The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly reasonable for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. While in the past the test for Markushtype claims was applied as liberally as possible, present practice which holds that claims reciting Markush groups are not generic claims (§ 803) may subject the groups to a more stringent test for propriety of the recited members. Where 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

631,F.2d 716, *; 1980 CCPA LEXIS 226, **; 206 U.S.P.Q. (BNA) 300

compound as a whole, and does not depend [**23] on there being a community of properties in the members of the Markush expression.

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation then "wherein R is A, B, C or D" shall also be considered proper.

SUBGENUS CLAIM

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A situation may occur in which a patentee has presented a number of examples which, in the examiner's opinion, are sufficiently representative to support a generic claim and yet a court may subsequently hold the claim invalid on the ground of undue breadth. Where this happens the patentee is often limited to species claims which may not provide him with suitable protection.

The allowance of a Markush type claim under a true genus claim would appear to be beneficial to the applicant without imposing any undue burden on the Patent and Trademark Office or in any way detracting from the rights of the public. Such a subgenus claim would enable the applicant to [*724] claim all the disclosed operative embodiments and afford him an intermediate [**24] level of protection in the event the true genus claims should be subsequently held invalid.

The examiners are therefore instructed not to reject a Markush type claim merely because of the presence of a true genus claim embracive thereof.

See also § § 608.01(p) and 715.03.

See § 803 for restriction practice re Markushtype claims.

580 F.2d 461, *; 1978 CCPA LEXIS 262, **; 198 U.S.P.Q. (BNA) 334

LEXSEE 580 F2ND 461

IN THE MATTER OF THE APPLICATION OF HOWARD C. HAAS

Appeal No. 78-536.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

580 F.2d 461; 1978 CCPA LEXIS 262; 198 U.S.P.Q. (BNA) 334

June 30, 1978, Decided

PRIOR HISTORY: [**1]

Serial No. 821,511.

COUNSEL:

Stanley H. Mervis, attorney of record, for appellant.

Charles A. Wendel, Karl F. Jorda, Harold C. Wegner, attorneys of record, for Amicus Curiae, Earl L. Tyner, Harry E. Westlake, Jr., of counsel.

Joseph F. Nakamura for the Commissioner of Patents, Fred E. McKelvey, of counsel.

OPINIONBY:

MARKEY

OPINION: [*462]

Before MARKEY, Chief Judge, RICH, BALDWIN, LANE, and MILLER, Associate Judges.

MARKEY, Chief Judge.

This appeal is from a decision of the United States Patent and Trademark Office (PTO) Board of Appeals (board) affirming a final rejection under 35 USC 121 of claims 7 and 8 of application serial No. 821,511, filed May 2, 1969, entitled "Novel Polymerization Initiators." nl/We reverse and remand.

n1/ A continuation-in-part of serial No. 630,222, filed April 12, 1967.

Invention

The invention is a group of benzoyl peroxides:

[Graphic omitted. See illustration in original.] useful as initiators for polymerization of vinyl-containing compounds or monomers. Haas states: "The substituent X does not participate in the polymerization initattion, but it does introduce into the resulting polymer a reactive, [**2] terminal group at one or both ends of the resulting polymer chain. Thus, while the resulting polymers may have different utilities, all of the claimed compounds have the same utility [i.e., polymerization initiators]."

Claims 7 and 8 are the sole claims on appeal:

7. A compound of the formula [Graphic omitted. See illustration in original.] wherein X is selected from the group consisting of alpha-monosubstituted chloro, bromo and fluoro alkyl groups containing from 1-3 carbon atoms, inclusive; and -C-H, C=O.

8. The invention of claim 7 wherein X is selected from the group consisting of alpha-monosubstituted chloro alkyl groups containing from 1-3 carbon atoms, inclusive; and -C-H, C=O.

Background

Haas comes before this court for the second time on the present application. In *In re Haas, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973)* (Haas I), the examiner held claims 1 and 2 withdrawn from further consideration under 35 USC 121 as drawn to "multiple patentable [sic, patentably] distinct inventions." n2/ This court held that "withdrawal" of a claim from consideration, [*463] under those circumstances, constituted a rejection

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n2/ Claim 2 was dependent from claim 1 and limited substituent X to the para position of the benzene rings. The "independent and distinct" inventions were thus alleged to fall within claim 1 alone or claims 1 and 2 taken together.

The board remanded the case to the examiner. The examiner rejected claims 1 and 2 "as improper Markush claims and for misjoinder [of invention] under 35 USC 121" because drawn to multiple "independent and distinct" inventions. Though initially arguing that claims 1 and 2 did not define "independent and distinct" inventions, Haas expressly abandoned that argument on appeal to the board and conceded "that his recited Markush group contains 'multiple independent and distinct inventions' in the same sense that a generic term may contain multiple independent and distinct inventions." In view of that concession, the board stated: "[The] only question presented by this appeal is whether or not a single claim which includes a plurality of independent and [**4] distinct inventions is legally rejectable." n3/ The board answered affirmatively.

n3/ Ex parte Haas, 188 USPQ 374, 376 (PTO Bd. App. 1975).

