From:
Sent: Friday, August 13, 2010 7:59 PM
To: Restriction_Comments
Cc:
Subject: Comments from AIPLA Biotechnology Committee

Greetings,

Thank you for soliciting comments on the USPTO's restriction practice. Attached are two documents. The first is a compilation of comments submitted by members of the AIPLA Biotechnology Committee. The second document was prepared by Brian Lathrop and may have also been submitted separately to you, but should be regarded as part of our compilation as well.

While the comments came from a large number of individuals practicing in a variety of settings, certain common themes are apparent. Most mention the need for a defined standard that is consistently applied such as “unity of invention” or other standard directed to independence, relatedness and/or distinction of inventions, especially for biological sequences. Further, clarity on whether an office action presents a restriction requirement or species election was raised on more than one occasion by our members. Moreover, the general view is that the office needs to be reminded that not all species need to be searched. Practice changes in rejoinder are suggested to include a review by the examiner of the original restriction once there are allowed claims in the application.

Best regards,

Karen Canady & Jim Kelley
Chair & ViceChair, Biotechnology Committee

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Response to USPTO Request for Comments
On Proposed Changes to Restriction Practice in Patent Applications

Compiled Comments From Members of the AIPLA Biotechnology Committee
August 2010

1. **What should be included in an Office action that sets forth a restriction requirement?**

Comment:

The Request states that the "Office is considering revising restriction practice to improve the quality and consistency of restriction requirements". The Office should begin by setting out to make restriction practice as set out in the MPEP consistent with the patent laws and rules. The controlling statute states that "*If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.*" (35 U.S.C. §121, emphases added) Similarly, the rules state that "*If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted […].*" (37 CFR §1.142, emphasis added) Although the phrase "independent and distinct" appears multiple times in the Rules, the phrase "independent or distinct" does not, nor does it appear in the statutes. The Office should revise restriction practice to meet the "independent and distinct" standard.

The Request also refers to the 2005 Green Paper on Restriction Practice but does not revisit the proposals and options in that document, even though five years later some of these proposals may make even more sense than they did in 2005, for example in view of the ability to reduce inter-office search and examination "shared burden". The USPTO's Strategic Plan (p.17) lays out as a goal the improvement of pendency and quality by work sharing between patent offices. One option that should be reconsidered as an alternative to revising restriction practice to meet the "independent and distinct" standard is transitioning to a unity of invention standard as used in PCT examination, which would put US examination more in line with examination in those offices that participate in the Patent Prosecution Highway.

The Request further states that "the Office is considering explaining that in addition to the rationales currently set forth in the MPEP, a serious burden in support of a restriction requirement may be based on the rationale that the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. In this situation, a serious search burden and/or examination burden may exist where issues relevant to one invention are not relevant to the other invention."

This statement is troubling as it appears that procedural issues (*i. e.*, restriction practice) are being confused with examination issues (*e. g.*, 101 or 112 patentability issues). Further, burden alone is insufficient justification for requiring a restriction. Applicants are entitled to claim their invention as they view it, without the claim being divided into fragments, as instructed by the Federal Circuit in criticizing restriction practice in the case of *In re Weber*:

> "We have decided in the past that § 112, second Paragraph […] allows the inventor to claim the invention as he contemplates it. […] 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. […] Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount."
>
> *In re Weber*, 580 F.2d 455 (Fed. Cir. 1978) (Emphases added.)

Comment:

The examining corps must provide reasoned explanations for independence, relatedness and distinction of biological sequences

The agency could comply with the court's directive in *Weber* by judiciously applying MPEP Section 803.02 which provides a "provisional election of species" for search and examination of species in a generic claim. If the elected species is allowable over the prior art, the search is extended to non-elected species. MPEP 803.02 however explicitly states that the examining corps need not examine all the species encompassed by the generic claim.

Comment:

Include a listing of what claims are in which groups (yes, I just received a RR where it was so vague, I had to call the examiner to even figure out the Groups – there was no listing). Clearly state what is a "Restriction Requirement" and what is an "Election of Species Requirement." I'm not convinced some of the new examiners know the difference.

Comment:

The Office Action should indicate a logical basis for restriction. The beauty of the unity of invention standard is that it is not only logical, but keeps the focus on the invention rather than on arbitrarily designated categories. If a single inventive concept links a variety of embodiments, the fact that each embodiment might fall into a different category of subject matter is irrelevant (nucleic acid, protein, antibody, methods all novel by virtue of the inventive feature).

Comment:

How about something other than circular reasoning and without boilerplate gibberish. ("The SEQ ID NOS are different inventions because they are different.") The fact is, in many cases where

you claim a process, the particular sequences are not a salient feature of the invention -- they simply recite various known proteins all having the same known function. And even when you are claiming novel sequences, they are often very similar to each other (and with the same function) yet restriction is required regardless

Comment:

For a national stage,
1. abide by unity of invention standard. If there is lack of unity because of a reference, then in the office action they must apply the reference under 102/103 or the restriction must be withdrawn. It is a treaty and treaties trump everything. This is a huge problem.
2. Issue is what to do on div/con after 371 if a new restriction is issued along US guidelines given 121 safe harbor rules.
3. Must address burden if searched abroad.

For US utility
1. They must show grouping, burden, distinctiveness. They must abide by the rules. See all the presentations on restrictions presented by Julie Burke especially the one on mistakes

Comment:

To minimize applicant confusion, the USPTO should clarify the MPEP to indicate to examiners that a restriction requirement must always set forth the reasons why the inventions (or species) are independent or distinct…. The USPTO should revise the MPEP to require examiners to group together inventions or species that are not patentably distinct from each other, and require election of either a single invention or species or single grouping of patentably indistinct species.

The burden standard is poorly defined… Thus, the USPTO should clarify the burden requirement for examiners, and emphasize that the burden is properly rebutted when applicants provide appropriate showings and/or evidence.

Comment:

Applicable test should be unity of the invention. Furthermore, generic claims have unity of invention, if structurally unrelated species are functionally substitutable for each other. PCT practice find unity of invention for structurally unrelated probes that possess the common function of binding to mRNA molecules related to the same disease state. (paraphrased from Brian Lathrop's comments).

Comment:

Office actions must include particular reasons for restriction requirement(s)

Cost Shifting. Unwarranted restriction requirements result in prosecution delays, excessive claim fees and costs, and superfluous filing of multiple divisional patents further increasing backlog. It is manifestly unfair to shift the burden and cost of inadequate explanation of policy or untrained

personnel to patent applicants. Because restriction practice has caused much confusion for Examiners with regard to the definition of serious burden and the definition of inventions as independent or distinct, the USPTO should include more specific and detailed language as to when restriction is required, and importantly, when restriction is *not* required, in the Examiner notes that accompany such form paragraphs. The USPTO should further include language recommending against restriction unless *necessary* in order to decrease backlog.

Distinctness. To minimize applicant confusion, the USPTO should clarify the MPEP to indicate to examiners that a restriction requirement must *always* set forth the reasons why the inventions (or species) are independent or distinct. For example, the revisions to form paragraphs 8.01, 8.02, and 8.21 set forth in the Changes to Restriction Form Paragraphs memorandum of January 21, 2010, requiring examiners to include an explanation as to why the species or grouping(s) are independent of distinct, are a worthwhile attempt to clarify the process for examiners. However, as written, such revisions are inadequate.

