Restriction Elections & Double Patenting[1]

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I. Introduction

Have you ever been at a party and been introduced to a new acquaintance? The host walks up to you with a stranger and a variation on the following theme occurs:

> The host says, "Joan, I'd like you to meet Sam. He is an old friend from college."
>
> Sam extends his hand in greeting and says, "Hi, glad to meet you. I'm a teacher with the New School in Arkansas."
>
> Taking his hand, you reply, "Nice to meet you to. Teaching is a wonderful profession."
>
> The host interrupts and says, "Joan is a patent attorney. I thought you two should meet."
>
> Sam continues, "Wow, Joan. What a coincidence! I've been working on this lever and was thinking of getting a patent. Let me tell you about it."

. . . and the conversation continues. Not a bad way to meet creative people (although billing can be a challenge).

Sometimes it is fun, sometimes it is socially challenging, but it is always interesting. People get excited about their ideas. The question that always comes around relates to "what is **the** patentable invention"? Is it a new lawn mower with a simplified steering control lever or the latest method of mowing the lawn? A discussion of the details might reveal other uses for the lever in farm tractors or as an assistance device for handicapped drivers. The client counseling session might uncover improvements to road systems. Oh, and don't forget that professional drivers may be less fatigued through the use of the new method of steering an eighteen-wheeler.

All of these things are "inventions," but are they "patentable inventions"? The United States Patent and Trademark Office (USPTO) teaches its examination staff that every patent application filed contains an invention. It is not their job to judge the creativity or merit of an invention; rather, their sole task is determining whether the invention meets the legal standards for patentability.

One definition of "invent" is "to originate or create as a product of one's own ingenuity, experimentation, or contrivance . . . [or] . . . to produce or create with the imagination."[4]

In *United Mattress Machinery Co. v. Handy Button Machine Co.*,[5] the 3rd Circuit noted that:

> It is significant that in most of the pertinent cases the proponent of the new use, like Mathewson, made a physical alteration in the prior art which enabled him to use the established principles of that art in a different way. But such a change in form, while calling for mechanical ingenuity, is not invention. Congress has made no attempt to define the term 'invention', either under the older law or in the new Patent Act. Instead, the courts, aided only by case law, have had to determine for themselves what constitutes invention and what does not.

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[4] Dictionary.com, definition of Invent, available at http://dictionary.reference.com/browse/invent.
[5] United Mattress Machinery Co. v. Handy Button Machine Co., 207 F.2d 1, 5 (3d Cir. 1953).

In more recent times, the Federal Circuit has relied upon 35 U.S.C. §101 in opining that an "invention" is defined to include any new and useful process, machine, manufacture or composition of matter and "thus is broad enough to include method patents."[6] In June 2013, the Supreme Court reiterated that there **are** boundaries for patent eligible subject matter under 35 U.S.C. §101. For example, in *Association For Molecular Pathology v. Myriad Genetics, Inc.*, the Court observed that even the fact that "[g]round breaking, innovative, or even brilliant discovery does not by itself satisfy the §101 [eligibility] inquiry.[7]

Thus, there is a clear distinction between the creative event that we call invention and the establishment of an event as meriting the grant of a limited monopoly that is judged as patentable.

A. Perspectives

Perhaps one of the greatest challenges facing a patent prosecutor is the translation of an inventor's concepts and ideas into a tangible product that we call a patent application. As a prosecutor, you have the benefit of full and relatively unrestricted access to the mind behind the invention. You can ask probing questions, consider variations, and discuss language and meanings. Even if the field of invention is beyond your own technical experience you get the opportunity to be the student, ask questions, and learn.

You then have the responsibility of translating the results of this interview into a written document that intends to meet the requirement of 35 U.S.C. §112.[8] In writing the patent application, you have the benefit of a guided tour of the invention.

On the other hand, once it leaves your desk (and is signed off by the inventor), the USPTO takes over. After winding its way through the administrative process, it ends up on the desk (or more accurately, the computer screen) of that entity known as a "patent examiner." This person must review the application for compliance with patentability standards and act in a quasi-judicial role. For better or worse, they have no *a priori* knowledge of what they are reviewing and limited time to gain an understanding of that presented to them.

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[6] Cardiac Pacemakers, Inc. v. St. Jude Med., Inc., 576 F.3d 1348, 1362 (Fed. Cir. 2009).

[7] Association For Molecular Pathology, et al. v. Myriad Genetics, Inc., et al., 569 U. S. ____ (2013).

[8] *See, e.g.,* MPEP §2164 available at http://mpep.uspto.gov/RDMS/detail/manual/MPEP/current/d0e18.xml#/result/RDMS/detail/manual/MPEP/current/d0e215224.xml?q=the%20purpose%20of%20the%20requirement&start=1&ccb=on&ncb=off&icb=off&fcb=off&ver=E9_R-11.2013&sort=relevance&syn=adj&cnt=10&results=compact&index=1#highlight:

> The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. However, to comply with 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.,* 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system). Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.

B. The Patent Examiner Handoff

While a patent examiner is trained that each patent application, without exception, contains the disclosure of at least one "invention," whether that invention (or those inventions) is patentable can only be determined after a substantive review.[9] The examination process requires review for compliance with all patentability requirements including those set forth in Title 35 of the United States Code; however, examiners are given a limited time to perform the required examination of the application and the complexity of patent applications is increasing over time.[10,11] Thus, to fully appreciate restriction and lack of unity practice and to develop strategies that allow one to make the most of them, one must understand the pressures and constraints that makes patent examining both fascinating and frustrating.[12]

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[9] 35 U.S.C. §131: "The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor."

[10] "Patent actions are usually long and costly. The law is recondite; the facts are highly technical and often obscure. Copious expert evidence is called to explain abstruse matters to a non-technical judge. The complexity is increased by the almost inevitable attack on the validity of the patent for 'lack of invention.'" Harry E. Potts, The Modern Law Review, Vol. 7, No. 3 (July 1944), pp. 113-123.

[11] *See, e.g.,* "Patent Examiner Count System," available at http://www.uspto.gov/patents/init_events/CountSystem.jsp#heading-3, and "Comments in Response to the Request for Comments on Green Paper Concerning Restriction Practice," available at http://www.uspto.gov/web/offices/pac/dapp/opla/comments/restriction/parker_knight.pdf.

[12] *See, e.g.,* Scott Wolinsky's article "An Inside Look At The Patent Examination Process," available at http://vklaw.com/publication/an-inside-look-at-the-patent-examination-process-updated-from-january-2007/. In one section of this article entitled "Time is Money: The USPTO 'Count' System," Wolinsky explains the following:

> An examiner earns a first "count" upon issuing a first report (office action) regarding the patentability of the patent application and a second "count" when the application is disposed of (allowed, abandoned, or when the examiner responds to an appeal). It is not unusual for an examiner to spend more than the time equivalent to one "count" to complete a first office action. The examiner does not receive extra credit for issuing a second non-final office action, a final office action, telephone interviews or an advisory action. The examiner is allowed to charge one hour of "other" time for each instance when a personal (in office) interview is held with an applicant and/or the applicant's representative.
>
> An examiner earns two "easy counts" when the prosecution of an allowed patent application that has not yet issued is continued such that new references submitted by the applicant can be considered. This, of course, assumes that the references are not deemed relevant enough by the examiner to warrant the withdrawal of the allowance.

Note that the examination production count system was updated following a USPTO Joint Labor and Management Count System Task Force agreement signed August 31, 2010 (*see, e.g.,* http://www.uspto.gov/patents/init_events/CountSystem.jsp, and http://popa.org/pdf/agreements/counts-counts-31aug2010.pdf. The following is a table that compares the examination production credit systems in place before and after the agreement.

Current Count System									Current	
Original Case (Non-RCE)			1st RCE			2nd & Subsequent RCEs			Counts	
FAOM	Final	All/Abn	FAOM	Final	All/Abn	FAOM	Final	All/Abn		
1.00		1.00							2	Original
1.00		1.00	1.00		1.00				2	1st RCE
1.00		1.00	1.00		1.00	1.00		1.00	2	2nd & Subsequent RCEs

New Count System									New	
Original Case (Non-RCE)			1st RCE			2nd & Subsequent RCEs			Counts	
FAOM	Final	All/Abn	FAOM	Final	All/Abn	FAOM	Final	All/Abn		
1.25	0.25	0.5							2.00	Original
1.25	0.25	0.5	1.00	0.25	0.5				1.75	1st RCE
1.25	0.25	0.5	1.00	0.25	0.5	0.75	0.25	0.5	1.50	2nd & Subsequent RCEs

Legend:
RCE = Request for Continued Examination
FAOM = First Action on the Merits
Final = Final Office Action
All/Abn = Allowance, Abandonment, or any other Disposal

The amount of time that an examiner has to review each application is dependent upon the technology being reviewed and the experience level of the examiner. Thus, the greater the number of "inventions" and the more complex the technology, the more difficult is the task the examiner must accomplish within a limited time. For a discussion of how the amount of time an examiner has to review each patent application (and consequently an understanding of part of the motivation for restriction) *see, e.g.,* Solicitation No. DOC52PAPT0901021 Patent Examiner Production Goals Study (PGS), "REQUEST FOR QUOTE (RFQ) & STATEMENT OF OBJECTIVES (SOO) Patent Examiners Production Expectancy Goals Re-Assessment and Adjustment" (Posted May 2009), available at http://www.uspto.gov/about/vendor_info/current_acquisitions/pgshom_rfqsoo_v2.doc. The following example is based on the pre-2010 goals adjustment.

How an examiner's production goal is determined

An examiner's assigned expectancy, or production goal, is an average amount of time an examiner is expected to spend examining an application from First Action to Final Disposal (the First Action and Final Disposition together are referred to as a Balanced Disposal). This amount of time is dependent upon the technology being examined and the examiner's grade. Generally speaking, the greater the complexity of examination of the technology, the more time allowed for the examiner to complete a Balanced Disposal. Also, the higher the grade (which generally corresponds to the experience the examiner has), the less time allowed for the examiner to complete a Balanced Disposal.