In its opinion, the board viewed the examiner's rejection as based on claiming an improper Markush group and misjoinder of invention under 35 USC 121. In affirming the examiner's rejection as based on claiming an improper Markush group, the board said "[whether] or not there is a statutory basis for such a rejection is of no real concern, since such a rejection has basis at least in established judicial doctrine," n4/ and that it was unnecessary to decide whether § 121 provided a basis for rejection. The board, nonetheless, proceeded to decide that question. In the board's opinion, § 121 did provide a basis for rejection because "[the] statute * * * broadly permits the Commissioner, in his discretion, to refuse to grant a patent on an application containing two or more independent and distinct inventions." n5/ Additionally, the board entered rejections under 37 CFR 1.196(b) based upon § 102(b), § 112, first paragraph, and § 112, second paragraph. One board member, dissenting-in-part, stated that he did not agree that "independent [**5] and distinct inventions" were claimed, despite Haas' admission.

n4/ Id.

n5/ Id. at 377.

Haas elected to carry on further prosecution before the examiner. 37 CFR 1.196(b). Following an amendment adding two claims numbered 6 and 7, the examiner finally rejected claims 1, 2, 6 and 7, inter alia, "as improper Markush claims and misjoinder under 35 USC 121." Other rejections included res judicata (claims 1 and 2), 35 USC 132 (claims 6 and 7, new matter), and 35 USC 102(b) (claims 1, 2, 6 and 7).A claim 5, apparently originally allowed, was rejected under 35 USC 112, first paragraph, because the board's § 1.196(b) rejection under § 112, first paragraph, of claims 1 and 2 applied to claim 5 as well. Haas proposed present claim 8 in an after-final amendment, 37 CFR 1.116, entered by the examiner with the understanding that claim 8 stood rejected for the same reasons applied to claims 5, 6 and 7.

On appeal, under a heading " 35 USC 121 Rejection," the board stated: "This rejection, as acknowledged by the appellant, raises the same issues as were involved in the Examiner's rejection under 35 USC 121 involved in the previous appeal." Noting that Haas had not raised any additional [**6] arguments and relied upon arguments made in the previous appeal, the board affirmed the rejection "for the reasons given by us [in the previous appeal]." The board proceeded to reverse the § 132 rejection, the res judicata rejection, and the § 102(b) rejection as to claims 7 and 8, but affirmed the § 102(b) rejection as to claims 1, 2, 5 [*464] and 6, and affirmed the § 112, first paragraph rejection of claims 1, 2, 5 and 6. The board further entered a 37 CFR 1.196(b) rejection of claims 1, 2, 5, 6, 7, and 8 under 35 USC 112, second paragraph. The dissenting board member in the previous appeal filed a concurrence again expressing his opinion that the claims, particularly claims 7 and 8, did not recite independent and distinct inventions, but agreed to the result in view of Haas' concession.

Prosecution again returned to the examiner. Haas cancelled claims 1, 2, 5 and 6, rewrote claim 7 in independent form, and otherwise amended the claims mooting all issues save the issue under § 121. Thus, on the third and final appearance before the board, only claims 7 and 8 remained and stood rejected "under 35 USC 121 as containing improper Markush groups and misjoinder of inventions [**7] in the combination of the members in said Markush groups." In that appearance, the board made final its previous decision affirming that rejection.

Issue

The claims are solely rejected under 35 USC 121 in accordance with the mandate in the Manual of Patent

Examining Procedure (MPEP) 803 as containing "improper Markush groups and [for] misjoinder of inventions" because those claims are viewed as directed to independent and distinct inventions.n6/ Accordingly, the issue is whether § 121 furnishes a basis for rejecting a claim.

n6/ There is no rejection and, consequently, no issue before us that the claims are drawn to improper Markush groups as described by the PTO in MPEP 706.03(y).

OPINION

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In In re Weber, decided of even date, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed in this case as a basis for rejection, that rejection is, on the authority of Weber, reversed.

The examiner's rejection of claims 7 and 8 herein as "improper Markush" claims is inextricably intertwined on this record with the application of § 121. The solicitor's brief states that the examiner is willing to examine claims [**8] 7 and 8 as a whole on their merits.

Accordingly, the decision of the board is reversed and the case is remanded for examination of claims 7 and 8 on their merits.

REVERSED AND REMANDED

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

OCT 1 1 2005

PFAHL et al.

J.

Application No. 10/224,288

Filed: August 19, 2002

FOR: **"OXIME DERIVATIVES FOR THE TREATMENT OF DYSLIPIDEMIA AND HYPERCHOLESTEREMIA"**

Confirmation No. 8436

Group Art: 1623

Examiner: Ward, Paul V.

RESPONSE TO OFFICE ACTION

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MAIL STOP AMENDMENT Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. Customer Number 23859

October 7, 2005

Sir:

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In the Office Action dated August 11, 2005, the examiner finalized a restriction requirement that purported to withdraw claims 18-20 and 22-26 from consideration, and rejected claims 1-17 and for alleged anticipation and/or obviousness over two references. Applicants' remarks and responses begin on page 2 of this paper.

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1623.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ENTE Application of:)
PFAHL et al.)) Confirmation No: 8436
Application No. 10/224,288) Group Art: 1623
Filed: August 19, 2002) Examiner: Ward, Paul V.
FOR: "OXIME DERIVATIVES FOR THE TREATMENT OF DYSLIPIDEMIA AND HYPERCHOLESTEREMIA")))

ELECTION UNDER RESTRICTION REQUIREMENT

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. Customer Number 23859

May 5, 2005

Sir:

In the Office Action for the captioned matter dated March 11, 2005, the examiner

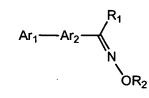
restricted the captioned application and required an election between thirteen groups of claims.