Further, to help applicants avoid filing unnecessary divisional applications, the USPTO should revise the MPEP to require examiners to group together inventions or species that are not patentably distinct from each other, and require election of either a single invention or species, or a single grouping of patentably indistinct species. Some examiners needlessly require multiple restrictions (*e.g.*, 5-way, 6-way, 10-way restrictions) within a grouping of patentably indistinct species. The Office should therefore revise the MPEP to indicate that applicants should not be required to elect a specific invention or species within a grouping of patentably indistinct species.

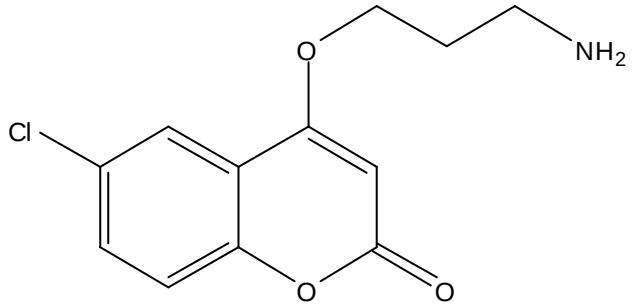
The following examples provide situations in which examiners consistently and inappropriately require restriction. Such examples should be included in form paragraph examiner notes as guidelines for Examiners.

Example 1: Species which are not patentably distinct from each other
Claim 1. (original) An antibody XYZ comprising a detectable label.
Claim 2. (new) The antibody of claim 1, where the detectable label is rhodamine.
Claim 3. (new) The antibody of claim 1, where the detectable label is fluorescein.
Claim 4. (new) The antibody of claim 1, where the detectable label is acridine orange.
Claim 5. (new) The antibody of claim 1, where the detectable label is ethidium bromide.

For this example, it is being assumed that the labels are all known in the prior art and obvious over each other. If it would have been obvious to add any of the various fluorescent dyes to the antibody XYZ, then the examiner should not require an election of species or restriction amongst the dyes recited in claims 2-5, per MPEP 806.04(b) and 808.01.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: When is it NOT appropriate to restrict? at 16, (September 2009). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

Example 2: Species are not patentably distinct because their scope is identical
Claim 1. A compound of formula I given by



Claim 2. The compound 6-chloro-4-(3-aminopropoxy)-1-benzopyran-2-one.
Claim 3. The chromane compound of formula I.

Claims 1, 2 and 3 are not distinct from each other as the claims merely define the same essential characteristics of a single disclosed embodiments of an invention.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: Restriction Practice Updates, at 29 (June 2010). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

Example 3: "Species" not distinct as claimed when the claims vary in breath or scope of definition.
Claim 1. An isolated nucleic acid molecule having SEQ ID No 1.
Claim 2. A vector comprising the nucleic acid molecule of claim 1.
Claim 3. A host cell comprising the vector of claim 2.

Claims 1, 2 and 3 are not distinct because claims 1, 2 and 3 vary in breadth or scope of definition.
claim 1 encompass (overlaps in scope with) claim 2.
claim 2 encompass (overlaps in scope with) claim 3.
claim 3 is encompassed by both claims 1 and 2.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: Restriction Form Paragraphs, at 31 (June 2010). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

Serious Burden In the Absence of a Restriction

Clarifying the burden standard. The burden standard is poorly defined and is a significant cause for concern. Thus, it is vitally important that the USPTO require examiners to clarify why there would be a serious burden in the absence of a restriction requirement. A prevalent industry concern shared by both practitioners and applicants is that restriction is often required even where there would not be a serious burden on the examiner. Thus, the USPTO should clarify the burden requirement for examiners, and emphasize that the burden is properly rebutted when applicants provide appropriate showings and/or evidence. Although the revisions to form paragraphs 8.01, 8.02, and 8.21 set forth in the Changes to Restriction Form Paragraphs memorandum of January 21, 2010, instruct the examiner to specify at least one reason the examination and search cannot be made without serious burden, the revisions are inadequate as written.

Burden is a rebuttable presumption. The MPEP provides that "[A] serious burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search …. [t]hat prima facie showing may be rebutted by appropriate showings or evidence by the applicant." *See* MPEP 803. However, appropriate showings or evidence by the applicant are often disregarded. Moreover, the MPEP

does not provide guidance to the Examiners for determining what showings or evidence are appropriate.

Suggested search is an appropriate showing. For these reasons, the USPTO should require withdrawal of restriction requirement(s) when an applicant provides a suggested search scope that includes a reasonable amount of art dependent on the technology at issue. Further, the USPTO should also include guidelines in the examiner notes that clarify when serious burden is not present. The following MPEP provisions should be emphasized in Examiner training and practice:

"Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper." MPEP 806
"Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction there between should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition." MPEP 806.03
"Where … the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions." MPEP 808.02
"If the subject matter was already examined together on the merits, it would not be a burden on the examiner to continue to examine the subject matter, even if it is directed to independent and distinct inventions."

There is no "additional burden" for application examination. The USPTO should not revise the MPEP to include an explanation that "a serious burden on the examiner" would encompass a search burden as well as an examination burden. Determination of allowable inventions necessitates examination of the application as well as a search of the prior art. Patent Examiners have traditionally performed both functions. No new "additional burden" is present because the Examiner's role in determining allowable claims necessarily and obviously includes an examination of the application as well as the prior art.

2. How can the process for traversing or requesting reconsideration of a restriction requirement be improved to achieve more consistent, accurate, timely, and cost-effective review?

Comment:

Restriction practice is not uniform among the examining corps. There should be mandatory and regular training of the entire examination corps (including supervisors) to ensure uniform restriction practice. Quality of restriction practice by examiner and art unit should be evaluated by tracking meaningful metrics (*e. g.*, the number of successful petitions to withdraw a restriction requirement) aimed at improving examiners' use of restrictions.

Examiners should fully understand the invention as set out in a broad claim and not set forth a restriction by arbitrarily selecting embodiments especially when the restriction is presented as a choice of only a subset of the embodiments contemplated by the broad claim, thus artificially creating an alleged examination and search "burden". A broadly claimed invention should not be arbitrarily assigned to different fields of art, *e. g.*, if a claim recites "eukaryote", the examiner should not arbitrarily require a restriction between "plant" and "animal".

Importantly, the petition process must be made timely! Delays in petition decisions force applicants to elect from among the sometimes limited or incomplete options set forth by the examiner, in order to avoid abandonment.

Comment:

Unwarranted restriction requirements can result in delays in prosecution, expenditure of excess claim fees, and/or the need to file multiple divisional applications… The agency should apply MPEP Section 803.02; and the agency should allow generic claims with unsearched species or subcombinations… The agency should clarify that the Board can review an intraclaim restriction requirement for unity of invention without a final agency agency.

Restriction requirements made without considering independence, related or distinction typically are revised or withdrawn entirely after review on petition. … Interviews with examiners can be extremely helpful in clarifying or revising intraclaim restriction requirements; however, absent consistent application of an understandable legal standard, reviewed restriction requirements themselves may require further revision.

Comment:

I have seldom had success traversing restriction requirements since Examiners never consider my remarks. I have had some success asking that restricted groups be reformulated, and have much success petitioning for review of ridiculous restriction requirements. I do not think the process can be improved because I do not believe the examiners care about it.