As an example of assigned expectancies based on complexity of examination, at the GS-12 level:

Class 14 (bridges) gets 17.5 Hours per Balanced Disposal.
Class 202 (distillation apparatus) gets 21.9 Hours per Balanced Disposal.
Class 725 (interactive video distribution systems) gets 31.6 Hours per Balanced Disposal.

Currently there are over 630 unique Class/Subclass technology designations with specific Hours per Balanced Disposal designations.

Below is a listing of the factors used to adjust for an examiner's grade level, called position factors:

Grade	Position Factor
GS-5	0.55
GS-7	0.70
GS-9	0.80
GS-11	0.90
GS-12	1.00
GS-13	1.15
GS-13, partial signatory	1.25
GS-14, full signatory	1.35
GS-15, senior	1.40
GS-15, expert	1.50

Using the above two numbers, in Class 14 (bridges):

A GS-12 examiner's expectancy would be 17.5 Hours per Balanced Disposal (BD).
A GS-7 examiner's expectancy would be 17.5 divided by the position factor of 0.7, or (17.5/0.7) = 25.0 Hours per BD. Therefore, within the same technology area, the less experienced GS-7 examiner gets more time than a GS-12 examiner.

A GS-14 examiner's expectancy would be 17.5 divided by the position factor of 1.35, or (17.5/1.35) = 13.0 Hours per BD. Therefore, within the same technology area, the more experienced GS-14 examiner gets less time than a GS-12 examiner.

In the "Hours per Balanced Disposal" expectancy number, a Balanced Disposal (BD) is also referred to as a "Production Unit". Each patent application only has two "counts" or credited work units. The first "count" or credit is given at the First Action on the Merits (FAOM) and the second "count" at Final Disposal. This is typically reflected in the formula:

"Balanced Disposal" or a "Production Unit" = (N+D)/2, where:

According to one inspector general report, the number of claims, length of application, and complexity of the technology being claimed is steadily increasing over time. Plus, the USPTO is under continual scrutiny regarding examination quality and timeliness even while they are being asked to examine an increasing number of applications per year. The USPTO's participation in the federal budgetary process adds further challenges as, even though fee funded, the USPTO is still subject to budgetary oversight including *inter alia* sequestration.[13] (Note, however, that the Leahy-Smith America Invents Act provides for a reserve fund to provide for continuing operations.[14]) Appropriately limiting the quantity of subject matter reviewed in each application is one tool that the USPTO uses to balance competing administrative burdens.[15]

> N = First Action on the Merits (FAOM)
> D = Final Disposal; either an Allowance, Abandonment, Examiner's Answer on Appeal, or an Interference
>
> In any given biweek or unit of time, both the amount of work an examiner is expected to do as well as how much work the examiner actually completed can be calculated easily using the above numbers coupled with the number of hours the examiner was examining during that unit of time. For example, a GS-14 examiner in Class 14 that has 70 hours of examining in biweek is expected to do 70 hours divided by 13.0 Hours per BD, or (70/13.0) = 5.4 BDs. If the examiner completes 6 FAOMs, 3 Allowances, and 2 Abandonments in that biweek, then they completed 6 N's and 5 D's.
>
> Calculating their percent achievement based on their expected achievement:
>
> > Expected Balanced Disposals (BDs): 70 hours divided by 13.0 Hours per Disposal, or (70/13.0) = 5.4 BDs
> >
> > Achieved Balanced Disposals (BDs): (N+D)/2 = (6+5)/2 = 5.5 BDs
> >
> > Percent Achievement: 5.5 BDs achieved divided by 5.4 BDs expected = 102%.
>
> An examiner's performance relative to a given production goal is used in evaluating their achievement relative to their performance appraisal plan, as well as their eligibility for telework programs, overtime, promotions, granting of signatory authority, and performance awards.

[13] *See, e.g.,* Gene Quinn's commentary in IPWatchdog. Gene Quinn, "*17 Members of Congress Push to Exclude USPTO from Sequester"* IPWatchdog (July 5, 2013, 8:00 AM), http://www.ipwatchdog.com/2013/07/05/17-members-of-congress-push-to-exclude-uspto-from-sequester/id=42951.

[14] Pub. L. 112-29, 125 Stat. 316 (September 16, 2011); §§10, 22.

[15] The USPTO is also continuing to reconsider its restriction practices. To this end, they have published a "green paper" in which they have solicited comments regarding revisions of current practice. This paper bears consideration in order to obtain a greater understanding of the USPTO's difficulty in finding a suitable balance among productivity, quality, and pendency. The full text of this document is available at http://www.uspto.gov/web/patents/greenpaper.pdf. While a number of comments were received in response to the publication of this document, the USPTO has not published any follow-on documents related to its green paper. The executive summary paper states:

> The United States Patent and Trademark Office (USPTO or Office) established a 21st Century Strategic Plan to transform itself into a quality-focused, highly productive, responsive organization supporting a market-driven intellectual property system. The plan included a study of the changes needed to implement a Patent Cooperation Treaty (PCT) style Unity of Invention standard in the United States. The Office is cognizant that some applicants and the public may not view its current restriction practice as an ideal practice, particularly as it is presently applied. For example, some applicants may need to pursue related claims in multiple applications under the current practice and therefore, the public faces delays in determination of the ultimate scope of patent protection particularly when the applications are filed serially. At the same time, data indicates that the majority of additional inventions presented in applications that are currently restricted are not pursued in divisional applications. Any changes to current practice that would result in the examination of more of

Finally, patent examination review involves the search and consideration of an increasing number of references as well as wider search areas available to examiners due to better automated tools including the Internet.[16]

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these inventions in a single application would then necessarily increase examination workload. The Office must consider the constraints its staffing and other resource limitations impose on the amount of additional workload that could be absorbed in the transition to a new restriction standard, while contemporaneously implementing the other priorities of the 21st Century Strategic Plan.

The USPTO sought public comment on a number of issues to help guide the scope and content of the study on the adoption of a PCT-style Unity of Invention standard in the United States. The public comments suggested broadening the scope of the study beyond just a PCT-style Unity of Invention standard in an effort to determine the best practice for restriction. Suggestions were made for other restriction standards that were considered to better serve the patent system, i.e. by modification of the existing national or PCT procedure, by creating a tiered system of relatedness of inventions, or by revision of the existing statutory interpretation. Four options for restriction reform were developed for further study based on the comments received and a detailed business-case analysis was performed on two of them.

The results of the study demonstrate that the implementation challenges would vary considerably with each of the options. In addition, to maintain an adequate revenue stream after transition to any of the restriction reform options, a revised fee structure would be necessary.

The first option of permitting applicant to request and pay for examination of additional inventions, while retaining the current restriction standard, would be significantly less difficult to implement than the remainder of the options. Its impacts are principally directed to staffing and fee revisions designed to maintain constant revenue. While this option, like all of the others, has a short-term negative impact on office-wide pendency, it is expected to introduce the least amount of uncertainty and negative impact on the overall patent system.

The second option of adopting the unity of invention standard, modified to require that the common feature satisfy the enablement and description requirements in addition to novelty and non-obviousness, is considered the second best alternative. However, adoption of this standard would include all of the impacts of the first option and a number of others. The second option would require additional initial training and subsequent monitoring of the examiners, as well as serious evaluation of each of the examination changes suggested in the original request for comment, to which the public was strongly opposed (Request for Comments on the Study of the Changes Needed to Implement a Unity of Invention Standard in the United States, 68 Fed. Reg. 27536 (May 20, 2003), 1271 Off. Gaz. Pat. Office 98 (June 17, 2003)). This option is considered to have a somewhat higher degree of uncertainty and negative impact on the overall patent system relative to the first option; nevertheless it has significantly less impact relative to the third and fourth options.

The third (three-tier fee structure) and fourth ("independent and distinct" standard) options introduce even greater changes to the existing system that would produce a number of new, significant challenges, some of which may not be predictable. It is not at all clear that the transition to either of these two options would result in an improved system, and such a transition may even cause significant quality and pendency degradation. Transition to either the third or fourth option is not recommended without an effective pilot evaluation of their long-term impact. Given the initial results, the limited resources of the Office, and the anticipated implementation issues, continued consideration of either of these two options beyond that described in this paper is not recommended.

Efforts to improve the quality and consistency of the restriction requirements in Technology Center 1600, particularly in applications directed to biotechnology, continued throughout and beyond the study. See Appendix XI – TC 1600 Restriction Action Plan. This plan includes additional training and oversight of restriction requirements, as well as posting of the training materials on the USPTO website following completion of the training. These steps should reduce the overall number of improper restriction requirements and should increase the ease with which requirements that are inconsistent with the training examples can be successfully traversed or corrected. The process of improving the quality and predictability of restriction requirements must be a collaborative effort; the TC 1600 Restriction Action Plan and this paper represent only the first step in an ongoing endeavor to discover feasible solutions. It is hoped that the improvements in quality and predictability expected from the restriction action plan alone will be perceived as significant progress toward the goal of achieving an appropriate balance between the priorities of the USPTO user community and limited USPTO resources.

[16] *See, e.g.,* Federal Register, May 27, 1999 (Volume 64, Number 102), Pages 28803-28806, available at http://www.gpo.gov/fdsys/pkg/FR-1999-05-27/pdf/99-13440.pdf, "Notice of Public Hearing and Request for Comments on Issues Related to the Identification of Prior Art During the Examination of a Patent Application."