Originally filed claims 1-26 were pending in the Application. Applicants herein enter amendments, and a listing of all currently pending claims begins on page 2 of this paper.

Remarks and responses to the restriction requirements begin on page 10 of this paper.

Listing of Claims

1. (Currently Amended) Compounds One or more compounds of the formula



wherein

- Ar₁ comprises a substituted aryl or heteroaryl ring wherein two substituents together with the aryl or heteroaryl ring of Ar₁ together form an additional cycloalkyl, substituted cycloalkyl, cycloalkenyl or substituted cycloalkenyl ring radicals optionally comprising 1 or 2 ring heteroatoms selected from O, S, SO, SO₂ and N, wherein N is further substituted with hydrogen, alkyl or substituted alkyl;
- b) Ar₂ is a substituted or unsubstituted aryl radical or a substituted or unsubstituted heteroaryl radical;
- c) R₁ is hydrogen, a substituted or unsubstituted amino radical, or a substituted or unsubstituted organic radical comprising from one to 12 carbon atoms; and
- R₂ is hydrogen, or a substituted or unsubstituted organic radical comprising from one to 12 carbon atoms;

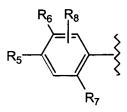
or a pharmaceutically acceptable salt thereof, wherein the compounds do not comprise the compound 3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydronaphthyl-2-yl)-4trifluoromethoxybenzaldehyde (hydroxyoxime).

- (Original) The compound of claim 1, wherein the Ar₁ aryl or heteroaryl ring and the additional cyclic ring radical bonded thereto have 1, 2, 3, 4, 5, 6, or 7 non-hydrogen substituent groups, and Ar1 and its substitutent groups together comprise between 6 and 30 carbon atoms.
- 3. (Original) The compound of claim 2, wherein the non-hydrogen substitutent groups are independently selected from the group consisting of an alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, halogen, hydroxyl, acyloxy, alkoxy,

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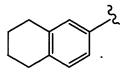
substituted alkoxy, acyl, amino, mono-substituted amino, di-substituted amino, carboxy, carboalkoxy, alkylcarboxamide, substituted alkylcarboxamide, dialkylcarboxamide, substituted dialkylcarboxamide, or alkylsulfonamide radical.

- 4. (Original) The compound of claim 1, wherein the additional cycloalkyl, substituted cycloalkyl, cycloalkenyl or substituted cycloalkenyl ring radical bonded to the aryl or heteroaryl ring of Ar₁ comprises from 1 to 8 additional ring carbon atoms exocyclic to the aryl or heteroaryl ring.
- 5. (Original) The compound of claim 1, wherein Ar_1 has the formula:

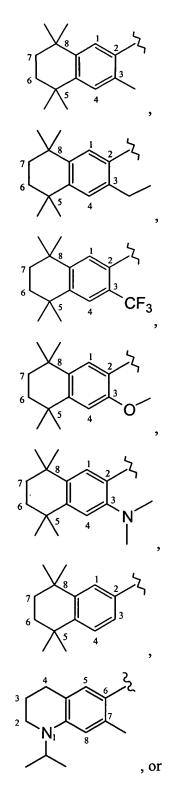


wherein: R_5 and R_6 together with the aromatic ring form a cycloalkyl, substituted cycloalkyl, cycloalkenyl or substituted cycloalkenyl optionally comprising 1 or 2 heteroatoms selected from O, S, SO, SO₂ and N, wherein N is further substituted with hydrogen, alkyl or substituted alkyl; and R_7 and R_8 are independently or together selected from the group consisting of hydrogen, alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, halogen, hydroxyl, acyloxy, alkoxy, substituted alkoxy, acyl, amino, mono-substituted amino, di-substituted amino, carboxy, carboalkoxy, alkylcarboxamide, substituted alkylcarboxamide, dialkylcarboxamide, substituted dialkylcarboxamide, and alkylsulfonamide radical.

6. (Original) The compound of claim 1, wherein Ar_1 comprises a substituted or unsubstituted ring radical of the formula:



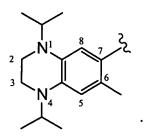
7. (Original) The compound of claim 1, wherein Ar_1 has one of following the formulas:



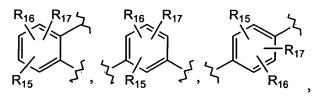
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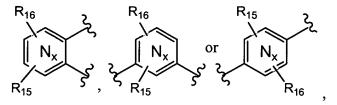


- (Original) The compound of claim 1, wherein the Ar₂ aryl or heteroaryl ring has 0, 1, 2, or 3 non-hydrogen substituent groups, and Ar₂ and its substitutent groups together comprise between 4 and 20 carbon atoms.
- 9. (Original) The compound of claim 8, wherein the non-hydrogen substituent groups are independently selected from the group consisting of an alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, halogen, hydroxyl, acyloxy, alkoxy, substituted alkoxy, acyl, amino, mono-substituted amino, di-substituted amino, carboxy, carboalkoxy, alkylcarboxamide, substituted alkylcarboxamide, dialkylcarboxamide, substituted alkylsulfonamide radical.
- 10. (Original) The compound of claim 1, wherein Ar_2 has one of the formulas:



wherein R₁₅, R₁₆ and R₁₇ are independently selected from the group consisting of a hydrogen, alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, halogen, hydroxyl, acyloxy, alkoxy, substituted alkoxy, acyl, amino, mono-substituted amino, di-substituted amino, carboxy, carboalkoxy, alkylcarboxamide, substituted alkylcarboxamide, dialkylcarboxamide, substituted dialkylcarboxamide, and alkylsulfonamide radical.