Comment:

Bad restrictions are worse than that. Look at the Amgen case and see a bad restriction followed by poor prosecution. Loss of consonance can lead to patents being held unenforcable later under double patenting. It's a real problem. This is the start of a chess game, wherein if you don't get it right the downstream consequences are huge. The practice is the most complex and arcane, least understood, and most ignored.

Comment:

Pre-appeal brief conference as a model. The USPTO should consider using the Pre-Appeal Brief Conference practice as a model for higher-level review of restriction requirements. This successful program offers applicants an avenue to request a panel of examiners to formally review the legal and factual basis of the rejections in their application prior to the filing of an appeal brief. The Pre-Appeal Conference program spares applicants the added time and expense of preparing an appeal brief if a panel review determines an application is not in condition for appeal. In the context of restriction practice, a review panel would spare applicants excessive and unnecessary claim fees and divisional filings from unwarranted applications to avoid dedication of unclaimed material to the public if such a panel determines that restriction is unnecessary. Applicants currently must file a petition to obtain review of a simple Examiner's

restriction, causing the file to leave the jurisdiction of the examining group. A Pre-Petition Restriction Conference would allow a panel in the group to review and overturn unnecessary restriction.

Petition. Although USPTO average restriction petition turn around time about 100 days (*See* Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: FY09 Restriction Petition Update: Comparison of U.S. and National Stage Restriction Practice (December 2009)), very often, turn around time is much longer. Practitioners and applicants are hesitant to file petitions, even where they can provide evidence that there is no serious burden or that the inventions are not separate and distinct, because of unpredictable lag time. Thus, the MPEP should be revised to include a time limit on the Office's decision on restriction-related petitions. For example, decisions on restriction petitions should be limited to three months or less.

3. What is necessary in order to restrict between "related product inventions or related process inventions?"

Comment:

Examples of commonly misapplied restriction requirement for examiners.

From another commenter: "One absurdity is for an examiner to restrict using the excuse that to search a database for a nucleic acid sequence and its translated protein product requires two different search efforts and two different databases."

Comment:

If an element of a product (or a step of a process) is not found within another and the product is separately patentable (or patentability is argued separately) that is sufficient. I think it is analagous to subcombination/subcombination analysis. Therefore, the fact they have separate functions (or can be used to make separate materials) is irrelevant.

Comment:

This goes back to the PTO's practice of ignoring the requirement for limiting restriction to independent and distinct inventions. Related products and related processes are only independent and distinct if they do not share a single inventive concept.

Comment:

Really arcane and would require a great deal of thought to address cogently.

Comment:

Because Examiners frequently require unwarranted restrictions, the USPTO must provide guidelines in addition to what is presently available to examiners where the relationship is not

specifically provided for in the MPEP. The USPTO should provide *examples* of commonly misapplied restriction requirements as guides for Examiners. Such illustrations should be included in a revised MPEP and/or form paragraph materials. Examples are provided below:

Example 4: Product/Process distinction
Claim 1. A process to reduce swelling by administering Compound X.
Claim 2. Compound X.
Using FP 8.20, the examiner reasoned that the product and process were distinct because the process can be accomplished by another materially different product, for example, applying ice.

This is incorrect. The process, as claimed, does not encompass application of ice. The process requires administration of Compound X. To establish distinction between Claim 1 and 2, the examiner must show that the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: When is it NOT appropriate to restrict? at 13 (September 2009). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

Example 5: Election by original presentation practice does not apply to dependent claims
In response to a non-final art rejection on Claim 1, applicants filed the following amendment to add dependent claim 2.
Claim 1. A composition comprising Protein X.
Claim 2. A composition comprising Protein X and a detectable label.
Because claims 1 and 2 would not have been restrictable from each other had they been presented earlier, new claim 2 should be entered and examined along with Claim 1, per MPEP 821.03.

Julie Burke, Quality Assurance Specialist, USPTO Presentation slides: When is it NOT appropriate to restrict, at 27 (September 2009). Available at: http://www.aipla.org/MSTemplate.cfm?Site=Biotechnology&CFID=9084300&CFTOKEN=44639222

An additional MPEP section is warranted. The USPTO should adopt the proposed MPEP section that would address restriction between related product/process inventions. It would behoove both examiners and applicants if support for a restriction requirement between two or more related process inventions could only be sustained if at least a two-way distinctness *and* a serious burden on the examiner would be present if restriction were not required. The proposed explanations set forth in 75 Fed. Reg. 33586 (June 14, 2010), that define when inventions can properly be considered distinct should be adopted as written.

4. The Office invites comments on changes in restriction practice involving claims with Markush groups that it is considering.

Comment:

Biological molecules (*e. g.*, nucleotide sequences), whether or not presented as a formal Markush group, should be treated like any other invention. Treating biological molecules any differently from other inventions contravenes Article 27 of the TRIPS Agreement, which states that there should be no technology-specific rules: *"Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of*

this Article, patents shall be available and patent rights enjoyable <u>without discrimination as to</u> the place of invention, <u>the field of technology</u> and whether products are imported or locally produced." (Emphases added.)

Practitioners have seen examination arbitrarily limited to 10 nucleotide sequences, and experience shows that examiners routinely require limitation to a single sequence, typically justifying this by alleging that each sequence "constitutes an independent and patently distinct invention" even when applicants demonstrate that a group of sequences share both structural or sequence similarity and claimed functional similarity or equivalence.

Comment:

The agency's current restriction policy reduces biotechnology patent value by arbitrarily decreasing claim breath. … The agency should prohibit intraclaim restriction requirements…

The agency should announce publically how many sequences it intends to search under the extended examination practice of MPEP Section 803.02. … The agency must tell the public how many sequences will be searched to determine patentability of the generic claim. The agency then should extend examination to that number of additional species in response to applicants' first RCE, to expedite prosecution.

The agency should accept that its policy of presumed independence and distinction of biological sequences is as impossible implement as the agency's failed 2005 attempt.

Comment:

First, the proposals confuse selection of species requirements and restriction requirements! That said, I believe claims can be examined for non-prior art reasons (compliance with 101, 112 first and 112 second) without undue effort even if the claim appears to encompass separately patentable subject matter. Therefore search for prior art only should be limited to the selected species.

Comment:

The original Markush I believe was 10 to the 27th power. You don't have to search each and every species in a Markush, chemical or biotech. The biotech guys have got to understand this

5. The Office invites comments on changes in rejoinder practice aimed to simplify what claimed inventions would be eligible for rejoinder upon the determination that all elected claims are allowable.

Comment:

The Request states that "The Office is considering whether to define ''rejoinder'' as the practice of withdrawing a restriction requirement as between some or all groupings of claims and

reinstating certain claims previously withdrawn from consideration that occurs when the following conditions are met: (1) All claims to the elected invention are allowable; and (2) it is readily apparent that all claims to one or more nonelected inventions are allowable for the same reasons that the elected claims are allowable."

This statement raises the question of what does "readily apparent" mean? How would an examiner know whether claims to non-elected inventions are patentable or not patentable if a search/examination has not been conducted? For example, claims with different species could conceivably have different effective filing dates and therefore be subject to different art. This questionable standard of "readily apparent" gives the examiner a way out so he/she does not have to rejoin/examine more claims.