While the USPTO is hiring more and more examiners and developing new training methods to help increase the quality of examination, simple arithmetic shows that even with 10,000 examiners a patent examiner must finish the review of one complete patent application per week. This review includes processing all formal activities, speaking with applicants, performing interviews, searching, reviewing literature, writing office actions, responding to applicants and, where necessary, responding to appeals. While many patent examiners receive bonuses for overproduction, they still consider that they do not have enough time to perform a quality examination of the full content of a patent application and therefore, they are looking for tools to limit the time needed for application reviews.[17] Frustrations with processing delays due to workload restrictions must be viewed in light of the quality of the product possible to be produced in the time allotted.

One of the major tools available to U.S. examiners is called "restriction" or, under international practice, "lack of unity." The use of these tools is highly contentious because they rely upon a subjective evaluation of the nature and boundary of a "single" invention. Patent examiners are also reluctant to alter their decisions once they have made determinations as to what comprises "an" invention (see below) based on evidence or an applicant's arguments. This would often involve more work (and time) on the part of the examiner. At the current time, patent examiners are given financial rewards based predominantly on their productivity and they are reluctant to examine more inventions or embodiments than necessary. Both USPTO management and the Congress are working to rectify this situation by providing rewards for high quality examination as well; however, until policies and laws change, examiners will continue to use the tools available to them that permit limiting the amount of time that it takes for patent application reviews.

II. Restriction Practice

While the specific legal authority for restriction practice (and double patenting practice) is set forth in 35 U.S.C. §121 and 37 CFR §§141 and 142,[18] its essential basis is in 35 U.S.C. §101 that

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[17] *See, e.g.,* "Report to the Ranking Member, Committee on Oversight and Government Reform, House of Representatives: U.S. PATENT AND TRADEMARK OFFICE Hiring Efforts Are Not Sufficient to Reduce the Patent Application Backlog," issued by the Government Accountability Office in September 2007. The report is available at http://www.gao.gov/new.items/d071102.pdf.

[18] The basis for restriction and double patenting practices is found in the following statute and rules:

35 U.S.C. §121. Divisional applications.

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

37 CFR §1.141. Different inventions in one national application.

> (a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an

defines not only the nature of the subject matter that is eligible for patenting, but also how many inventions a patent applicant is entitled to in a single application.

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain **a patent** therefor, subject to the conditions and requirements of this title. (Emphasis added.)

A. Restriction

For our current purposes, we focus on the terms "invents" and the use of the singular "a" when referring to what an applicant is entitled. Thus, "a patent" issued to "(w)hoever invents or discovers" has been interpreted as statutory support for the conclusion that one is only entitled to one invention per patent. Restriction, however, is at the discretion of the examiner in charge of the examination. Understanding both the authorities and pressures under which patent examiners function is important if one is to maximize the return on a given patent application. In addition, it is also important to understand the business needs associated with a given patent application and, in appropriate circumstances, be prepared to explain these needs to patent examiners (while, of course, exercising discretion with business confidential knowledge). This human side of patent prosecution, which often begins with restriction requirements, will serve a prosecutor well in both the short and long terms since it opens relationships that are likely to be mutually beneficial.

The nuts and bolts of restriction practice are discussed in detail in chapter 800 of the USPTO's Manual of Patent Examining Procedure (MPEP).[19] This provides instructions for the examiner regarding restriction and double patenting laws, regulations, and procedures.[20] In addition, while

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allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§1.75) or otherwise include all the limitations of the generic claim.

(b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.

37 CFR 1.142. Requirement for restriction.

(a) 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, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

(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.

[19] Manual of Patent Examining Procedure (MPEP), Ninth Edition, March 2014, available at http://www.uspto.gov/web/offices/pac/mpep/.

[20] *See, e.g.,* MPEP §802.01 Meaning of "Independent" and "Distinct." Although 35 U.S.C. §121 states that in order to set forth a restriction requirement and therefore examine less than all of the claims originally presented in a patent application, an applicant must present claims that are both independent *and* distinct, based upon a variety of reasons and case law decisions, the

many believe that it is improper to require "restriction" *within a single claim*, the patent office has held that if more than one independent or distinct invention is claimed in a single claim, such a claim may be "restricted."[21] Therefore, in response to a restriction requirement, a patent applicant could be required to rewrite even a single claim such that it claims only a single invention as defined by the patent examiner.

When an examiner believes that more than one invention is claimed, the applicant must choose which invention will be examined in that application. Such a requirement for "election" is an administrative **requirement** even if an applicant believes that the restriction requirement is improper.[22] The claims that are not chosen are withdrawn from consideration in that application although they may be presented in a later filed "divisional" application.[23] The requirements for divisional and other types of continuing applications are discussed in MPEP Chapters 200 and 600. These chapters are commended to the reader.

If, after presentation of argument or evidence that a restriction requirement is improper, an examiner maintains the requirement and makes it final, an applicant may file a petition for reconsideration of the restriction requirement by a higher authority. It is important to keep in mind that even if such a petition is filed (see below), prosecution of the patent application continues in parallel and therefore an applicant must continue to be mindful of the statutory and shortened statutory time limits that are associated with prosecution of the application itself. If the petition is ultimately granted, the patent examiner will be required to go back and provide a complete examination on the improperly separated claims. An office action setting forth any rejections of said claims must be non-final.

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requirement for parsing patent claims into separate applications has been interpreted as requiring that the inventions are independent *or* distinct.

[21] For example, *see* MPEP §2434 where it is stated that:

> [n]ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. 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.

Therefore, if one were to present a claim such as "A polynucleotide selected from the group consisting of SEQ ID NO: 1-1000," an examiner would be able to restrict this claim into 1000 different applications unless it could be shown, for example, that the sequences were obvious, one over the other. Caution needs to be exercised when presenting such an argument since downstream litigation invalidating the patentability of one polynucleotide could thereby implicate the enforceability of other polynucleotides. This same principle is often applied to both Markush and "generic" claims even though they might more properly be considered linking claims that merit other practice.

[22] *See* MPEP §818 *et seq.* and 37 CFR §§1.143 and 1.144.

37 CFR §1.144. Petition from requirement for restriction.

> After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see §1.181).

[23] A later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division." A divisional application is often filed as a result of a restriction requirement made by the examiner. The divisional application must claim the benefit of the prior nonprovisional application under 35 U.S.C. §§121 or 365(c). *See* MPEP §201.11 for the conditions for receiving the benefit of the filing date of the prior application. The divisional application should set forth at least the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Prosecution strategies admixing continuation, continuation-in-part, and divisional applications is highly fact specific and intersects technical innovation and legal strategies. Here, we note that even though a restriction requirement may be technically proper, prosecuting and maintaining multiple patent applications and patents can be very costly due both to prosecution costs and maintenance fees that must be paid once a patent issues. It is for this reason that when drafting patent applications, it is critical that the drafter understand not only the technology but also the business decisions behind the use of the patent system. An appreciation of product development pipelines, funding situations, and business commitments to particular invention embodiments should all be accounted for when drafting patent applications and deciding upon restriction elections.

B. Unity of Invention

For applications filed under 35 U.S.C. §371, the international standard is applied pursuant to 35 U.S.C. §372.[24] The international standard for restriction is the unity of invention standard; however, when a continuation or divisional application of an application originally filed under 35 U.S.C. §371 is filed under 35 U.S.C. §111, 35 U.S.C. §121 is the standard that is applied for restriction of the claims of the continuation or divisional application. Even writing the preceding sentence is technically challenging, so the reader is advised to exercise care in concluding what law applies to which patent application and be mindful that such a conclusion can change during prosecution. The recent enactment of the Patent Law Treaty (PLT)[25] and its concomitant enacting laws and regulations are designed to relieve some of the administrative burdens of a nation based patent system. However, unless substantive global patent harmonization is established, each patent application **at each point in time** will be based on their own circumstance-based legal standards.

Anecdotal reports and personal observations suggest that use of the restriction standard of 35 U.S.C. §121 results in more groups of claims than when considered under lack of unity standards. (Note, however, that 35 U.S.C. §372[26] permits the use of restriction practice even in international applications that are originally filed under the PCT if the Director so determines and the international application designates but does not originate in the United States.)

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[24] 35 U.S.C. §372. National stage: Requirements and procedure:

> (a) All questions of substance and, within the scope of the requirements of the treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office.
>
> (b) In case of international applications designating but not originating in, the United States—
>
> (1) the Director may cause to be reexamined questions relating to form and contents of the application in accordance with the requirements of the treaty and the Regulations;
>
> (2) the Director may cause the question of unity of invention to be reexamined under section 121, within the scope of the requirements of the treaty and the Regulations; and
>
> (3) the Director may require a verification of the translation of the international application or any other document pertaining to the application if the application or other document was filed in a language other than English.

[25] *See, e.g.*, World Intellectual Property Organization. Patent Law Treaty. Available at http://www.wipo.int/treaties/en/ip/plt/, Patent Law Treaties Implementation Act of 2012, Pub. Law 112-211 (December 19, 2012), and the USPTO's "Comments on Changes to Implement the Patent Law Treaty," available at http://www.uspto.gov/patents/law/comments/plt_npr.jsp.

[26] *See* 35 U.S.C. §372 (b)(2) *supra.*

Unity of invention (for applications filed under 35 U.S.C. §371) is explained in 37 CFR §1.475, as follows:

> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
>
> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and a process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

When the USPTO is reviewing claims in an international application the unity of invention standard applies. Under PCT Rule 13.1:

> The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Unity of Invention is considered to be fulfilled (and thus, no separation of claims appropriate) when

> . . . a group of inventions is claimed in one and the same international application and . . . there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.[27]

[27] *See, e.g.,* PCT Rule 13 *et seq.* available at http://www.wipo.int/pct/en/texts/rules/r13.htm#_13.

As a practical matter, when determining whether such a "contribution" over the art exists, the USPTO should provide evidence in the form of a novelty defeating reference. When traversing an assertion that unity is lacking, it is tempting to argue that a lack of unity requirement is inappropriate because no examination burden exists. Citation of a reference, however, does not indicate that a comprehensive search has been performed. Further, "burden" does not justify a finding of lack of unity under international standards; rather, it would be necessary to evidence contribution over the art of the special technical future. Unfortunately, time constraints and differing use of international standards makes overcoming a lack of unity requirement problematic.