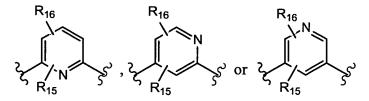
11. (Original) The compound of claim 1, wherein Ar_2 has one of the formulas;



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wherein N_x is 1 or 2 and the nitrogen atoms are unsubstituted ring atoms, R_{15} , R_{16} are independently selected from the group consisting of a hydrogen, alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, halogen, hydroxyl, acyloxy, alkoxy, substituted alkoxy, acyl, amino, mono-substituted amino, di-substituted amino, carboxy, carboalkoxy, alkylcarboxamide, substituted alkylcarboxamide, dialkylcarboxamide, substituted dialkylcarboxamide, and alkylsulfonamide radical.

12. (Original) The compound of claim 1, wherein Ar_2 has one of the formulas:



wherein R₁₅, and R₁₆ are independently selected from the group consisting of a hydrogen, alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, halogen, hydroxyl, acyloxy, alkoxy, substituted alkoxy, acyl, amino, mono-substituted amino, di-substituted amino, carboxy, carboalkoxy, alkylcarboxamide, substituted alkylcarboxamide, dialkylcarboxamide, substituted dialkylcarboxamide, and alkylsulfonamide radical.

- 13. (Original) The compound of claim 1, wherein R_1 is hydrogen, alkyl or substituted alkyl.
- 14. (Original) The compound of claim 1, wherein R_1 is hydrogen.
- 15. (Original) The compound of claim 1, wherein R_2 is hydrogen, alkyl or substituted alkyl.
- 16. (Original) The compound of claim 1, wherein R_1 and R_2 are hydrogen.
- 17. (Currently Amended) A compound having the formula:

3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-4-methoxybenzaldehyde oxime,

3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl) 4-

trifluoromethoxybenzaldehyde oxime,

3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-4dimethylaminobenzaldehyde oxime,

3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-2-fluoro-4-

methoxybenzaldehyde oxime,

5-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-6-methoxy-3-

pyridinecarboxaldehyde oxime,

6-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-5-methoxy-2-

pyridinecarboxaldehyde oxime,

3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-4-methoxy-6-

hydroxybenzaldehyde oxime,

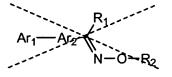
3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-4,6-dimethoxybenzaldehyde oxime,

3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydro-2-naphthyl)-4,6-dihydroxybenzaldehyde oxime,

3-(1,4-Diisopropyl-6-methyl-1,2,3,4-tetrahydro-7-quinoxalinyl)-4methoxybenzaldehyde oxime, or

a pharmaceutically acceptable salt thereof.

18. (Currently Amended) A process for preparing a compound having the formula: of claim 1



Formula (XV)

wherein:

 Ar₁ comprises a substituted aryl or heteroaryl ring wherein two substituents together with the aryl or heteroaryl ring of Ar₁ together form an additional cycloalkyl, substituted cycloalkyl, cycloalkenyl or substituted cycloalkenyl ring radical optionally comprising 1 or 2 ring heteroatoms selected from O, S, SO, SO₂ and N, wherein N is further substituted with hydrogen, alkyl or substituted alkyl;

- b) Ar₂ is a substituted or unsubstituted aryl radical or a substituted or unsubstituted heteroaryl radical;
- c) R₁ is hydrogen, a substituted or unsubstituted amino radical, or a substituted or unsubstituted organic radical comprising from one to 12 carbon atoms; and

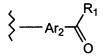
 R₂ is hydrogen, or a substituted or unsubstituted organic radical comprising from one to 12 carbon atoms;

comprising the steps of:

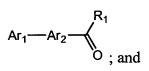
 i) coupling an Ar₁ precursor compound with an Ar₂ precursor compound to give a biaryl carbonyl containing compound; wherein:

(1) the Ar_1 precursor compound has the structure:

(2) and the Ar₂ precursor compound has a carbonyl group and has the structure:



(3) and wherein the biaryl carbonyl containing compound has the structure:



ii) condensing the biaryl carbonyl containing compound with a hydroxylamine derivative having the structure:

to give a compound of Formula (XV)<u>claim 1</u>, or a pharmaceutically acceptable salt thereof.

19. (Original) The process of claim 18 wherein one of the Ar_1 or Ar_2 precursor compounds is an aryl boronic acid or ester, and the other Ar_1 or Ar_2 precursor compound is an aryl halide, triflate, or diazonium tetrafluoroborate.

- 20. (Original) The process of claim 18, wherein the coupling is conducted in the presence of a palladium catalyst.
- 21. (Original) A pharmaceutical composition comprising one or more compounds of claim 1 and a pharmaceutically acceptable carrier, for administration in mammals for modulating lipid metabolism, carbohydrate metabolism, lipid and carbohydrate metabolism, or adipocyte differentiation.
- 22. (Original) A pharmaceutical composition of claim 21 wherein the administration treats type 2 diabetes, polycystic ovary syndrome or syndrome X.
- 23. (Original) A method of modulating lipid metabolism, carbohydrate metabolism, lipid and carbohydrate metabolism, or adipocyte differentiation in a mammal, comprising administering the pharmaceutical composition of claim 21 to a mammal in an amount that is effective to change the rate of lipid or carbohydrate metabolism, or change the rate of adipocyte differentiation, as compared to the rate of lipid or carbohydrate metabolism, or the rate of adipocyte differentiation that occurs in the absence of the pharmaceutical composition.
- 24. (Original) The method of claim 23 wherein the mammal is a human.
- 25. (Original) A method of treating type 2 diabetes comprising administering to a mammal diagnosed as having type 2 diabetes an amount of the pharmaceutical composition of claim 21 that is effective to treat the type 2 diabetes.
- 26. (Original) The method of claim 25 wherein the mammal is a human.