Comment:

Adopt the proposed changes to rejoinder practice set forth in 74 Fed. Reg. 33586 (June 14, 2010) USPTO should seek to promote rejoinder of as many claims as possible. Examiner should revisit his/her original restriction requirement in view of the art cited and analysis applied during the prosecution of allowed claims. Further, the USPTO should require that the Examiner expressly state the restriction continues to be appropriate, and where applicable, which claims are eligible for rejoinder or would be eligible for rejoinder after amendment.

Comment:

ALL claims to be rejoined require "further search and/or consideration" (for written description and enablement at least), therefore no nonelected claims will never be rejoined.

Comment:

The problem with rejoinder is people don't do it. You can lose subject matter if not pursued. However, if you file the RCE to go after the rejoinable subject matter, you may lose patent term adjustment. The question is do you want to do that or put in a divisional. Individual practices are all over the place on this. I don't think many give it much thought. You are lucky if you get an examiner to follow-up on allowance. We have checklists to check whether there is rejoinable subject matter and ask at the notice of allowance. Having everything in one application is easier and cleaner from a consonance perspective

Comment:

While I agree the Restriction process is certainly not consistent or reliable at present, I don't have any particular suggestions that could make it better. The biggest problem in my biotech practice is the when we are dealing with a specific gene or protein for which the sequence is specified, yet the Examiners divide up the gene the method of using , the protein etc , which adds unnecessary time and costs, since all depend on the same specific SEQID No. But I don't know how they can fix that. I just know that my university clients will do one or maybe two patents and then let the rest go because of cost, which seems really unfair. Maybe all could be examined together for a slight increase in search cost over one "invention" alone. Its still the sequence that

makes the invention unique no matter how it is claimed - so it should not be divided if the claims are specific and interrelated.

6. The Office invites comments specifically pointing out other areas in which restriction practice could be improved.

Comment:

Possibilities include initiating a flexible fee-adjustable searching system and improvement/modernization of the Office's IT systems. The USPTO Strategic Plan (p.11) admits that a "one size fits all" approach to examination does not work. Examination practice can be multi-tracked in aspects other than the timing of the start of substantive examination, for example through fee options to have more than a single invention searched and examined.

There is lack of transparency regarding the use of IT for searches, especially relating to biological sequences. It would be beneficial to disclose to the public the cost per search of a biological sequence, or alternatively to disclose that the cost to the Office is a blanket cost not dependent on the number of sequences searched. As practitioners we strongly presume that there is no significant cost burden based on our in-house experience.

Comment:

Request that the examiners give us more than 24 hours to respond to a telephonic Restriction Requirement.

Comment:

The simplest thing the USPTO can do to improve the quagmire of current restriction practice is to adopt the WIPO unity of invention rules and associated Guidelines.

Comment:

We get rather a large number of poorly supported restriction requirements. I would like it if the office could spell out some common situations in which there is or is not "undue burden" on the Examiner. For example, every QAS with whom I have spoken on the issue agrees that if two groups of claims have been examined together on their merits, then there is no undue burden if the Examiner continues to do so. Nonetheless, I routinely receive restriction requirements in the middle of prosecution, requiring that we divide claims that have been examined together, in which no amendment is alleged to have caused the claims to acquire independent and distinct characteristics.

Comment:

I think if you have a claims that overlap (e.g., when claim 1 reads "SEQ ID NO:1 or a sequence 95% identical to SEQ ID NO:1", claim 2 reads "SEQ ID NO:2 or a sequence 95% identical to SEQ ID NO:2", and the venn diagrams of the two overlap), restriction should not be made.

Comment:

The Unity of Invention Standard benefit the USPTO would benefit the applicant and public. The US Restriction Practice requires applicants to open multiple applications, pay for multiple examinations, and pay multiple maintenance fees, adding up to thousands of dollars in additional expenses for claims that are directed to the "same inventive concept." If the applicant were able to pay additional fees to prosecute all of the inventions in the same application the USPTO would receive more money up front and be compensated for any additional work required and the applicant would not have to pay the exponential increase in costs. Additionally, the public would be better served having all claims to the "same inventive concept" issue in a timely manner instead of the current process where some claims are delayed or modified before issuing years later.

Comment:

The examining corps cannot possibly be expected to examine each sequence or possible combination of sequences of a DNA array with thousands, even hundreds of thousands of probes.

August 5, 2010

The Honorable David J. Kappos,
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
PO Box 1450
Alexandria, Virginia 22313-1450

Re: Response to Request for Comments on Proposed Changes to Restriction Practice

Dear Mr. Kappos:

I appreciate the opportunity to provide comments to improve restriction practice. I am an attorney at Drinker Biddle & Reath LLP. My comments solely reflect my personal views and do not represent those of either Drinker Biddle & Reath LLP or its clients.

I served as a patent examiner in biotechnology art units in the United States Patent and Trademark Office ("the agency") during 1996-1998. I have practiced before the patent bar since February 1999. During much of that time, I have prosecuted patent applications before the various art units of Technology Center 1600 (TC1600). I have prepared and filed nine petitions to revise or withdraw restriction requirements, all of which were granted by TC1600 Group Directors.

Executive Summary

The agency invites public comments on a number of specific issues relating to restriction requirements.[1] The commenter responds directly to a proposed change to restriction requirements made to generic claims reciting biological sequences (i.e., nucleic acid and protein sequences). The agency

[1] Request for Comments on Proposed Changes to Restriction Practice in Patent Applications, 75 Fed. Reg. 33,584 (June 14, 2010).

uses a DNA array as an example.[2] To the extent the agency proposes to limit the scope of DNA array claims to a small number of elected and searched sequences (which is the agency's *de facto* policy), the agency's proposal is not in accordance with the law and thus should be set aside as unlawful.[3] The agency cannot restrict biological sequences recited in a generic claim having unity of invention. The agency instead must comply with judicial precedent by applying a "provisional election" of species, as set forth in the Manual of Patent Examining Practice (MPEP) § 803.02. The agency routinely allows claims to chemical genera (i.e., Markush groups), reciting many unsearched species. The agency likewise should allow generic claims having unsearched biological sequences. Finally, the agency should tell the public how many sequences the examining corps will search and examine in a single application, using the extended search procedure of MPEP § 803.02.

For far too long, the agency has abused restriction requirement policy to reduce its administrative burden to the detriment and disparate treatment of the biotechnology industry, relative to the chemical and pharmaceutical industries. It is time for the agency to end intraclaim restriction requirements and establish policies—consistent with the law—that facilitate and expedite the issue and grant of patent applications.

1. The agency cannot restrict biological sequences recited in a generic claim in view of *In re Weber*.

The agency considers "whether restriction would be proper between a subcombination claim to an individual DNA molecule selected from a list of alternative embodiments." Unfortunately, the agency fails to specify explicitly whether it is considering a restriction requirement under 37 C.F.R. § 1.142 or a provisional election of species under MPEP § 803.02. In the absence of a clear

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[2] *Id*., at 33,596.

[3] 5 U.S.C. Section 706(2)(A) (1994) (stating that agency actions, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law are held unlawful and set aside).

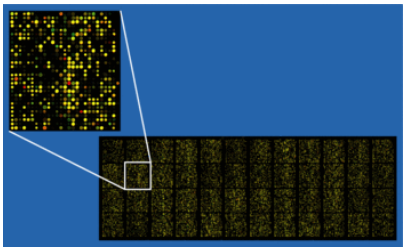
statement from the agency, the commenter assumes the agency proposes to make the restriction requirement under 37 C.F.R. § 1.142.