C. Species Election

Restriction (and Lack of Unity) requirements indicate the presence of independent or distinct inventions being claimed within a single patent application; however, there are instances where a single application may claim different patentably indistinct embodiments of a single invention. For example, consider a claim to a chair with three or four legs. In this case, the distinction between three and four legged chairs may be minor (i.e., obvious), but may, nonetheless, represent a burden on the examiner.[28] In such an instance, an examiner may set forth a "species election" requirement instead of a "restriction requirement." MPEP §806.04 discusses many different situations regarding species elections; however, the most important point to note is that if/when an elected species (or embodiment) of an invention is found to be allowable, it is incumbent upon the examiner to extend the search to the remainder of the species until they are reasonably certain that the full scope of the claim is patentable. This may, in effect, cause patent prosecution to be extended. Thus, while administratively required, it is sometimes difficult to enforce this standard.

In extreme cases, there may be so many embodiments within a single claim, that such would be an impossible exercise. For example, the authors have seen patent applications that include single claims that for all intents and purposes have an infinite number of embodiments. In such cases, it is often useful to discuss the claim with the examiner in either a telephonic or in-person interview and negotiate mutually acceptable language.[29] Note that administrative burden is not *per se* justification for an examiner to avoid expanding searches to include additional species once one (or more) are found allowable. It is incumbent upon the applicant to point out situations where expanded search and examination is appropriate while, at the same time, being mindful of the burden being placed on the examiner. Negotiation skills are useful in finding an appropriate middle ground and setting reasonable expectations for future interactions with the examiner involved.

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[28] A principle requirement for a valid restriction or species election requirement is that the examination of all the claims or embodiments of an invention would be "burdensome" upon the examiner. No matter how many claims or species present in a patent application, if the examiner cannot demonstrate burden, then a restriction or species election is improper. In such cases, if a discussion with the examiner does not serve to resolve the issue, a petition may be appropriate.

[29] Where an application includes claims directed to different embodiments or species that could fall within the scope of a generic claim, restriction between the species may be proper if the species are independent or distinct. 37 CFR §1.141, however, provides that an allowable generic claim may link a reasonable number of species embraced thereby. The practice is set forth in 37 CFR §1.146.

D. Restriction of Claims Containing Markush Groups

Another type of intraclaim "restriction" arises with claims drafted in "Markush" format. MPEP §803.02 states that:

> A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." *See Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The members of the Markush group (A, B, and C in the example above) 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 responsible 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. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See MPEP §2173.05(h).

It is also of note that while MPEP §803.02 states that if only a small number of embodiments are claimed in a Markush claim, no species election requirement should be made.[30] As a matter of practice, however, even though one could traverse an intraclaim restriction on this basis, it rarely carries the day.

An examiner may also require an election of a single species of the invention prior to examination on the merits. The response to such a "species election" requirement must include a recitation of the claims that read on the elected species. Following election, the Markush-type claim will be examined fully with respect to the elected species to determine patentability. **If the elected species of the Markush-type claim is found to be allowable, then it is incumbent upon the examiner to extend examination to the non-elected species.** As a practical matter, this is often overlooked at the end of prosecution and it is wise to politely remind the examiner if this situation arises. This practice is similar to a situation known as "rejoinder."

E. Rejoinder

Rejoinder involves withdrawal of a restriction requirement between an allowable elected invention and a non-elected invention and examination of the formerly non-elected invention on the merits. In MPEP §821.04(a) it is stated that:

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[30] For more detailed scenarios related to Markush practice, the reader is referred to cases such as *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), that note that 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. Also see *In re* Harnisch, 631 F.2d 716, 206 USPQ 300(CCPA 1980) that notes both that an applicant is entitled to an examination and that the USPTO has the authority to promulgate rules to permit it to operate efficiently. In *Ex parte* Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), it is noted that unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature. MPEP §803.02 adds the additional requirement that the common structural feature is essential to that utility.

> Where restriction was required between independent or distinct products, or between independent or distinct processes, and all claims directed to an elected invention are allowable, any restriction requirement between the elected invention and any nonelected invention that depends from or otherwise requires all the limitations of an allowable claim should be withdrawn.

While an initial restriction requirement may be proper, the courts have addressed the concept of rejoinder in two cases, *In re Ochiai* and *In re Brouwer*.[31] For example, in cases where a product is found patentable, it may be possible to rejoin appropriately limited process claims (i.e., those with all the limitations of an allowable product claim).

If this situation presents itself, and if one wishes to take advantage of it, **do not automatically cancel the withdrawn claims**; rather, it is advisable to **amend the withdrawn process claims** along with associated product claims during prosecution. A withdrawn claim that does not recite all the limitations of an allowable claim will not be rejoined. While an applicant may be given the opportunity to make such an amendment upon the finding of an allowable product claim, this may be denied, particularly in complex arts such as biotechnology, because rejoined claims must be fully examined for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112 (MPEP §821.04). This is explained in MPEP form paragraph 8.21.04.

Form Paragraph 8.21.04: Notice of Potential Rejoinder of Process Claims in Ochiai /Brouwer Situation

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the

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[31] *In re* Ochiai, 71 F. 3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re* Brouwer, F.3d, 37 USPQ2d 1663 (Fed. Cir. 1996). *See* http://www.uspto.gov/web/offices/com/sol/og/con/files/cons104.htm:

> . . . to facilitate examination under 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

F. Nuts and Bolts of a Restriction Requirement

A restriction requirement is a formal administrative matter and must be administratively established. MPEP §803 requires that:

> Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.
>
> Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.
>
> . . .
>
> For purposes of the initial requirement, 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 as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP § 806.04 - § 806.04(i) and § 808.01(a).[32]

After being assigned an application and reviewing formal matters, the assigned patent examiner will usually review the claims for two general purposes, subject matter jurisdiction and restriction.

1. Subject Matter Jurisdiction

No single examiner has the expertise to examine all technical subject matter areas. As a practical matter, examiners are tasked with application review based upon the classification of the claims. In the past, the USPTO has relied upon a unique classification system known as the U.S. Patent Classification System.

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[32] Note that an examiner must have at least "partial signatory authority" in order to advance a restriction requirement. If there is a question regarding an examiner's authority in any matter, one should verify the examiner's authorizations by referral to either a Primary Patent Examiner or a Supervisory Patent Examiner. *See* MPEP Chapter 1000 for a discussion of who has what authority (e.g., signatory authority) at the USPTO.

According to the USPTO:[33]

> The USPC is a system for organizing all U.S. patent documents and many other technical documents into relatively small collections based on common subject matter. Each subject matter division in the USPC includes a major component called a class and a minor component called a **subclass**. A class generally delineates one technology from another. Subclasses delineate processes, structural features, and functional features of the subject matter encompassed within the scope of a class. Every class has a unique alphanumeric identifier, as do most subclasses.
>
> A class/subclass pair of identifiers uniquely identifies a subclass within a class (for example, the identifier "2/456" represents Class 2, Apparel, subclass 456, Body cover). This unique identifier is called a **classification symbol**, or simply a **classification**, or USPC classification, to distinguish it from classifications of other patent classification schemes. A subclass represents the smallest division of subject matter in the USPC under which documents may be collected.

However, the global classification system was recently adopted by the USPTO. On January 2, 2013, the USPTO announced that the Cooperative Patent Classification System (CPC) is a . . .

> product of a joint partnership between the USPTO and the EPO to develop a common, internationally compatible classification system for technical documents used in the patent granting process that incorporates the best classification practices from both offices. It will be used by the USPTO and more than 45 patent offices – a user community totaling more than 20,000 patent examiners – all sharing the same classifications helping to establish the CPC as an international standard.[34]

As the USPTO implements the CPC, some shifting and adjusting of bases and rationales for restriction and lack of unity requirements may occur. As a practical matter, however, examination burden will remain the major reason for parsing inventions among separate patent applications.

Even though electronic search systems permit the concurrent search of multiple patent classes, classification of differently claimed inventions (regardless of classification system) in different categories is one means of establishing the examination burden used to justify restriction. Therefore, when doing their initial claim review, examiners will parse claims into broad

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[33] *See, e.g.,* "OVERVIEW OF THE U.S. PATENT CLASSIFICATION SYSTEM (USPC): Overview of the U.S. Patent Classification System (USPC)," available at http://www.uspto.gov/patents/resources/classification/overview.pdf.
[34] *See* www.uspto.gov/news/pr/2013/13-01.jsp.

categories (products and processes) and then narrower groupings such as methods of making and methods of using various products.

For example, consider the following set of claims:

1. A chemical compound having the formula A-B-C.

2. A composition comprising the compound of claim 1.

3. A pharmaceutical composition comprising a compound having formula A-B-C.

4. A tire comprising a rubber tread comprising a chemical compound having the formula A-B-C.

5. A fire truck comprising the tire of claim 4.

6. A method of reducing skidding comprising coating a tire with a compound having the formula A-B-C.

Now imagine that you have just had your morning coffee and then picked up a patent application containing claims to a chemical, a drug, a tire, a truck, and a skid reducing method. You consider that while you used to work for a major tire manufacturer and you have loved fire trucks since you were a child, you know little about the pharmaceutical industry. In an attempt to get a quick understanding of what the invention is all about, you do a fast scan of the application and see that the inventors have developed a sticky compound that they have found reduces tire skidding under damp conditions. They also found that the compound would slow the release of medicines during digestion.

The examiner only has about twenty hours to do the entire patent application review and they know that they are only supposed to examine inventions involving truck tires. So, what are they to do?