REMARKS

Original claims 1-26 are pending in the application.

Claim 1 has been amended to clarify that the claimed genus of compounds reads on any one compound from the genus or a mixture of two or more compounds from the recited genus. Support for this amendment can be found, *inter alia*, in original claim 1, specification page 11, page 43, lines 24-25, and page 14, lines 7-9. This amendment does not narrow claim 1.

Claims 1 and 17 have also been amended to exclude the species compound 3-(3,5,5,8,8-Pentamethyl-5,6,7,8-tetrahydronaphthyl-2-yl)-4-trifluoromethoxybenzaldehyde (hydroxyoxime). Support for the amendment can be found in original claim 17 and in Example 20.

Claim 18 was originally filed as an independent claim directed to a method of preparing compounds of the indicated structure, wherein the compounds are identical in structure to the compounds of claim 1. Claim 18 has been amended to conform to and be dependent on claim 1, so as to be suitable for subsequent rejoinder under the procedure of MPEP § 821.04, if and when claim 1 is subsequently found to be allowable.

In view of the indicated recitations of support in the specification, no new matter is introduced pursuant to the forgoing amendments, and the amendments should be entered. Subsequent to entry of the amendments, original claims 1-26 will remain pending in the application.

Restriction Requirement

The Office Action dated March 11, 2005 restricted the 26 original claims of the Application into the thirteen groups listed below:

Group I	Claim 1, wherein Ar_1 is an aryl, and Ar_2 is an aryl (classifiable in class 585, subclass various);
Group II	Claim 1, wherein Ar_1 is an aryl, and Ar_2 is a heteroaryl (classifiable in class 546, subclass various);
Group III	Claim 1, wherein Ar_1 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 546, subclass various);
Group IV	Claim 1, wherein Ar_1 is a heteroaryl, and Ar_2 is a heteroaryl (classifiable in class 549, subclass various);
Group V	The process of preparing according to claim 18;
Group VI	Claims 23-24, wherein Ar_1 is an aryl, and Ar_2 is a aryl (classifiable in class 424);
Group VII	Claims 25-26, wherein Ar_1 is an aryl, and Ar_2 is an aryl (classifiable in class 514);
Group VIII	Claims 23-24, wherein Ar_1 is an aryl, and Ar_2 is a heteroaryl (classifiable in class 424);
Group IX	Claims 25-26, wherein Ar_1 is an aryl, and Ar_2 is a heteroaryl (classifiable in class 514);
Group X	Claims 23-24, wherein Ar_1 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 424);
Group XI	Claims 25-26, wherein Ar_1 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 514);
Group XII	Claims 23-24, wherein Ar_1 is a heteroaryl and Ar_2 is an heteroaryl (classifiable in class 424); and
Group XIII	Claims 25-26, wherein Ar_1 is a heteroaryl, and Ar_2 is a heteroaryl, and Ar_2 is an aryl (classifiable in class 514).

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Applicants Hereby Provisionally Elect Group I, With Traverse

Applicants respectfully traverse and request reconsideration of the restriction requirement, because each of the Restriction Groups I-IV and VI-XIII improperly divides one or more claims into sub-claims based on the chemical classification of the aromatic Ar_1 and Ar_2 groups as aryl or heteroaryl groups. The Office Action attempts to justify these divisions because "The inventions of Groups I-XIII are separate and patentably distinct...."

A restriction requirement that splits Applicants claims, including claim 1, into subclaims violates well established law. As noted in MPEP § 803.02:

"Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which Applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility."

The Office Action made no attempt to show that Applicants' claims lack Unity of Invention, and therefore failed to establish a *prima facie* justification for restricting Applicants individual claims into subclaims. Moreover, an allegation that Applicants' claims contain patentably distinct embodiments cannot by itself justify subdividing an individual claim into subclaims. As was held by the *Weber* court:

As a general proposition, an applicant has a right to have each claim examined on the merits.... If, however, a single claim is

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required to be divided up and presented in several applications, that claim would never be considered on its merits....

It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

In re Weber at 458.

The Harnish court also stated:

In *Haas II* (see note 6, supra), this court held that § 121 could not be used as the basis for rejecting a single claim or compelling its replacement by a plurality of narrower claims before examination on the merits would be made.

In re Harnish at 721.

The Harnish court also commented on the prior holding from In re Jones, 34 CCPA

1150, 162 F.2d 479, 74 USPQ 149 (1947), stating "the compounds must be considered as wholes

and not broken down into elements or other components." See In re Harnish at 722.

Accordingly, it was improper for the Office Action to restrict the compounds of the invention

based on the aryl/heteroaryl distinction within the Ar₁ and Ar₂ groups, while ignoring the other

common structural features of the compounds of the claims.