The Court of Claims and Patent Appeals (CCPA) reviewed intraclaim restriction requirements made between species of chemical compounds encompassed within a generic claim.[4] The CCPA prohibited the agency from restricting embodiments recited in a single claim, because of the possibility that the resulting fragmentary claims would not be equal to the original claim:

> If . . . a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim.[5]

The court's prohibition arises from applicants' substantive rights under 35 U.S.C. § 112, second paragraph, to claim their invention as they see fit.[6]

Some technologies are disclosed as many, sometimes hundreds of thousands, of structurally distinct but functionally related biological sequences. For example, a DNA array may contain probes immobilized on a chip:[7]



The probes may have complementary sequences to mRNA from multiple genes involved in a disease state, for example. mRNA expression is detected by hybridization to the unique probes on the array having sequences complementary to the mRNAs. Typically, arrays can be used with a single probe

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4 *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978).

5 *Weber*, 580 F.2d at 458, 198 USPQ at 331.

6 *Weber*, 580 F.2d at 458-59, 198 USPQ at 332.

7 "DNA Microarray," Wikipedia, *at* http://en.wikipedia.org/wiki/DNA_microarray (last updated July 31, 2010.

or a combination of probes; however, more probes may be used to provide a clearer diagnosis.

The agency's current restriction policy requires array claims to "comprise" ***one*** elected and examined probe or combination of probes.[8] If the probes are interchangeable, the array can just as easily be used with probes or combinations of probes that were never examined and that are not protected by the claim. For example, a competitor could avoid infringement of an array "comprising probe A" in a thousand-probe array simply by removing probe A. The inventor would have provided a thousand useful probes to the public, but the agency would have issued a claim of little commercial value in return. This policy is unfair and discriminatory. A claim limited to a single searched and examined probe or combination of probes is a fragmentary claim not equal to the whole. The holding in *Weber* prohibits this inequitable result.

The agency ***publicly admits*** this policy contradicts *Weber*; however, the agency believes that 37 C.F.R. § 1.146, Elections of Species, trumps judicial precedent:

> Although dividing one generic claim by restriction may not be appropriate under *Weber*, making a requirement for an election of species for initial search and examination purposes would be permissible under § 1.146.[9]

Federal agencies do not decide when it is appropriate to follow judicial precedent.[10] This agency constantly will be confronted with new, complex

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[8] The agency intended to codify this policy into the federal regulations. *See* Examination of Patent Applications That Include Claims Containing Alternative Language, 72 Fed. Reg. 44992-45001 (proposed Aug. 10, 2007) (to be codified at 37 C.F.R. pt. 1). The agency provided an opportunity for the public to comment on its proposal, but the agency has not yet responded to those comments.

[9] 72 Fed. Reg., at 44995.

[10] *See, e.g.*, *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) ("Omission of a relevant factor required by precedent is both legal error and arbitrary agency action."); *National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp.*, 817 F.2d 74, 75 (9th Cir. 1987) (agencies are "not free to refuse to follow circuit precedent."); *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 73 USPQ2d 1409, 1416, 1417 (Fed. Cir. 2005) ("[T]he Patent and Trademark Office does not have the responsibility, or the authority, to depart from the law, or to make or change the policy embodied in the law, or to reinterpret the statute in a way that departs from congressional intention or judicial interpretation.") (Newman, J, dissenting).

technologies that test its administrative abilities to provide expeditious, quality examination. The courts have proven unsympathetic, however, to the agency's attempts to interpret the law to reduce its administrative burden.[11] In any event, the agency's interpretation of 37 C.F.R. § 1.146 contradicts the clear language of the rule.[12] 37 C.F.R § 1.146 authorizes only restriction between patentably distinct species recited in different, dependent claims. 37 C.F.R. § 1.146 further requires examination of the generic claim on the merits in its entirety.[13] 37 C.F.R. § 1.146 does not contradict the holding in *Weber*; nor does it authorize intraclaim restriction, even between patentably distinct species recited in the same generic claim.

2. The *Harnisch* decision sets forth a generally applicable test to determine whether claims possess "unity of invention."

The agency believes that the CCPA authorized it to make rules governing intraclaim restriction requirements to generic claims lacking "unity of invention."[14] In the precedential *In re Harnisch*[15] decision, the CCPA authorized the agency to

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[11] *See In re Gelnovatch*, 595 F.2d 32, 201 USPQ 136, 146 (CCPA 1979) ("The advent of a wholly new technology confronts the Patent and Trademark Office (PTO) with administrative problems in performing its vital service to the public interest in encouraging true progress of the useful arts. The solution to administrative problems does not lie, however, in so interpreting the law as to reduce an administrative burden.").

[12] 37 C.F.R. § 1.146 states:

> In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable. However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application.

[13] In at least this sense, 37 C.F.R. § 1.146 is in harmony with PCT practice, which requires examination on the merits of all independent claims. *See* PCT International Search and Preliminary Examination Guidelines, revised March 25, 2004 ("ISE Guidelines"), at Chapter 10.06.

[14] 72 Fed. Reg., at 44995.

[15] *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980).

determine appropriate steps to take if a generic claim lacks unity of invention.[16] The agency, however, alleges that the *Harnisch* court "did not set forth a generally applicable test for the Office to follow" to determine whether claims possess unity of invention.[17] The agency is incorrect. The CCPA clearly articulated the general standard for determining unity of invention (emphasis in original):

> 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. This case, we find, does not involve such inventions.[18]

The agency has long interpreted "independent and distinct" in 35 U.S.C. § 121 to mean "independent *or* distinct."[19] The CCPA emphasized that the standard to be applied for ***intraclaim*** restriction requirements is "independent ***and*** distinct." The agency cannot apply an inconsistent standard for unity of invention.[20] Instead, agency interpretations that are inconsistent with judicial precedent are set aside as unlawful, even if the agency's interpretation merits *Chevron* deference.[21]

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[16] *Harnisch*, 631 F.2d at 722, n. 6, 206 USPQ at 305-06, n.6 (CCPA 1980) ("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."); *see also* MPEP § 803.02 (interpreting *Harnisch*).

[17] 72 Fed. Reg., at 44995 ("The *Harnisch* court did not set forth a generally applicable test for the Office to follow in determining whether, in an application filed under 35 U.S.C. 111(a), alternatives within a claim have 'unity of invention,' nor did it suggest a specific mechanism by which the Office could refuse to examine a claim that lacks 'unity of invention.' ").

[18] *Harnisch*, 631 F.2d at 722, 206 USPQ at 305-06.

[19] MPEP § 802.01.

[20] *See, e.g.*, 72 Fed. Reg., at 44994 (discussing and applying the agency's limiting interpretation of unity of invention to species that "(1) share a common utility, and (2) share a substantial structural feature essential to that utility").