Well, first things first. They will eventually have to set forth the restriction requirement in writing, so they will turn to their handy-dandy form paragraphs, conveniently located in MPEP §812.01:

> If an examiner determines that a requirement for restriction should be made in an application, the examiner should formulate a draft of such restriction requirement including an indication of those claims considered to be linking or generic.
>
> The MPEP outlines the components of a restriction requirement as follows:[35]
>
> Statement of the requirement to restrict and that it is being made under 35 U.S.C. §121.

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[35] *See, e.g.,* MPEP §817 *et seq.*

Identify each group by Roman numeral.

List claims in each group. Check accuracy of numbering of the claims; look for same claims in two groups; and look for omitted claims.

Give short description of total extent of the subject matter claimed in each group, pointing out critical claims of different scope and identifying whether the claims are directed to a combination, subcombination, process, apparatus, or product.

Classify[36] each group.

Take into account claims not grouped, indicating their disposition.

Linking claims (see discussion below):

Identify;

Statement of groups to which linking claims may be assigned for examination.

Other ungrouped claims . . .

Allegation of independence or distinctness.

Point out facts which show independence or distinctness . . .

Provide reasons for insisting upon restriction . . .

2. Sample Restriction Requirement

In our example, a restriction requirement might look like this:

Claims 1-6 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

Group I: Claim 1, drawn to a chemical compound having the structure A-B-C, classified in class 560, subclass 126 [CPC…].

Group II: Claims 2 and 3, drawn to chemical compositions, classified in class 514, subclass 16.2 [CPC…].

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[36] Note that the USPTO is undergoing transition to the use of an international classification system. For additional information, the reader is referred to the Cooperative Patent Classification website, available at http://www.cooperativepatentclassification.org/about.html.

> The Cooperative Patent Classification (CPC) was initiated as a joint partnership between the USPTO and the EPO where the Offices have agreed to harmonize their existing classification systems (ECLA and USPC, respectively) and migrate towards a common classification scheme. This was a strategic decision by both offices and is seen as an important step towards advancing harmonization efforts currently being undertaken through the IP5's Working Group 1 on Classification.
>
> The migration to CPC was developed based in large part on the existing European Classification System (ECLA) modified to ensure compliance with the International Patent Classification system (IPC) standards administered by the World Intellectual Property Organization (WIPO).

Group III: Claim 4, drawn to a tire, classified in class 152, subclass 167 [CPC…].

Group IV: Claim 5, drawn to a fire truck, classified in class 280, subclass 830 [CPC…].

Group V: Claim 6, drawn to an anti-skidding method, classified in class 152, subclass 167 [CPC…].

The inventions are independent or distinct, each from the other because…

. . .

Because these inventions are independent or distinct for the reasons given above, there would be a serious burden on the examiner if restriction is not required, and because the inventions have acquired a separate status in the art in view of their different classification, divergent subject matter, and would require distinct (though potentially overlapping) fields of search, restriction for examination purposes as indicated is proper.

3. Administrative Matters

The examiner may choose to advance a restriction requirement either via telephone, in writing, or both. In order to expedite prosecution, patent examiners are encouraged to use telephonic restriction practice.

The MPEP states that following an initial determination that restriction is appropriate:

> . . . the examiner should telephone the attorney or agent of record and request an oral election, with or without traverse, after the attorney or agent has had time to consider the restriction requirement. However, no telephone communication need be made where the requirement for restriction is complex, the application is being prosecuted by the applicant pro se, or the examiner knows from past experience that an election will not be made by telephone.[37]

If the examiner finds a telephonic restriction requirement to be appropriate they will contact an applicant and record the results as part of the initial patentability review (first-action-on-the-merits/FAOM). An applicant may, at their discretion, provide an immediate verbal response, or they may request that the requirement be made in writing. Even in a verbal response, an applicant should indicate whether the election is made with or without traverse.[38] If applicant

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[37] *See, e.g.,* MPEP §812.01.

[38] A traversal is a formal denial of the permissibility of restriction requirement. As a procedural matter, a patent applicant is required to elect an invention for examination even if they do not agree to its validity. An election of an invention **with** traverse preserves an applicant's ability to provide formal reasons why the requirement is inappropriate. If an election is made **without** traverse, the presumption is that the applicant agrees with that the claimed inventions would support independent patents and should be separated for examination and review.

does not specify, the next Office Action will issue indicating that election was made **without** traverse and could result in loss of appeal rights.

Telephonic restriction is an efficient means of moving application review along; however, it is permissible to request the requirement to be sent in writing. While the latter response may delay prosecution, it has several advantages. First, if the requirement is complex, it is often easier to understand it in writing. Second, a written response provides a means of communicating with clients that may facilitate their making critical business decisions. Third, the implications of a restriction or election requirement may not always be immediately apparent. Fourth, in some instances, a patent examiner may find patentable subject matter immediately; thereby limiting the time an applicant has to file continuing applications. Therefore, it is advisable to carefully consider these factors, as well as other strategic and business reasons before making either an oral or written election. Each situation must be independently evaluated.

Depending upon whether a telephonic election has been made, an examiner will use one of the following form paragraphs to record the results:[39]

Form Paragraph 8.23: Requirement, When Elected by Telephone

> During a telephone conversation with [1] on [2] a provisional election was made [3] traverse to prosecute the invention of [4], claim [5]. Affirmation of this election must be made by applicant in replying to this Office action. Claim [6] withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Form Paragraph 8.23.01: Requirement, No Election by Telephone

> A telephone call was made to [1] on [2] to request an oral election to the above restriction requirement, but did not result in an election being made.

As a formal matter, an applicant is required to elect an invention for prosecution, even if the requirement is traversed. According to MPEP §818.03(b):

> As noted in the second sentence of 37 CFR 1.143, a provisional election must be made even though the requirement is traversed.

Form Paragraph 8.22: Requirement for Election and Means for Traversal

> Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143[40]) and (ii) identification of the claims encompassing the elected invention.

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[39] *See* MPEP, Chapter 800, esp. §§812.01 *et seq*.

[40] 37 CFR §1.143. Reconsideration of requirement.

> If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving the reasons therefor. (See §1.111). In requesting reconsideration the

> The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.
>
> Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

G. Response to Restriction Requirement

The reader is referred to MPEP §818 *et seq*. for a thorough discussion of the requirements for a response to a restriction or election of species requirement. In short, whether an applicant elects an invention for examination via telephone or following a written requirement, 37 CFR §111(b) requires that any reply or traversal by an "applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection [or administrative requirement] in the prior Office action. . . . The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. . . ."[41]

Following receipt of a restriction requirement, an applicant may choose to provide substantive reasons why the requirement is inappropriate (e.g., why the claims are not independent or distinct). Examples of such substantive reasons include:

> certain claims (i.e., linking claims) link various claims in different groups together (see discussion below);
>
> there are claims in different groups that are classified in the same class and subclass;
>
> the international standard of "unity of invention" is used, and the restricted claims possess a technical relationship involving one or more of the same or corresponding special technical features (i.e., those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art); and
>
> there are groups of claims that could be subject to rejoinder.

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applicant must indicate a provisional election of one invention for prosecution, which invention shall be the one elected in the event the requirement becomes final. The requirement for restriction will be reconsidered on such a request. If the requirement is repeated and made final, the examiner will at the same time act on the claims to the invention elected.

[41] *See, e.g.,* MPEP §818.03(a).

1. Sample Traversals

In our hypothetical, for example, the examiner may assert that the differing classification of the technologies being claimed is sufficient to justify restriction. Reference to the restriction requirement, however, reveals that the inventions of groups III and V are classified in the same class and subclass, and therefore the USPTO has failed to establish a *prima facie* burden for examining both inventions at the same time.

Note that while the use of classification systems as a rationale for restriction may seem antiquated in an electronic age where a single search may suffice to cover all areas of technology, a requirement for restriction is based on a variety of factors. For example, not only is a search required, but also the examiner must review increasingly large search result sets. Further, subtle differences between even closely related technologies can significantly impact prosecution in both crowded and unpredictable arts. Consider, for example that there may be subtle distinctions between fire trucks and eighteen-wheelers that might affect conclusions of obviousness or fields of search. Similarly, what might be considered a novel and nonobvious ketone-based compound might be an obvious variation on a known polymeric thread. Different examination and legal practices have evolved over time that account for the nature and complexity of different types of inventions. The USPTO assigns applications in different technologies to different administrative units (Art Units) in order to provide for the specializations required.

In our example presented above, based on current administrative practices, the different inventions parsed by the examiner might be assigned to any of art units 1621, 1654, 1747, 3611, or 3617.[42] Further, the examiners assigned may have technological backgrounds ranging from undergraduate mechanical or chemical engineering degrees to doctorates in pharmaceutical chemistry. Thus, any traversals regarding why a restriction requirement is improper should address not only overlapping fields of search but also why a single individual would reasonably be considered to be able to review all the claimed inventions together.

Some sample responses might include:

First, your election (with or without traverse):

1. In response to the Restriction Requirement mailed_____, Applicant elects, with traverse, Group_____ (claims____), drawn to a(n)_____.

2. In response to the Restriction Requirement mailed ___ _____, Applicant elects, without traverse, Group_____ (claims____), drawn to a(n)_____.

[42] For a complete list of Art Unit assignments arranged by subject matter classification, see http://www.uspto.gov/patents-application-process/patent-search/understanding-patent-classifications/patent-classification.

Then, on to the arguments (in situations where you traverse):

3. Applicant respectfully requests reconsideration and withdrawal or modification of the restriction requirement. It is respectfully submitted that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner. That is, all the claims are so interrelated that a search of one group of claims will reveal art to the others.

4. Were restriction to be effected between the claims of Groups, a separate examination of the claims in these [total number of groups] groups would require substantial duplication of work on the part of the U.S. Patent and Trademark Office. Even though some additional consideration would be necessary, the scope of analysis of novelty of all the claims of Groups **** would have to be as rigorous as when only the claims of Group I, for example, were being considered by themselves. Clearly, this duplication of effort would not be warranted where these claims of different categories are so interrelated.