Indeed, Applicants' claims compounds possess Unity of Invention because of their common structural features and utilities. In describing Unity of Invention, MPEP § 1850 D, recites that "A common structure is present, *i.e.*, a significant structural element is shared by all of the alternatives...." and that "the words 'significant structural element is shared by all of the

alternatives' refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures...."

Applicants' claimed compounds, including the compounds of independent claim 1, possess a core of common structural features that include:

- a) an oxime or oxime derivative group having a carbon atom that is bonded to
- an aromatic Ar₂ group comprising an aromatic aryl or heteroaryl ring, which is bonded to
- an aromatic Ar₁ group comprising an aromatic aryl or heteroaryl ring, having two substituents that together form
- d) an optionally substituted cycloalkyl or cycloalkenyl ring that may optionally comprise ring heteroatoms.

The Ar₁ and Ar₂ ring groups share the planar and conjugated structure of an aromatic ring group regardless of whether the Ar₁ and Ar₂ rings are an aryl or a heteroaryl group, and also share the other common structural features recited above. Therefore the compounds of claim 1 share a linked core of common structural features, even though there can be some variation in the common structural core or peripheral substituents. Moreover the compounds of claim 1 can have common utilities as evidenced by dependent claims 34-46 and 70-81. Without wishing to be bound by scientific theories that are extremely difficult or impossible to prove, Applicants reasonably believe it is the <u>combination of common structural features</u> recited for the compounds in claim 1 that produce binding to the biological target sites, and the resulting utilities. Therefore, the compounds of Applicants' claim 1 (and dependent claims) possess Unity of Invention.

Therefore, because the compounds of claim 1 and all the dependent claims possess Unity of Invention, and because the Office Action did not meet its burden to show that Unity of Invention was lacking, it was legally improper for the Examiner to impose restriction Groups I-IV, which subdivide compound claim 1 and its dependent compound claims into subclaims. Similarly, Restriction Groups VI-XIII are improper because they also improperly attempt to subdivide claims 23-26 into subclaims. Accordingly, the Restriction Requirement was improper and should be reconsidered and withdrawn. Applicants respectfully decline to amend or withdraw the claims as requested by the Restriction Requirement, in anticipation of the possible filing a Petition for withdrawal of the Restriction Requirement.

Addition of Ortho McNeil Pharmaceutical Inc. As Co-Assignee

Applicants request that the records of the Application be amended to recite Ortho McNeil Pharmaceutical Inc as a co-Assignee of the current application.

The inventors' rights in the current Application were assigned to Incyte San Diego Inc, (formerly Maxia Pharmaceuticals Inc.) as per the inventor Assignments recorded on September 30, 2002 at Reel 013335, Frame 0417, of the records of the Office. As recited in the enclosed Assignment document, which is being concurrently sent for recordation in the records of the Office, on or about November 1, 2000, Maxia entered into a Collaborative Research Agreement with Ortho McNeil Pharmaceutical Inc. That agreement was subsequently amended on or about February 2003 to grant Ortho McNeil a joint ownership interest in patents resulting from the activities contemplated by that Agreement.

Subsequently Maxia became a subsidiary of Incyte Corporation and was re-named Incyte San Diego Inc., as documented by the enclosed document from the Delaware Secretary of State.

Recently, Incyte San Diego Inc. and Ortho McNeil formalized the transfer of a co-ownership interest in the relevant U.S., International, and foreign patent applications that resulted from the collaborations, as documented in the attached Assignment Agreement. The current patent application is listed on page 6/12 of the enclosed Assignment document as one of the patent applications in which Ortho McNeil acquired a joint ownership interest.

Accordingly, <u>Applicants hereby request that the records of the Application be amended to</u> <u>list Incyte San Diego Inc. and Ortho McNeil Pharmaceuticals Inc. as co-Assignees in the</u> <u>application, and any subsequently issued patent</u>. The undersigned will continue as prosecuting attorney for the application, at the current correspondence address.

CONCLUSION

Applicants have entered certain minor amendments of originally pending claims 1-26. Applicants have, in response to the Restriction Requirement stated in the Office Action, provisionally elected restriction Group I, with traverse, but request reconsideration and withdrawal of the Restriction Requirement on the ground that the Commissioner may not properly impose a restriction requirement that has the effect of splitting any of Applicants individual claims, which possess Unity of Invention, into subclaims.

Applicants request that the records of the Application be amended to recite Ortho McNeil Pharmaceutical Inc as a co-Assignee of the current application.

Enclosed herewith is a Supplemental Information Disclosure Statement, Supplemental Information Disclosure List, and the documents recited thereon which must be submitted to the Office. The Supplemental Information Disclosure Statement should be considered because it is being submitted prior to the mailing of a first Office Action on the merits.

Enclosed herewith is a Request for a One Month Extension of Time and a Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$120.00, for a one month extension of time. This amount is believed to be correct; however; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Mark A. Murphy, Ph.D.

Registration No. 42,915

NEEDLE & ROSENBERG, P.C. Customer Number 23859 (678) 420-9300 Phone (678) 420-9301 Fax

CERTIFICATE OF EXPRESS	S MAILING
I hereby certify that this correspondence and any documents referenced herein as be Postal Service as Express Mail No. EL970609950US in an envelope addressed to: 0 22313-1450, on the date relow?	ing enclosed herein are being deposited with the United States Commissioner for Patents, P. O. Box 1450, Alexandria, VA

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ASSIGNMENT

This assignment agreement (Assignment) effective as of November 1, 2002 is by and between **INCYTE SAN DIEGO INC**. ("**INCYTE SAN DIEGO**" formerly "Maxia Pharmaceuticals, Inc." or "MAXIA"), a wholly owned subsidiary of Incyte Corporation having a place of business at Building E336, Experimental Station, Route 141 & Henry Clay Road, Wilmington, Delaware 19880 U.S.A. and **ORTHO MCNEIL PHARMACEUTICAL INC**., a Delaware corporation doing business at Route # 202, P.O. Box 300, Raritan, New Jersey 08869-0602 U.S.A.,.