[21] *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001) (stating that agency interpretations not in accord with the law are reversed, even when the agency merits *Chevron* deference); *Groz v. Quigg*, 10 USPQ2d 1787, 1789 (D.D.C. 1988) ("There is strong authority for the proposition that agency action inconsistent with its own precedent is arbitrary and capricious."); *Graphic Communications Int'l Union, Local 554 v. Salem-Gravure Div. World Color*

Applying the "independent and distinct" standard above, the CCPA found unity of invention[22] of a genus encompassing a vast number of highly structurally diverse chemicals.[23] The agency argued that the administrative burden of examining such a large, diverse genus would be overwhelming.[24] The agency indeed notes that a genus claim like that in *Harnisch* may encompass an astronomical number, e.g., 2.63 x 10^{14}, of species.[25] The CCPA, however, was not persuaded by the agency's argument. The *Harnisch* court instead relied on

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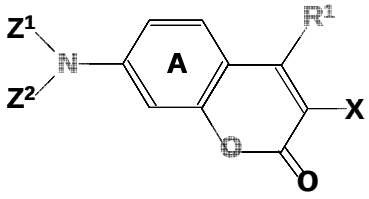
Press, Inc., 843 F.2d 1490, 1493 (D.C. Cir. 1988) (vacating agency decisions that depart from established precedent without a reasoned explanation).

[22] *See Harnisch*, 631 F.2d at 722, 206 USPQ at 305 ("We conclude that the board here was factually in error in not recognizing that all of appellant's claimed compounds are dyes. . . .").

[23] *See Harnisch*, 631 F.2d at 717, 206 USPQ at 302 (citing the Board's argument that claim 1 included "polyfused N-heterocyclics, cyclic, acyclic and aromatic amines, aryloxyalkylamines, amides, sulfonamides, phthalimides, quaternary ammonium salts, phosphorous heterocyclics, phosphates, aldehydes, azomethines, hydrazones, ethers, esters, halogens, alcohols, nitriles, piperidines, furanes, pyrroles, indoles, amongst others"). Claim 1 recited:

> Courmarin compounds which in one of their mesometric limiting structures correspond to the general formula
>
> 
>
>
> wherein
>
> X represents aldehyde, azomethine, or hydrazone,
> R^1 represents or alkyl,
> Z^1 represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring and
> Z^2 represents hydrogen, alkyl, cycloalkyl, or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring
>
> and wherein
>
> Z^1 and Z^2 conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dye-stuff chemistry.

[24] *See Harnisch*, 631 F.2d at 717, 206 USPQ at 302 (citing the examiner's argument that the claimed compounds were classified into six separate subclasses); *see also* n.23, *supra*.

[25] *See* J. LeGuyader, "Proposed Rule Changes—Search and Examination of Alternative (Markush) Claims," Biotechnology/Chemical/ Pharmaceutical Customer Partnership Conference, Slide 29, *available at* http://www.cabic.com/bcp/091207 (presented September 12, 2007).

its holding in *In re Jones*,[26] where structurally diverse species were held to be related by a ***common function***:

> Notwithstanding their various properties, the [*Jones*] court found all of the compounds included in the claims were plant growth stimulants, thus having a common function.[27]

Functionally related species are expected to be much harder to search than structurally related species, which can be searched by computer-assisted structural comparison. The CCPA, however, refused to discriminate against certain inventions on the basis of the relative burden of search imposed on the agency.

The *Harnisch* test determines unity of invention by whether species are "related." The agency itself has long interpreted "related" inventions, i.e., those that would possess unity of invention, as having a ***disclosed*** relationship in ***any*** of "design (e.g., structure or method of manufacture), operation (e.g., function or method of use), or effect."[28] The MPEP states:

> The term "independent" (i.e., unrelated) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. For example, a process and an apparatus incapable of being used in practicing the process are independent inventions.[29]

Under *Harnisch* and *Jones*, a genus possesses unity of invention if the species are disclosed as related in function or method of use, even if not by structure. Applying the *Harnisch* unity of invention standard, DNA array claims generally would possess unity of invention as well. While probes of the array may be structurally unrelated, they nevertheless may be disclosed as having the same function or operation, e.g., diagnosing the same disease. Because the probes share a common disclosed function, they are related. The generic claim thus

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[26] *In re Jones*, 162 F.2d 479, 74 USPQ 149 (CCPA 1947).

[27] *Harnisch*, 631 F.2d at 722, 206 USPQ at 305.

[28] MPEP § 802.01.

[29] *Id.*

would possess unity of invention, and restriction between the probes or their subcombinations would be prohibited.

The *Harnisch* standard, appropriately interpreted, is in harmony with PCT practice. The *Harnisch* court deliberately chose the term "unity of invention," because it was "intelligible internationally."[30] Under international practice, generic claims have unity of invention, if structurally unrelated species are functionally substitutable for each other.[31] For example, PCT practice finds unity of invention for structurally unrelated probes that possess the common function of binding to (structurally unrelated) mRNA molecules related to the same disease state.[32] This example would apply—and unity of invention would be found—if the probes were immobilized in a DNA array.

In a memorandum in 2007, the agency stated that it would presume that each biological sequence is an "independent and distinct" invention.[33] The agency, however, noted in the same document:

> Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule.[34]

The agency considers no other type of compounds* per se *independent and distinct. The agency's presumption is unique to biological sequences and is driven solely by the need to reduce its administrative burden of examining

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30 *Harnisch*, 631 F.2d at 721, 206 USPQ at 305.

31 PCT International Search and Preliminary Examination Guidelines, revised March 25, 2004 ("ISE Guidelines"), Chapter 10.17.

32 ISE Guidelines, Chapter 10.53.

33 *See* J. Doll, Commissioner for Patents, "Examination of Patent Applications Containing Nucleotide Sequences," *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf (dated Feb. 22, 2007); *see also* MPEP § 803.04 ("These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq*.").

34 *Id.,* at *3.

biological sequences.[35] In 2005 the agency briefly experimented with a restriction standard based on whether inventions were "independent and distinct."[36] The agency's standard again arbitrarily interjected numerous requirements inconsistent with the *Harnisch* court's unity of invention standard.[37] The agency found that this standard could not be implemented effectively.[38] The agency instead must adopt an "independent and distinct" standard for restriction requirements based solely on whether species are disclosed as related. This standard is consistent with *Harnisch* and the PCT, and it can be understood by reference to the MPEP's long-standing interpretation of "related" inventions.

Implementing the agency's current policy of presuming independence and distinction has proven problematic. Restriction requirements made without considering independence, relatedness, or distinction typically are revised or withdrawn entirely after review on petition. In fiscal year 2009, for example, fully 78% of all petitions of restriction requirements were granted or granted-in-part, and 16 Office Actions on the merits were withdrawn as incomplete.[39] Further, months of pendency can be lost during the petitions process, impeding the agency's strategic goal of an average total pendency of 20 months. Interviews with examiners can be extremely helpful in clarifying or revising intraclaim

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[35] A search of functionally related compounds is unquestionably much more difficult than a computer assisted alignment of biological sequences using the BLAST algorithm, for example.

[36] USPTO Study on Restriction Reforms, at *5-6, *available at* http://www.uspto.gov/web/patents/greenpaper.pdf (first posted December 22, 2005).

[37] *Id.*, at *6 ("Inventions would be independent if there is no common feature(s) among the inventions. In addition, inventions would be independent if they share a common feature(s), but the common feature(s) does not define over the prior art and/or satisfy the enablement and written description requirements of 35 U.S.C. § 112."). The agency's standard is also inconsistent with the PCT. For example, adequacy of the disclosure is irrelevant to unity of invention under the PCT, as in the U.S. *See* ISE Guidelines, Chapters 10.01, 10.02; *Harnisch*, 631 F.2d at 721, 206 USPQ at 305 (distinguishing unity of invention from scope of enablement).