And/or, one could argue (usually in vein) burden on applicant by including something like:

5. Further, Applicant submits that for restriction to be effected between the claims in Groups ****, it would place an undue burden by requiring payment of [number of groups minus one] separate filing fees for examination of the non-elected claims, as well as the added costs associated with prosecuting [total number of groups] applications and maintaining [total number of groups] patents.

And, one needs to consider species election requirements by, for example, submitting something like:

6. With respect to the species election, this election is with traverse to the extent that it is understood that (a) the requirement will be withdrawn upon the finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found patentably distinct from the elected or allowed claims. Applicant traverses on the grounds that the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner.

Don't forget to include that you reserve your rights! For example:

7. Applicant reserves the right to pursue examination of any non-elected claims in continuation or divisional applications.

2. Linking Claims

In some instances, the ability to separate related claims from each other can present challenges both to the applicant and the USPTO. According to MPEP §809, "[t]here are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper,

but presented in the same case are one or more claims (generally called "linking" claims) which, if allowable, would require rejoinder of the otherwise divisible inventions."

Linking claims and the inventions they link together are usually either all directed to products or all directed to processes. The most common types of linking claims are: (2) genus claims linking species claims; and (2) subcombination claims linking plural combinations.

For example, in situations where one claim presents a genus and another enumerates particular species subsumed by the genus, the genus claim may be considered to "link" what would otherwise be patentably distinct or separable inventions.

Thus, careful consideration of choice of claim language and style can avoid or preclude a restriction requirement. If linking claim language is present, applicant is advised to bring it to the attention of the USPTO if overlooked.

This is discussed in greater detail in MPEP §809:[43]

> The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability. Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the application claims to the nonelected invention or inventions. Where such withdrawn claims have been canceled by applicant pursuant to the restriction requirement, upon the allowance of the linking claim(s), the examiner must notify applicant that any canceled, nonelected claim(s) which depends from or requires all the limitations of the allowable linking claim may be reinstated by submitting the claim(s) in an amendment. Upon entry of the amendment, the amended claim(s) will be fully examined for patentability.

3. Rejoinder

A review of the sample restriction requirement above reveals that the invention of claims 1 and 6 are related as a product (A-B-C) and a method of use (anti-skidding method). While an initial restriction requirement may be proper, in cases where a product is found patentable, it may be possible to rejoin appropriately limited process claims (i.e., those that require all the limitations of an allowable product claim).

Although this is discussed above, it is worth repeating. If this situation presents itself, and if one wishes to take advantage of it, **do not automatically cancel the withdrawn claims**; rather, it is

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[43] *See, e.g.,* "Linking Claims" available at http://www.uspto.gov/web/offices/pac/mpep/documents/0800_809.htm.

advisable to **amend the withdrawn process claims along with associated product claims** during prosecution.

4. Petition Process

A restriction (or lack of unity) requirement is an administrative requirement. Therefore, disputes regarding the propriety of a restriction are petitionable rather than appealable. It is important to know that even if one files a petition the patentability review process continues concurrently. Filing a petition does not stay prosecution of the elected invention although positive results from a petition may require an examiner to expand their examination. Review of a petition requirement is considered an agency decision under the Administrative Procedures Act and following a denial and final decision by a patent Group Director (or his delegate) and a review by the USPTO's Petitions Office, administrative review may be made to the DC court of appeals or the Federal Circuit (depending upon the situation).

Pursuing administrative review is as much a business decision as it is a matter of law. Administrative appeal can be time consuming and expensive and could potentially delay patent issue or appeal.

III. Double Patenting

It was noted at the beginning of this section that the fundamental basis of restriction is that an applicant is only entitled to one invention in a patent.[44] The converse of this statement is also true -- An applicant is only entitled to one patent per invention.

MPEP §804 notes that:

> The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that: [t]he public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.

As noted above, while the specific legal authority for restriction practice and double patenting practice is set forth in 35 U.S.C. §121 and 37 CFR §§141 and 142, its essential basis is in 35 U.S.C. §101 that defines not only the nature of the subject matter that is eligible for patenting, but also how many inventions a patent applicant is entitled to in a single application.

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain

[44] This practice is discretionary. The USPTO may issue multiple inventions in a single patent.

> **a patent** therefor, subject to the conditions and requirements of this title. (Emphasis added.)

In the 1800's the Supreme Court interpreted "a patent" to mean that "two valid patents from the same invention cannot be granted either to the same or to a different party."[45] This type of double patenting is known as statutory double patenting.

In view of the public policy noted above, the doctrine of double patenting has several purposes: (1) to prevent the use of multiple patents for a multiplicity of suits against an alleged infringer; and (2) to prevent improper extension of the term of patent protection by obtaining patents on successively filed applications directed to the same invention.[46]

The Federal Circuit stated in *Gilead Sciences, Inc. v. Natco Pharma Limited*, that "[f]ederal courts for over a century have applied the principles of the doctrine as a means to preserve the public's right to use not only the exact invention claimed by an inventor when his patent expires, but also **obvious modifications** of that invention that are not patentably distinct improvements. . . . With the addition of §253 in 1952, however, Congress slightly altered the effect of the bar on double patenting. [This] statutory provision . . . in part permits a patentee to disclaim any terminal part of the term of his patent without a disclaimer of claim scope" (emphasis added).[47] A terminal disclaimer aligns the expiration dates of two or more patents. In effect, this creates a single term of limited exclusivity. Thus, a terminal disclaimer, which is permitted by 35 U.S.C. §253(b),[48,49] can be used to overcome the prohibition on double patenting, but it is important to note that this is only for nonstatutory double patenting, which is discussed in greater detail below.

A. Types of Double Patenting

Double patenting rejections safeguard against inappropriate patent extensions under two doctrines, one statutory and one nonstatutory.[50] The first type of double patenting is the "statutory" or "same invention" type double patenting rejection based on 35 U.S.C. §101 and a

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[45] *See, e.g.*, Miller v. Eagle Mfg. Co., 151 U.S. 186, 197 (1894).

[46] Irah H. Donner, Patent Prosecution: Law, Practice, and Procedure, 8th Edition, Chapter 12, Section VIII.

[47] Gilead Sciences, Inc. v. Natco Pharma Limited, 753 F.3d 1208 (Fed. Cir., April 22, 2014), *petition for cert. filed* (Docket No. 14-647).

[48] 35 U.S.C. 253 Disclaimer.

(a) IN GENERAL.--Whenever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing and recorded in the Patent and Trademark Office, and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.

(b) ADDITIONAL DISCLAIMER OR DEDICATION.--In the manner set forth in subsection (a), any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

[49] A Terminal Disclaimer (TD) requires common ownership, or, if under a joint research agreement, an agreement not to separately enforce the subject patents, and a TD aligns the expiration dates of the subject patents.

[50] Nonstatutory double patenting could include a rejection that is not the usual "obviousness-type" double patenting rejection. This type of double patenting rejection is rare and is limited to the particular facts of the case. *In re* Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

second is the judicially created doctrine of nonstatutory "obviousness-type" double patenting.[51] Since the doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, the focus of any double patenting analysis necessarily is on the claims in the multiple patents or patent applications involved in the analysis.

1. Statutory Double Patenting

Statutory double patenting applies where an applicant claims the same invention in two or more patent applications.[52] This is precluded by 35 U.S.C. §101. A test for double patenting is whether a claim in a first application or patent could be literally infringed without literally infringing a corresponding claim in a second application or patent.[53] That is, if there is an embodiment of the invention that falls within the scope of one claim, but not the other, then the scope of the claims are not identical, and statutory double patenting does not exist. For example, as explained in MPEP §804(II)(A), the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to, or substantively the same as, a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine." On the other hand, claims may be differently worded and still define the same invention. Thus, a claim reciting a widget having a length of "36 inches" defines the same invention as a claim reciting the same widget having a length of "3 feet."

Statutory double patenting rejections may be overcome by canceling duplicate claims such that they only appear in one patent, amending the claims to avoid duplicative language that would make the claims entirely coextensive, or showing that the rejection is in error.

While obviating a statutory double patenting issue is usually simple, remember that **a terminal disclaimer is not effective** in overcoming a statutory double patenting rejection.

2. Nonstatutory, Obviousness-type Double Patenting

If an applicant claims similar inventions that would be considered to be obvious variations of each other, the courts have created a judicial remedy that prevents prolongation of the patent term by prohibiting claims in a second patent that are not patentably distinct from claims in a first patent.[54]

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[51] Before consideration can be given to the issue of double patenting, two or more patents or applications must have at least one common inventor and/or be either commonly assigned/owned or non-commonly assigned/owned but subject to a joint research agreement pursuant to the CREATE Act (Pub. L. 108-453, 118 Stat. 3596 (2004)).

[52] Note that the language of two conflicting claims does not necessarily need to be identical for a statutory double patenting issue to exist. The question is whether or not the potentially conflicting claims cover the exact subject matter. If there is any difference at all, no matter how minor, between the scope of the claims under consideration, the situation would fall under nonstatutory double patenting and may be resolved by, *inter alia*, the filing of a terminal disclaimer.

[53] *In re* Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

[54] The judicially created obviousness-type and nonobviousness-type double patenting preclusions are based upon two well-established public policy doctrines. The first is to guard the *quid pro quo* of the patent system by limiting inappropriate timewise monopoly extension and the second is to prevent multiple patent suits where different patent owners enforce the same or similar inventions. *See, e.g.,* Gilead Sciences, Inc., Hoffmann-La Roche, Inc., F. Hoffmann-La Roche, Ltd., and Genentech, Inc. v. Natco Pharma Limited and Nato Pharma, Inc., Case No. 2013-1418 (Fed. Cir., April 22, 2014) for a discussion of a brief history of the double patenting doctrine.