WHEREAS, MAXIA, on November 1, 2000 entered into a Collaborative Research Agreement (the "Agreement") with ORTHO MCNEIL PHARMACEUTICAL INC., and the R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, a division of Ortho McNeil Pharmaceutical Inc. doing business at Route # 202, Raritan, New Jersey, 08869-0602 U.S.A., collectively referred to herein as "ORTHO" and

WHEREAS, the Agreement was amended by a document entitled "Maxia Agreement Amendment" ("the Amendment") that was effective November 1, 2002 and executed by MAXIA and ORTHO's officers during February 2003; and

WHEREAS the Agreement and the Amendment (collectively the "Amended Agreement") provides in Section 4 of the Amendment that Maxia patents claiming Collaboration Compounds shall be jointly owned by Maxia and Ortho.

NOW, THEREFORE, pursuant to and subject to all the terms, conditions, and obligations of the Amended Agreement, and in consideration of the sum of Ten Dollars (\$10.00) in hand paid, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, INCYTE SAN DIEGO does hereby assign and transfer unto ORTHO MCNEIL PHARMACEUTICAL INC:

- 1. a joint ownership interest in all the patent applications and patents, including a joint ownership interest in any Letters Patent which have already issued or may in the future issue from the Patent Applications listed in the Tables of Appendix I ("the Collaborative Patent Applications and Patents"); and
- 2. a joint ownership interest, and a joint owners interest in any subsequently filed U.S., International, or Foreign National application(s) that claim priority to the Collaborative Patent Applications and Patents, including any reissue, reexamination, division, continuation-in-part, extension or continuations thereof and the corresponding issued patents,

This document shall be governed, construed, and interpreted in all respects in accordance with the laws of the State of Delaware, United States of America.

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IN WITNESS WHEREOF, I have executed this assignment this <u>20</u>th day of , 2005. **INCYTE SAN DIEGO INC.** Name of authorized officer Patricia A. Schreck Print: Title: Directo aware State of hiv Castle County of On this 20^{th} day of α ___, 2005, before me, a Notary Public came _ _, to me known and known to be the individual described in, and who executed the foregoing assignment, and he/she duly acknowledged the same to be his/her free act and deed. <u>lemple</u> 3/14/06 Notary Public My Commission Expires:

Q,

IN WITNESS WHEREOF, I have executed this assignment this ______ day of March , 2005.

ORTHO MCNEIL PHARMACEUTICAL INC Name of authorized officer STELLEN & BORMA Print: Title: ASSS SECY

State of

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County of middlesex

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On this _24th day of _____, 2005, before me, a Notary Public came Steven P. Berman, to me known and known to be the individual described in and who executed the foregoing assignment, and he/she duly acknowledged the same to be his/her free act and deed.

an V. nicholson

Notary Public

My Commission Expires: 3/16/2009

ARN V. NICHOLSON **NOTARY FUBLIC OF NEW JEESEY** Commission Explanes 3/16/2009

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Tables Listing The Collaborative Patent Applications and Patents Existing as of March 01, 2005

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13099.0013U2	U.S. Utility Serial No. 09/652,810	08/31/2000 (F) U.S. Patent Issued 02/04/2003 (F)	United States	Issued as U.S. Patent No. 6,515,003
13099.0013U4	U.S. Continuation Application Serial No. 10/334,932	12/31/2002 (F)	United States.	Continuation of 13099.0013U2 Issued as U.S. Patent No. 6,765,013
13099.0013U5	U.S. Continuation Application Serial No. 10/894,411	07/19/2004 (F)	United States	Continuation of 13099.0013U4
13099.0013P1	PCT/US00/24,222 Publication No. WO 01/16122	08/31/2000 (F) 03/08/2001 (P)	PCT	Inactive
13099.0013BR1	P1001.3671-9	08/31/2000 (F)	Brazil	
13099.0013CA1	2383347	08/31/2000 (F)	Canada	
13099.0013CN1	00815079.6	08/31/2000 (F)	China	Abandoned
13099.0013EA1	200300311	08/31/2000 (F)	Eurasia	Abandoned
13099.0013EP1	00957950.9	08/31/2000 (F)	Europe	
13099.0013JHUI	PO203367	08/31/2000 (F)	Hungary	
13099.0013IL1	148361	08/31/2000 (F)	Israel	
13099.0013JPI	2001-519689	08/31/2000 (F)	Japan	
13099.0013MX1	2002-002257	08/31/2000 (F)	Mexico	
13099.0013NO1	20020960	08/31/2000 (F)	Norway	