[38] *Id.*, at *21.

[39] *See* J. Burke, USPTO, "FY09 Restriction Petition Update; Comparison of US and National Stage Restriction Practice," Biotechnology/Chemical/Pharmaceutical Customer Partnership Conference, at Slides 2, 9, and 46, *available at* http://www.cabic.com/bcp/ (presented December 9, 2009).

restriction requirements; however, absent consistent application of an understandable legal standard, revised restriction requirements themselves may require further revision. And the examining corps may refuse to give a prior restriction requirement full faith and credit.[40] The unfortunate result is that a single application may contain multiple, inconsistent intraclaim restriction requirements. Vacillation of this sort increases uncertainty, extends pendency, and wastes valuable time and resources. The agency should accept that its policy of presumed independence and distinction of biological sequences is as impossible implement as the agency's failed 2005 attempt.

The agency recently took positive steps to correct its restriction policy. In January 2010, the agency published form paragraphs that require the examining corps to provide reasoned explanations for imposing restriction requirements, including a consideration of independence and distinction—irrespective of technology.[41] Use of the approved form paragraphs is expected to resolve much of the inconsistency in the agency's current restriction practice. At present, however, the approved form paragraphs still have not been used. This delay highlights the value of implementing the agency's strategic plan of reengineering the MPEP to summarize and update the text with greater frequency, to ensure rapid and consistent implementation of policy changes by the examining corps.

3. The agency should clarify the circumstances under which the Board of Patent Appeals and Interferences has subject matter jurisdiction over intraclaim restriction requirements.

The petitions process results in serious delays in pendency, even when petitions are granted. The delay in prosecution to obtain a final agency action following reconsideration of denied petitions is expected to be considerable, as

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[40] *See* J. Burke, USPTO, "FY09 Restriction Petition Update; Comparison of US and National Stage Restriction Practice," Biotechnology/Chemical/Pharmaceutical Customer Partnership Conference, at Slides 19 and 30, *available at* http://www.cabic.com/bcp/ (presented December 9, 2009).

[41] *See* R. Bahr, Assoc. Comm'r Patent Examination Policy, USPTO, "Changes to Restriction Form Paragraphs," *at* http://www.uspto.gov/patents/law/exam/20100121_restrctn_fp_changes.pdf (January 21, 2010).

well. Petitioners must obtain a final agency action before a district court can review the action under the Administrative Procedures Act. An alternative route to appellate review would reduce pendency and costs.

Appellate review of intraclaim restriction requirements is in fact available at the Board of Patent Appeal and Interferences ("Board") and the Federal Circuit. The CCPA held that it had subject matter jurisdiction over claim ***objections*** for encompassing non-elected subject matter. The CCPA found such objections to be a *de facto* rejections, which the agency could not use to avoid judicial review.[42] The Board recently acknowledged that it may have subject matter jurisdiction over intraclaim restriction requirements of biological sequences in some cases.[43] It is unclear whether the Board can review a *de facto* rejection only if the agency has made a final agency action. Applicants would benefit by having a clearly delineated path of appellate review to the Board and, if necessary, to the Federal Circuit. The Board should assume subject matter jurisdiction on appeal, following denial of a petition under 37 C.F.R. § 1.144 by the technology center director. This policy would expedite prosecution, reduce costs, and reduce delays for reconsideration of denied petitions.

4. The agency could reduce its administrative burden by judiciously applying the procedures set forth in MPEP § 803.02.

The CCPA understood that its holding in *Weber* could create a significant examination burden on the agency. Without the ability to restrict species into separate applications, the agency potentially would have to examine a vast number of compounds encompassed by a single generic claim in one application. The *Weber* court encouraged the agency to exercise its discretion to

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[42] *In re Hass*, 486 F.2d 1053, 1056, 179 USPQ 623, 626 (CCPA 1973) (treating an objection over a claim as an improper *Markush* group as a *de facto* rejection); *see also Weber*, 580 F.2d at 459, 198 USPQ at 332 (noting an exception to the rule in *In re Hengehold*, 440 F.2d 1395, 169 USPQ 473 (CCPA 1971)); *Harnisch*, 631 F.2d at 721, 206 USPQ at 304-05.

[43] *Ex parte Valkirs*, Appeal 2007-0628, Application No. 10/225,082, at *4, n.1 (Bd. Pat. App. Inter. April 17, 2007) (non-precedential) (noting that the issue of whether a restriction requirement was a *de facto* rejection was "premature" in this appeal).

determine how much searching it will do for a single search fee. But the court also noted that the agency must balance its administrative burden with applicants' paramount rights under 35 U.S.C. § 112:

> Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.[44]

The implications of *Weber* are clear. The agency is not permitted to limit the scope of applicants' claims by an intraclaim restriction requirement. But neither is the agency thereby obliged to search and examine every species encompassed by a generic claim.

The agency could comply with the court's directive in *Weber* by judiciously applying MPEP § 803.02, which provides a "provisional election of species" for search and examination of species in a generic claim. If the elected species is allowable over the prior art, the search is extended to non-elected species. MPEP § 803.02, however, explicitly states that the examining corps need not examine all the species encompassed by the generic claim:

> [S]hould the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species***.

The MPEP is a set of instructions for the examining corps.[45] The public relies on the agency to follow its own procedures.[46] Agencies cannot arbitrarily ignore their procedures,[47] nor can agencies act inconsistently from case-to-case.[48]

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[44] *Weber*, 580 F.2d at 458-59, 198 USPQ at 332 (footnote omitted).

[45] *In re Kaghan,* 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967) (the MPEP "is primarily a set of instructions to the examining corps of the Patent Office from the Director."); *see*

The agency generally does not apply MPEP § 803.02 to biotechnology inventions, unless compelled by petition under 37 C.F.R. § 1.144. TC1600 granted six petitions in FY2009 to replace intraclaim restriction requirements with provisional elections under MPEP § 803.02.[49] Grants of petitions arguably would merit *Skidmore* deference from the courts.[50] They likewise should receive deference from the agency itself. The agency thus should state publicly that it will prohibit intraclaim restriction requirements in favor of provisional elections of species. The agency is encouraged to make such a statement in response to the present request for public comments.

Given the complexity of the chemical genus at issue in *Harnisch* and similar cases, the CCPA clearly viewed examination of each species of a chemical genus as unnecessary. The agency likewise historically has considered a search of each species in a chemical genus as unnecessary to determine patentability. The agency's treatment of generic claims reciting chemical species provides ample precedent for the same treatment of generic claims reciting species of biological sequences, e.g., DNA array claims. The agency should take a consistent position with respect to biotechnology and

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also MPEP, Forward (the MPEP "outlines the current procedures which the examiners are required or authorized to follow.").

[46] *Patlex Corporation v. Mossinghoff*, 226 USPQ 985, 989 (Fed. Cir. 1985) (stating that the MPEP "is made available to the public and … describe[s] procedures on which the public can rely").

[47] *Groz v. Quigg*, 10 U.S.P.Q.2d 1787, 1789 (D.D.C. 1988) ("There is strong authority for the proposition that agency action inconsistent with its own precedent is arbitrary and capricious."); *Graphic Communications Int'l Union, Local 554 v. Salem-Gravure Div. World Color Press, Inc*., 843 F.2d 1490, 1493 (D.C. Cir. 1988) (vacating as arbitrary and capricious agency decisions that depart from established precedent without a reasoned explanation).