As explained in MPEP §804(II)(B), a nonstatutory, obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s).[55] A double patenting rejection of the obviousness-type, if not based on an anticipation rationale, is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art.[56] Therefore, the analysis used in an obviousness-type double patenting rejection parallels the analysis used in a 35 U.S.C. §103(a) rejection, and the factual inquiries set forth in *Graham v. John Deere Co.*[57] are used when making an obvious-type double patenting rejection.

In a nonstatutory, obviousness-type double patenting evaluation, the question at issue concerns the claims *per se* rather than the overall disclosure of a reference patent (or copending application). Thus, the disclosure of the reference patent (or copending application) may not be used as prior art.[58] As further explained in MPEP §804(II)(B), however, this does not mean that one is precluded from all use of the patent disclosure. For example, the specification can be used as a dictionary to learn the meaning of a term in the patent claim, or those portions of the specification that provide support for the patent claims may be examined to determine whether a claim in the application defines an obvious variation of an invention claimed in the reference patent (or copending application).

Nonstatutory, obviousness-type double patenting includes rejections based on either a one-way determination of obviousness or a two-way determination of obviousness. This is explained in greater detail in MPEP §804(II)(B). If the application at issue is the later-filed application or both are filed on the same day, a one-way determination of obviousness is used.[59] That is, the question is whether the invention defined in a claim in the application would have been anticipated by, an obvious variation of, the invention defined in a claim in the patent. If the application at issue is the earlier-filed application (and the reference patent is the later-filed application), a two-way test is applied only when the applicant could not have filed the claims in a single application **and** there is administrative delay.[60] When the USPTO makes a two-way obviousness determination, the *Graham* obviousness analysis is done twice, once with the application claims as the claims in issue, and once with the patent claims as the claims in issue. Where a two-way obviousness determination is required, an obvious-type double patenting rejection is appropriate only where **each** analysis compels a conclusion that the invention defined in the claims in issue is an obvious variation of the invention defined in a claim in the other application/patent. Thus, even if the application at issue is the earlier-filed application, a one-way determination of obviousness is used by the USPTO to support an obviousness-type double patenting rejection in the absence of a finding: (A) of administrative delay on the part of the

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[55] *See, e.g.*, *In re* Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re* Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re* Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).
[56] *In re* Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967).
[57] Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).
[58] General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992).
[59] *See, e.g.*, *In re* Berg, 140 F.3d 1438, 46 USPQ2d 1226 (Fed. Cir. 1998).
[60] *In re* Berg, 46 USPQ2d 1226 (Fed. Cir. 1998).

USPTO causing delay in prosecution of the earlier filed application; and (B) that applicant could not have filed the conflicting claims in a single (i.e., the earlier-filed) application.

As with any other rejection, a nonstatutory, obviousness-type double patenting rejection advanced by the USPTO only serves to shift the burden to applicant. In response, one may provide evidence or argument that the rejection is inappropriate or improper. A rationale similar to that used in combatting an obviousness rejection under 35 U.S.C. §103 may be successful. Also, in limited circumstances (e.g., if the application at issue is the earlier-filed application (e.g., claiming a genus) and the reference patent is the later-filed application (e.g., claiming a nonobvious species)) applicant could argue that a two-way analysis is required (obvious in both directions) upon a showing of administrative delay by the USPTO **and** that applicant could not have avoided filing separate applications (e.g., nonobvious claimed species not known at time of filing earlier-filed genus application).[61]

Remember, however, that the question at issue concerns the claims *per se* rather than the overall disclosure of a reference patent (or copending application). Thus, an applicant's response must refer to the language of the conflicting claims, their relationship to one another, their scope and overlap, and whether or not they would be considered to extend the patent monopoly. Also, because obviousness-type double patenting (ODP) is based upon an equitable doctrine, to be successful it is advised that one tailor the arguments to address equity rather than simply what one or ordinary skill in the art would have considered obvious.

Alternatively, one straightforward means of obviating a nonstatutory (obviousness-type) double patenting rejection is to file a terminal disclaimer (TD). A TD joins the patents under consideration such that they must be commonly owned and, with the exception of administrative issues such as patent term extensions or adjustments, they expire on the same day.[62] A detailed explanation of TDs may be found in MPEP §1490, authorized under 37 CFR §1.321.

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[61] The Federal Circuit in Gilead Sciences, Inc., Hoffmann-La Roche, Inc., F. Hoffmann-La Roche, Ltd., and Genentech, Inc. v. Natco Pharma Limited and Nato Pharma, Inc., Case No. 2013-1418 (Fed. Cir., April 22, 2014) held that an earlier-filed, earlier-expiring patent could qualify as an obviousness-type double patenting reference to a later-filed, later-expiring patent, based on the presumption that the later-filed, later-expiring patent did not claim obvious variants of the invention claimed in the earlier-filed, earlier-expiring patent.

[62] *See, e.g.,* USPTO Terminal Disclaimer Forms, available at http://www.uspto.gov/forms/forms_alpha.jsp, and "Terminal Disclaimers and PTO: Proposal for a Test Case," available at http://www.patentlyo.com/patent/2010/06/terminal-disclaimers-and-pto-proposal-for-a-test-case.html?cid=6a00d8341c588553ef0133f248b0e9970b:

> The impact of a terminal disclaimer depends upon what was actually disclaimed. Although applicants can draft their own terminal disclaimer, most folks use the form provided by the USPTO. (SB-0025). The PTO Form disclaims the term of the later-issued patent that extends beyond the earlier-issued patent's term. Regarding PTA, the Form expressly ties the later-issued patent's term to the PTA-adjusted term of the earlier-issued patent.
>
> Although not expressly stated, the Form seems to imply that the PTA of the later-issued patent can be cut-short by the disclaimer. That result, however, is not compelled by the law. In theory (and largely in practice) PTA is based on patent office delay. As such, the equitable basis of the nonstatutory double patenting doctrine might not apply to require disclaimer of PTA.

3. Nonstatutory, Nonobviousness-type Double Patenting

Nonstatutory double patenting could include a rejection that is **not** the usual "obviousness-type" double patenting rejection. Note that the MPEP in several sub-sections of MPEP §804(II) states that even if there is no nonstatutory, obviousness-type double patenting "this does not necessarily preclude a rejection based on another type of nonstatutory double patenting . . . a nonstatutory double patenting rejection based on the fundamental reason to prevent unjustified timewise extension of the right to exclude granted by a patent." This type of double patenting rejection "is rare and is limited to the particular facts of the case"[63] and is from a CCPA case *In re Schneller*.[64]

An *In re Schneller* type of double patenting rejection is only appropriate where patent protection for the invention, **fully disclosed in and covered by the reference**, would be extended by allowance of the claims in the later filed application. For a more thorough discussion of these three types of obviousness-type double patenting rejections see *Chisum on Patents*, §9.03.

Contrast the situation in *Schneller* with that in a recent holding of the CAFC where a later filed patent to an obvious species was found invalid under the double patenting doctrine. (AbbVie Inc. v. Kennedy Inst. of Rheumatology Trust, No. 13-1545 (Fed. Cir. 2014)). The court analyzed the double patenting principle based on whether or not the species claims in the continuing application would have been obvious over the parent patent's disclosure. The court could have, arguably, found that the later issued case was fatally flawed as a matter of public policy since the later issued species patent was a direct continuation of the parent patent and was, therefore, based on the identical disclosure. Nonetheless, courts have avoided invoking *Schneller*, likely because of a danger of arbitrary application of its doctrine.

As with nonstatutory, obviousness-type double patenting, a straightforward means of obviating a nonstatutory, nonobviousness-type double patenting rejection is to file a terminal disclaimer (TD).

B. Safe Harbor

Note that there may be advantages to having received a restriction requirement under 35 U.S.C. §121. For example, in *Pfizer Inc. v. Teva Pharms. USA, Inc.*:[65]

> The third sentence of section 121 provides a safe harbor to patents that issue on applications filed as a result of a restriction requirement:
>
> > A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original

[63] MPEP §804, available at http://www.uspto.gov/web/offices/pac/mpep/documents/0800_804.htm.
[64] *In re* Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).
[65] Pfizer Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1353 (2008).

> application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

Note, however, that the safe harbor provisions of 35 U.S.C. §121 are not available in the absence of a restriction requirement or if such a requirement is withdrawn. When drafting initial claim sets, one should be mindful of both the pitfalls and advantages of restriction. For example, claim presentations optimized to "draw" restriction requirements followed by adjustment of pending claim sets could preserve downstream divisional filing rights.[66]

C. Provisional Rejections

The nonstatutory double patenting rejection is one of the few "provisional" rejections that may be made since the problem associated with obvious variants of claims appearing in different patent applications does not manifest until a patent actually issues. Since the rejection does not become "actual" until at least one of the conflicting claims issues in a patent, it is not necessary to file a terminal disclaimer (TD) until allowable subject matter is identified. In fact, a suitable response to a nonstatutory double patenting rejection would be an acknowledgement that a TD, or other suitable response, will be filed at a suitable time (e.g., upon an indication of otherwise allowable subject matter). It is ill advised to file the TD early in prosecution because claims may be canceled or amended during prosecution and obviate the need for the TD.

Note that the presence of a provisional obviousness-type double patenting rejection should not preclude the allowance of an application, if that provisional rejection is over another pending patent application. As noted in MPEP §804 (emphasis added):

> The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application . . . **If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining . . . the examiner should withdraw that rejection and permit the . . . application to issue as a patent without a terminal disclaimer.**

Nonetheless, if the ODP rejection is appropriate, a terminal disclaimer should be required before the second/additional application is allowed.