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13099.0013NZ1	517993	08/31/2000 (F)	New Zealand	
13099.0013PH1	1-2000-02380	08/31/2000 (F)	Philippines	
13099.0013PL1	P-354334	08/31/2000 (F)	Poland	
13099.0013UA1	2002032523	08/31/2000 (F)	Ukraine	
13099.0013THI	060030	08/31/2000 (F)	Thailand	
13099.0013TW1	98117764	08/31/2000 (F)	Taiwan	
13099.0013ZA1	2002/2064	08/31/2000 (F)	South Africa G	Granted as ZA Patent No. 2002/2064
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	Inactive	es Allowed	Inactive				
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1. DELENCEDATOS (E) AN CALLER SA CALLER S	03/08/2001 (F)	03/08/2002 (F)	03/07/2002 (F) 09/19/2002 (P)				
RUMUNUMAN A ANTHONORADAN ANTALANA	U.S. Provisional No. 60/274,342	U.S. Utulity No. 10/098,184 U.S. Publication No. 2003/0105333	PCT/US02/07342 Publication No. WO 02/072543	2002254171	PCT/US02/07342	02723389.9	2002-571459
	13099.0016U1	13099.0016U2	13099.0016P1	13099.0016AUI	13099.0016CA1	13099.0016EP1	13099.0016JP1

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	Inactive		Inactive		
TERRITOR/	United States	United States	PCT	Europe	Japan
6 (F) (P) (P)	8/17/2001(F)	08/19/2002 (F) 05/01/2003 (P)	08/19/2002 (F) 02/23/2003 (P)	08/19/2002 (F) 05/26/2004 (P)	08/19/2002(F)
	U.S. Provisional Serial No. 60/313,199	U.S. Utility Serial No. 10/224,288 U.S. Publication No. 2003/0083357	PCT/US02/26476 Publication No. WO 03/016267	02794929.6	2003-521195
No.	10/100.66061	13099.0017U2	13099.0017P1	13099.0017EP1	13099.0017JP1

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(f) (f)	United States	PCT Inactive,	Europe	Japan
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Level of the second sec	U.S. Utility Serial No. 10/298,024 U.S. Publication No. 2003/0144329 A1	PCT/US02/36583 Publication No. WO 03/043998	02789654.7	2003-545635
REFERENCE NOT TO THE TRANSPORT	13099.0018U2	13099.0018P1	13099.0018EP1	13099.0018JP1

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13099.0020U1	U.S. Provisional Serial No. 60/362,702			Inactive
13099.0020U2	U.S. Utility Serial No. 10/384,352 U.S. Publication No. 2003/021643	03/06/2003 (F) 11/20/2003 (P)	United States	
13099.0020P1	PCT/US03/06784 Publication No. WO 03/075924	03/07/2003 (F) 09/18/2003 (P)	PCT	Inactive.
13099.0020AU1	20003-225682	03/07/2003 (F)	Australia	
13099.0020BR1	P10308278-4	03/07/2003 (F)	Brazil	
13099.0020CA1	2478342	03/07/2003 (F)	Canada	
13099.0020CN1	03810148.3	03/07/2003 (F)	China	
13099.0020EP1	03744197.9	03/07/2003 (F)	Europe	
13099.0020IL1	163952	03/07/2003 (F)	Israel	
13099.0020IN1	3003/DE1NP/2004	03/07/2003 (F)	India	
13099.0020JP1	PCT/US03/06784	03/07/2003 (F)	Japan	
13099.0020KR1	10-2004-7014099	03/07/2003 (F)	Korea	
13099.0020MX1	2004-008733	03/07/2003 (F)	Mexico	
13099.0020NO1	2004-4250	03/07/2003 (F)	Norway	

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D		New Zealand	Philippines	Russia	Thailand	Taiwan	South Africa
		03/07/2003 (F)	03/07/2003 (F)	03/07/2003 (F)	03/07/2003 (F)	03/07/2003 (F)	03/07/2003 (F)
		535745	PCT1-2004-501382	2004129752	080721	092105025	2004/8057
	den and a second se	13099.0020NZ1	13099.0020PH1	13099.0020RUI	13099.0020TH1	13099.0020TW1	13099.0020ZA1

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13099.0021UI	U.S. Provisional Serial No. 60/362,732	03/08/2002 (F)	United States	Inactive
13099.0021U2	U.S. Utility Serial No. 10/384,391 U.S. Publication US 2004/0034004 A1	03/06/2003 (F) 02/19/2004 (P)	United States	
13099.0021P1	PCT/US03/07240 Publication No. WO 03/075858	03/07/2003 (F) 09/18/2003 (P)	PCT	Inactive
13099.0021AU1	2003223233	03/07/2003 (F)	Australia	
13099.0021CA1	2478765	03/07/2003 (F)	Canada	1
13099.0021EP1	03719363.8	03/07/2003 (F)	Europe	
13099.0021IL1	163953	03/07/2003 (F)	Israel	
13099.0021JP1	PCT/US03/07240	03/07/2003 (F)	Japan	
13099.0021TH1	080722	03/07/2003 (F)	Thailand	
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REFERENCE NO.	APPLICATION/PATENT NUMBER FULING DATE (F) TERRITORY/ PUBLISHED (P) COUNTRY	FULING DATE (F) (1) FUBLISHED (P)	TERRITORY/ COUNTRY	COMMENTS	
13099.0023U1	U.S. Provisional Serial No. 60/464,388	04/18/2003 (F)	United States	Inactive	
13099.0023U2	U.S. Utility Serial No. 10/827,111	04/18/2004 (F)	United States		
13099.0023P1	PCT/US04/12284 Publication No. WO 2004/093809	04/19/2004 (F) 11/04/2004 (P)	PCT		

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