[48] *Cf. Teva Pharm. USA Inc. v. FDA*, 51 USPQ2d 1432, 1439 (D.C. Cir. 1999) (finding the FDA's statutory interpretation arbitrary and capricious because of unexplained inconsistent treatment on a case-by-case basis).

[49] *See* J. Burke, USPTO, "FY09 Restriction Petition Update," at Slide 18, *available at* http://www.cabic.com/bcp/120909/JBurke_RCandRPR.ppt (presented December 9, 2009) (turning restriction requirements into provisional elections of species).

[50] *See United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001).

chemical inventions. The agency thus should acknowledge that the extended examination under MPEP § 803.02 will not necessarily be applied to each biological sequence reciting in a generic claim. The agency thereby would avoid a charge of *de facto* discrimination against biotechnology inventions.[51]

The agency unquestionably has a legitimate need to limit the search and examination of complex biotechnology inventions. Even in 1978, when *Weber* was decided, the court realized that the agency had a pressing need—and the authority—to control its administrative burden of examining complex claims.[52] The examining corps cannot possibly be expected to examine each sequence or possible combination of sequences of a DNA array with thousands, even hundreds of thousands, of probes. The agency recently stated:

> Controlling examiners' caseloads is a much more significant concern in 2007 than it was in 1978. The volume and complexity of patent applications continue to outpace the examining corps' current capacity to examine them. The result is a pending—and growing—application backlog of historic proportions. Thus the Office does not believe that controlling the amount of searching per filing fee will, by itself, resolve the administrative issues raised by the use of Markush or alternative language.[53]

The agency, however, ***fails to explain*** why controlling the amount of searching for a single claim fee would not resolve the agency's ability to handle its backlog. The agency has not considered the less-drastic and less-damaging alternatives to controlling its administrative burden of allowing generic claims containing unexamined biological sequences and their subcombinations. The agency must develop a policy that respects the law and applicants' paramount rights under the patent statutes, while protecting the examining corps from a potentially overwhelming burden of search. Accordingly, the agency should acknowledge

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[51] The agency should be mindful of TRIPS, Article 27.1, which provides that "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology."

[52] *See Weber*, 580 F.2d at 458-59, 198 USPQ at 332.

[53] 72 Fed. Reg., at 44993-94.

that quality examination does not require an examination of each biological sequence in a generic claim.

5. The agency should announce publicly how many sequences it intends to search under the extended examination practice of MPEP § 803.02.

The agency also needs to reduce pendency for examination of complex claims, when applying § MPEP 803.02. At present, if an examiner finds the provisionally elected species allowable, the agency issues an Advisory Action (if the last rejection was made final) and invites an election of another species for further examination. Applicants must file a Request for Continued Examination (RCE) to elect the next species.

This procedure can result in large delays in prosecution. At present, the agency could require applicants to file a RCE for ***each*** round of extended examination. If the agency decided to examine ten biological sequences recited in a generic claim, for example, applicants might have to file as many as nine consecutive RCEs to extend examination to each elected species! Each RCE would drastically increase pendency, particularly since RCEs are no longer placed on examiners' "amended" docket. Further, patent term adjustment would be unavailable under 35 U.S.C. § 154(b) after the first RCE was filed.[54] This procedure must be streamlined significantly to allow the agency to reach its strategic goal of reducing the average pendency to 20 months.

The agency must tell the public how many sequences will be searched to determine the patentability of the generic claim. The agency should provide applicants this information in the Office Action setting forth the provisional election of species. The agency then should extend examination to that number of additional species in response to applicants' first RCE, to expedite prosecution. This would allow the agency to predict and control the resources required for examination. It would also allow applicants to estimate the costs of

[54] Patent term adjustment available under 35 U.S.C. § 154(B) for pendency of more than three years end when applicants file a RCE under 35 U.S.C. § 132(b).

prosecution and develop strategies to deal with unexamined sequences in the application. The agency stated previously that it would examine ten nucleic acid sequences in a single Office Action "to encourage and promote growth in this technology"[55] This guideline, in fact, is still stated in the MPEP.[56] It seems reasonable for the agency to continue this policy in the context of an extended examination under MPEP § 803.02.

The United States biotechnology industry as of April 2008 possessed a market capitalization of $360 billion with revenues from publicly traded companies reaching $58.8 billion in 2006. There were 180,000 people employed in U.S. biotechnology companies in 2006.[57] More than most industries, the value of biotechnology is heavily based on patents. The agency's current restriction policy reduces biotechnology patent value by arbitrarily decreasing claim breadth. The agency's restriction policy further complicates patent enforcement. Filing a plethora of divisional applications directed to related species increases the risks of double patenting, complicates ownership if terminal disclaimers are required, and potentially increases the onerous reporting requirements associated with "substantially similar claims."[58] And, of course, the fees and prosecution costs associated with multiple divisional applications are burdensome, as well. The agency should see the recent collapse of the cap-and-trade market for sulfur emissions as a cautionary tale:

> The market's collapse shows how vulnerable market-based approaches to reducing air pollution are to government actions.

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55 *See* J. Doll, Commissioner for Patents, "Examination of Patent Applications Containing Nucleotide Sequences," passim, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf (dated Feb. 22, 2007).

56 *See* MPEP § 803.04.

57 Guide to Biotechnology 2008, Biotechnology Industry Organization, *at* http://bio.org/speeches/pubs/er/BiotechGuide2008.pdf.

58 *See Larson Mfg. Co. of South Dakota Inc. v. Aluminart Prods. Ltd.,* 90 USPQ2d 1257 (Fed. Cir. 2009); *McKesson Information Solutions Inc. v. Bridge Medical Inc*., 487 F3d 897, 82 USPQ2d 1865 (Fed. Cir. 2007).

> That could scare off investors, who won't commit to a market where the rules can change at any minute.[59]

Like the sulfur emissions market, biotechnology is not invulnerable to government policies that vary from case-to-case and from year-to-year. The agency should take steps now to address problems with its restriction policy, before the biotechnology industry suffers further harm.

6. Summary.

The agency must end intraclaim restriction requirements and establish policies consistent with the law that facilitate and expedite the issue and grant of patent applications. The agency can take immediate steps to improve its restriction policy:

(1) The agency should prohibit intraclaim restriction requirements;

(2) The examining corps must provide reasoned explanations for independence, relatedness, and distinction of biological sequences;

(3) The agency should clarify that the Board can review an intraclaim restriction requirement for unity of invention without a final agency action;

(4) The agency should apply MPEP § 803.02; and the agency should allow generic claims with unsearched species or subcombinations; and

(5) The agency should announce how many sequences it intends to search under MPEP § 803.02.

These changes are well within the agency's authority. Because they rely on the enforcement of existing procedures, they can be accomplished without revision

[59] Mark Peters, "Changes Choke Cap-and-Trade Market," Wall Street Journal, *available at* http://online.wsj.com/article/NA_WSJ_PUB:SB10001424052748704258604575360821005676554.html (posted July 12, 2010).

of the Code of Federal Regulations or the MPEP. The commenter looks forward to the agency's response to these recommendations.

Respectfully submitted,

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