In addition, there are a myriad of different situations and conflicts that can arise between applications that claim similar subject matter. This can be especially problematical when dealing

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[66] There are numerous strategic pathways that can leverage restriction. For example, by focusing examination on specific claim features and embodiments highlighted by restriction, critical patentability features may be identified that can then be added to later filed claims in the same or continuing applications. Further, some technologies yield the greatest economic returns early in technology cycles (e.g., quickly evolving IT innovations) while others at the end of patent terms (e.g., pharmaceuticals.) Thus, the timing of issuance of different "invention" filing, prosecution, and issuance, can optimize economic value. Finally, divisional filings may garner different returns of Patent Term Adjustment (PTA) that can be optimized by filing and prosecution strategies. *See, e.g.,* 35 U.S.C. §154, 37 C.F.R. §1.701 *et seq.,* MPEP Chapter 800, and Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010), Exelixis, Inc. v. Mr. David Kappos (as PTO Director) (E.D. Va., November 1, 2012), and Exelixis, Inc. v. Honorable David J. Kappos, (E.D. Va., January 28, 2013).

with large entities that are either geographically separate or use multiple patent prosecution firms that may not be aware of conflicting subject matter. Further complicating double patenting issues are situations in which collaborations between different entities result in an invention and include not only distinct legal entities but also different divisions of the same company.

One means of avoiding being blindsided by conflicting claims in different applications is when making inventorship determinations. When reviewing an invention disclosure, take care to look at the affiliation of all the inventors as well as the location at which the invention was made. One should also consider, for example, the source of materials used in the making of an invention. In many instances, inventors may be unaware that other parties may also be inventors or that others may have filed patent applications. Reference to MPEP §804 and its accompanying charts demonstrates the myriad of situations that can arise and that must be sorted out when considering potential double patenting situations.

A complete discussion of double patenting would support a paper of its own if not a complete book. Therefore, the reader is advised to thoroughly review MPEP §804 and be certain to make full and complete inquiries when considering both inventorship and conflicting patent applications. With that said, a brief discussion of two practice tips is appropriate.

D. Duty of Candor/Disclosure

The USPTO is responsible for examination of patent applications and is, of course, the entity responsible for patent issuance. Nonetheless, the courts have held that the neither the USPTO nor the patent examiner is held responsible for knowing that conflicting patent applications and patents exist or might issue. Patent applications with related subject matter are routinely assigned to different examiners. In fact, applications by the same inventive entities and claimed subject matter are often separately considered.

The applicant is in the best position to understand what technology has been sought for patenting and what related applications have been filed. Therefore, it is advisable to bring related applications to the attention of the USPTO **in each application** (whether considered prior art or not) to ensure consideration of duplicate or overlapping subject matter.

In addition, it is noted that during patent prosecution and post-grant proceedings, double patenting issues might arise. While the prior art provisions of 35 U.S.C. §102 are normally thought of as relating to third party disclosures, double patenting issues arise between conflicting applications and patents where the same or obvious variants are claimed. Thus, an applicant's own work will be scrutinized to guard against inappropriate patent grant. Issues not raised during prosecution may also be used in infringement defenses alleging patent invalidity/unenforceability.

Finally, it is noted that just as with any other rejection, the initial burden is on the USPTO to present a *prima facie* showing that the rejected claim conflicts with one in either another application or a patent. Similarly, a response to any such rejection is the same as responding to any other rejection with the exception that nonstatutory double patenting rejections may be resolved without prejudice by either the filing of a terminal disclaimer or reliance on the so-

called "Create Act,"[67] originally set forth in 35 U.S.C. §103(c)(2)[68] and revised to now be recited in 35 U.S.C. §102(c).[69]

E. Conflicting Applications

The General Agreement on Tariffs and Trade (GATT) and the Associated Uruguay Round Agreements Act (URAA)[70] changed the patent term from 17-years from issue to 20-years from the earliest effective filing date. Thus, two (or more) related patent applications claiming patentably indistinct subject matter might have terms that expire on different dates.

Consider, e.g., two related applications where both one claims a genus of compounds, and the second a species. In many patent prosecutions, a species claim might issue on one patent application and a second application prosecuted in an attempt to obtain broader coverage. If the genus is found patentable it should be subject to an obviousness-type double patenting rejection in order to ensure that both the genus and the species patents co-expire and are linked for enforcement purposes. It is possible, however, that a lack of prior art issues could permit a species patent to avoid claiming priority of an earlier patent application. The genus patent might, however, face broader prior art challenges requiring it to claim an earlier priority date.

In this situation, the earlier effective filing date of the genus patent would cause it to expire before the expiration of the species patent. A terminal disclaimer could overcome a double patenting rejection in the genus application, however, this would not affect the term of the species patent, effectively extending the patent monopoly beyond the 20-yr statutory term (at least for the species.)

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[67] Pub. L. 108-453, 118 Stat. 3596 (2004) and the Leahy-Smith America Invents Act of 2011, P.L. 112-29, enacted September 16, 2011. Available at http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf.

[68] 35 U.S.C. §103 was amended by the Leahy-Smith America Invents Act of 2011, Pub. L. 112-29, enacted September 16, 2011. Prior to the changes made therein, 35 U.S.C. §103(c)(2) stated that:

> For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if—
>
> (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
>
> (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
>
> (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

[69] 35 U.S.C. §102(c), effective date March 16, 2013, recites:

> (c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—
>
> (1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;
>
> (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
>
> (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

[70] Pub. L. 103-465, 108 Stat. 4809 (1994).

This is clearly against public policy, but since the government has no means for rejecting a patented invention, no double patenting issue would exist in the species patent. This might be considered as a basis for holding the species patent either unenforceable or invalid.[71]

To ensure that strongest possible patents, it is always advisable to be aware of related patents and patent applications and consider all pairwise combinations of inventions for double patenting issues.

F. Restriction and Double Patenting under the Leahy-Smith America Invents Act (AIA)

The AIA does not *per se* include changes that alter restriction or double patenting. The fact that all applications are, however, as a matter of first impression, considered based upon their effective filing date rather than date of invention will likely have consequences for both issues.

For example, The Innovation Act, H.R. 9, introduced in the 114th Congress, in § 9(c), seeks to codify the double-patenting doctrine for First-Inventor-To-File patents by amending Chapter 10 of title 35 to statutorily define conflicting claims between patents as prior art under specific conditions. This amendment is purportedly intended to replace judicially-created doctrines regarding undue timewise extensions of monopoly by issuance of multiple patents with distinct expiration dates and separate enforceability (ownership/assignment). The proposed statute reads as follows:

> **"§ 106. Prior art in cases of double patenting**
>
> "A claimed invention of a patent issued under section 151 (referred to as the 'first patent') that is not prior art to a claimed invention of another patent (referred to as the 'second patent') shall be considered prior art to the claimed invention of the second patent for the purpose of determining the nonobviousness of the claimed invention of the second patent under section 103 if—
>
> "(1) the claimed invention of the first patent was effectively filed under section 102(d) on or before the effective filing date of the claimed invention of the second patent;
>
> "(2) either—
>
> "(A) the first patent and second patent name the same inventor; or
>
> "(B) the claimed invention of the first patent would constitute prior art to the claimed invention of the second patent under section 102(a)(2) if an exception under section 102(b)(2) were deemed to be inapplicable and the claimed invention of the first patent was, or were deemed to be, effectively filed under section

[71] The Federal Circuit in Gilead Sciences, Inc. v. Natco Pharma Limited, Case No. 2013-1418 (Fed. Cir., April 22, 2014) held that an earlier-filed, earlier-expiring patent could qualify as an obviousness-type double patenting reference to a later-filed, later-expiring patent, based on the presumption that the later-filed, later-expiring patent did not claim obvious variants of the invention claimed in the earlier-filed, earlier-expiring patent.

> 102(d) before the effective filing date of the claimed invention of the second patent; and
>
> "(3) the patentee of the second patent has not disclaimed the rights to enforce the second patent independently from, and beyond the statutory term of, the first patent."

In the words of one of the advocates of the proposed legislation, the proposed double patenting codification seeks to limit the application of double patenting principles . . . to the situation where at least one of the claimed inventions in one . . . patent was not prior art under §103 of title 35 with respect to at least one claimed invention of . . . [another] patent. This would overrule current Federal Circuit law. Applying double patenting principles has the undesirable effect of penalizing the same inventor . . . for having made each of the two patentably distinct discoveries that otherwise could have been separately and validly patenting and separately enforced for separate patent terms.

Although this same legislation was passed in the House of Representatives, similar legislation in the Senate was not brought to a vote. Various interested groups (including the AIPLA) have contributed to the discussion regarding this legislation, including suggestions for improving it and reducing or eliminating unintended consequences. Thus, it remains to be seen how nonstatutory double patenting will be treated under the AIA.

IV. Closing Remarks

A patent is a limited right granted by a nation that fosters innovation. In exchange for this right, an inventor agrees to dedicate their invention to the public at the end of a patent term. Whether one is considering restriction or unity practice, separation of inventions into separate applications is a two-edged sword. From the perspective of a patent office, it provides a tool for managing workload and aiding both in enhancing quality and reducing pendency. An applicant is provided with a means of parsing their technologies into manageable parts that can be efficiently managed and implemented (whether directly through manufacture or indirectly through licensing). Restriction also represents one of the most difficult aspects of the examination process since it is performed at the start of the examination process, often with limited information. Unity practice solves part of this by requiring that the examiner have at least some understanding of the prior art prior to advancing a lack of unity requirement. Nonetheless, since all technology is "related" in some regard, separating what an applicant presents into reasonable parts that represent fairness to all parties involved in patent prosecution is often subjective and results in compromises that are considered unfair by all parties.

Regardless of how one feels about separating one's related inventions, increasing workloads and greater utilization of the patent system throughout the world makes the use of restriction/lack of unity practice a necessity and will remain both a prosecution and business challenge for some time to come.

In closing, it is noted that restriction/unity practice occurs at the beginning of the patent application review process and sets the stage for the entire process. The implications of this are

often overlooked, but careful consideration in claim drafting and during the invention election process will pay back rewards downstream making the investment in time well worth the effort.